October 28, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Comments on Submissions Concerning First Amendment Issues
Docket No. 02N-0209

Dear Sir or Madam:

This letter provides the comments of the Washington Legal Foundation (WLF) on the submissions responding to the FDA's request for public comment on First Amendment issues.[1]

As a non-profit public interest law and policy center with many members and supporters who wish to disseminate or receive truthful information about FDA-regulated products, WLF has a long-standing interest in the issues raised by FDA's request for comments. We want to commend FDA once again for taking the initiative to harmonize its regulatory activities with First Amendment mandates, and for inviting public comment on these issues. FDA's request has prompted a remarkable outpouring of thoughtful, often-provocative submissions on critical legal and public health issues, which should be of great assistance to the Agency as it goes about the task of evaluating and reforming its existing speech restrictions. In this submission, we have addressed two of the principal topics discussed in the initial set of comments to FDA: (1) the

[1] 67 Fed. Reg. 34942 (May 16, 2002).

dissemination of information about off-label uses of FDA-approved drugs and devices;[2] and (2) direct-to-consumer (DTC) advertising of prescription drugs.

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I. THE DISSEMINATION OF INFORMATION ON OFF-LABEL USES

By reducing barriers to the exchange of truthful scientific and medical information on off-label uses of drugs and devices, FDA can advance two important goals: facilitating physicians' access to information that may help them to improve patient care, and honoring its obligation to respect constitutionally-protected freedoms. While this does not require FDA to lift all of its restrictions on speech by drug or device manufacturers concerning off-label uses of their products, it plainly does require some modest reforms in FDA's regulatory regime. In particular, the First Amendment does not permit FDA to penalize manufacturers for disseminating peer-reviewed journal articles or reference textbooks on off-label uses to medical professionals, or for suggesting content or speakers to independent CME providers for programs discussing off-label uses (although FDA can require disclosures concerning manufacturers' financial interests and the fact that the uses are not FDA-approved, and can sanction false or misleading speech). The rationale for these principles was discussed in detail in the WLF I – WLF III decisions[3] and in our initial submission, and will not be repeated here.

[2] This issue is discussed in greater detail in WLF's initial comments of September 13, 2002.

[3] See Washington Legal Found. v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998)("WLF I"); Washington Legal Found. v. Friedman, 36 F. Supp.2d 16 (D.D.C. 1999)("WLF II"); Washington Legal Found. v. Henney, 56 F. Supp.2d 81 (D.D.C. 1999)("WLF III"); Washington Legal Found. v. Henney, 202 F.3d 2000 (D.C. Cir. 2000)("WLF IV"); Washington Legal Found. v. Henney, 128 F. Supp.2d 11 (D.D.C.

While many of the parties responding to FDA's request for comments urged FDA to recognize and uphold these principles, FDA spurred a robust public debate that naturally produced a variety of dissenting views. We address here the views expressed in September 13, 2002 comments submitted by six members of Congress (Senator Kennedy, Senator Durbin, Senator Schumer, Congressman Waxman, Congressman Brown, and Congresswoman DeLauro).[4]

While these comments are detailed, their principal argument is that manufacturer-disseminated information about off-label uses can properly be banned because it is "inherently misleading." More specifically, the theory is that before the 1962 amendments to the Food, Drug and Cosmetic Act (FDCA), drug manufacturers could market drugs without an FDA determination concerning effectiveness; that Congress passed the 1962 amendments based on evidence that manufacturers were making false or misleading claims that physicians found difficult to evaluate, and that the pre-1962 regime was thus inadequate; and that the evidentiary record underlying the 1962

2000)("WLF V").

[4] These congressional comments were by no means the only comments FDA received expressing concerns about relaxing existing restrictions on speech about off-label uses. However, a number of comments expressed such concerns without focusing on a legal rationale that would assertedly permit FDA to retain its existing speech restrictions. For example, the September 13, 2002 comments submitted by Public Citizen Health Research Group argued that the information in peer-reviewed journals is not comparable to information vetted by FDA's drug approval process, discussed four instances in which manufacturers allegedly disseminated false or misleading information about off-label uses, and concluded that "[t]o the extent that the FDA has authority under the law to regulate . . . off-label promotion, the agency should err on the side of public protection and not pander to . . . the pharmaceutical industry." (Emphasis added.) However, the extent to which FDA has authority under the law to regulate speech concerning off-label information is the key issue that FDA confronts.

amendments demonstrates that information on a product's effectiveness for a particular use is "inherently misleading" unless it has been vetted by FDA's rigorous approval

process.[5] As a rationale for banning manufacturers' dissemination of information such as peer-reviewed journal articles, this theory has two basic flaws.[6]

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[5] The argument is perhaps best encapsulated at page 16 of the comments (under the heading "Unsubstantiated Promotional Claims Shown to be Inherently Misleading"), which states that:

> The evidence accumulated by Congress before passage of the 1962 Amendments to the FDCA demonstrated that, without benefit of pre-market review of a drug's effectiveness by an objective body, it simply was not possible for most physicians to discern which products were effective and which were not. Three features of the pre-1962 scheme caused promotional claims about unproven uses to be inherently misleading: (1) physicians relied heavily on promotional information from manufacturers, much of which was misleading; (2) what reliable, objective evidence existed was difficult or impossible for average physicians to find because they were too busy to track down scattered, often unpublished data on hundreds of new drugs; and (3) in the absence of required testing, few . . . companies conducted . . . studies that would provide reliable evidence of their products' effectiveness. . . .

(Footnote omitted.)

[6] In addition to the points discussed below, it must be noted that the health care system has undergone a fundamental transformation in the 40 years since enactment of the 1962 FDCA amendments. In particular, the proposition that manufacturer-disseminated information on off-label uses is inherently misleading because it typically involves unsubstantiated assertions that physicians cannot evaluate in any meaningful way does not describe the current environment. Manufacturers today have many incentives to generate reliable, objective evidence concerning new uses of approved products: they can expand the market for a product by conducting the research necessary to seek FDA's approval for an off-label use; they can reduce product liability risks by obtaining FDA approval for new indications; and they operate in a marketplace where health care professionals and institutions, managed care organizations, and public and private insurers demand objective evidence of a product's benefits as a basis for making treatment and reimbursement decisions. Likewise, these various decisionmakers have the capability and motivation to evaluate the evidence concerning the benefits of competing therapies. In fact, even in the context of treatments that are not subject to FDA approval (surgical procedures, for example) the demand for "evidence-based medicine" has grown increasingly powerful. See, e.g., Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine, 268 JAMA 2420-25 (1992) (although randomized clinical trials were rare in 1960, "[i]t is now accepted that virtually no drug can enter clinical practice without a demonstration of its efficacy in clinical trials" and "the same randomized clinical trial method increasingly is being applied to surgical therapies, and diagnostic tests") (footnotes omitted). Modest reforms allowing drug and device manufacturers to disseminate information such as peer-reviewed journal articles will not turn the clock back to 1962 or give manufacturers a mistaken impression that making unsubstantiated assertions about their products represents a sound business strategy.

First, FDA and Congress have repeatedly recognized that off-label use is an accepted part of the practice of medicine, and that the exchange of off-label information between physicians and manufacturers can be valuable in helping physicians to identify and evaluate new treatment options that may benefit certain patients. For example, FDA recently explained that:

> Congress . . . has generally refrained from providing . . . for the FDA to limit a physician, as part of the practice of medicine, from prescribing any legally available product for a particular patient . . . . Consistent with that background, the FDA has permitted physicians to prescribe approved drugs for [off-label] uses . . . . That policy reflects the FDA's recognition that certain off-label uses perform an important therapeutic role in certain areas of medical practice, and that undue restrictions on such uses could have adverse health consequences.[7]

Consistent with its recognition that off-label uses have an important therapeutic role in certain areas, FDA has long acknowledged that physicians need accurate scientific and medical information on off-label uses, and that (in least in some circumstances) it is appropriate for manufacturers to disseminate such information. For example, in 1996 Congressional testimony, an FDA official stated that:

> [I]n certain circumstances, off-label uses of approved products are appropriate, rational, and accepted medical practice. FDA knows that there are important off-label uses of approved drugs. In this context, it is important that physicians have access to accurate information . . . .
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[7] Brief for the Petitioners in Thompson v. Western States Medical Center, 2001 WL 1605836, *28 (emphasis added).

> . . . Generally, FDA does not prohibit the dissemination of information to health care professionals. Physicians access information about off-label uses through compendia, journal articles, continuing medical education programs, symposia, and professional meetings. Physicians also have access to a number of databases that provide information about off-label uses . . . . In addition, FDA does not prohibit a manufacturer from providing a physician information about off-label uses if the physician requests that information . . . . Drug companies [also] may distribute independent reference texts even if they contain certain information about off-label uses . . . so long as the texts do not have a significant focus on an off-label use of the manufacturer supporting dissemination of the text. . . . [A]ll of these sources of information can be very important to good medical practice.[8]

Similarly, the FDA stated in 1994 that there was a "need for reliable scientific data and information on unapproved uses of approved products" and that "because the agency recognizes the importance of dissemination of reliable scientific information on . . . unapproved uses, it has developed a number of policies related to dissemination of such information."[9] These include FDA's Final Guidance on Industry-Supported Scientific and Educational Activities (which explicitly provides that "most industry-supported scientific and educational activities are not inherently misleading," and that the lack of complete information on the risks of off-label uses "does not make all discussions about unapproved uses misleading" provided that the limitations on the data are

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[8] February 22, 1996 testimony of William B. Schultz, FDA Deputy Commissioner for Policy, before the Senate Committee on Labor and Human Resources, http://www.fda.gove/ola/1996/s/447.htm (emphasis added).

[9] 59 Fed. Reg. 59820, 59822, 59825 (Nov. 18, 1994).

disclosed);[10] FDA's policy allowing manufacturers to respond to unsolicited requests for information on off-label uses;[11] and FDA's acknowledgement that manufacturers must be free to submit original research on off-label uses to peer-reviewed journals given "the need among health care professionals for peer review and dissemination of the latest significant scientific data and information on drugs and devices in scientific journals."[12]

Congress too has recognized that manufacturer-disseminated scientific and medical information on off-label uses can be valuable to health care professionals. In enacting Section 401 of FDAMA,[13] Congress sought to ensure "that health care practitioners can obtain important scientific information about uses that are not included in the approved labeling of drugs, biological products, and devices" while also encouraging manufacturers to seek FDA approval for these uses.[14]

Thus, FDA and Congress have both recognized that the off-label use of drugs and devices is an accepted part of medical practice,[15] and that information on off-label uses

10 62 Fed. Reg. 64074, 64079 (Dec. 3, 1997).

11 59 Fed. Reg. at 59824. See also 63 Fed. Reg. 64556, 64558 (Nov. 20, 1998) ("manufacturers who wish to furnish unapproved use information . . . may do so . . . in response to an unsolicited request. Otherwise, they must comply with the requirements set forth in section 401 of FDAMA [the FDA Modernization Act of 1997] and [its implementing regulation]").

12 59 Fed. Reg. at 59823 (emphasis added).

13 21 U.S.C. §§ 360aaa - 360aaa-6.

14 H.R. Conf. Rep. No. 105-399 (Nov. 9, 1997), 1997 WL 703162 (Leg. Hist.), *99.

15 In fact, in Section 214 of FDAMA, "Practice of Medicine," Congress explicitly provided that "[n]othing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." As explained in the provision's legislative history, it was intended to "emphasize that the FDA should not interfere in the practice of medicine," since "the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA." H.R.

can be reliable and important to physicians - - even though such information has not been validated by the FDA, and even when it is disseminated by the product's manufacturer. This contradicts the theory that information on off-label uses (whether disseminated by manufacturers or other parties) is "inherently misleading" simply because it lacks FDA's imprimatur. As the First Amendment caselaw makes clear, a particular category of information cannot be valuable and inherently misleading at the same time.

For example, in Western States Medical Center v. Shalala, 69 F. Supp.2d 1288 (D. Nev. 1999), aff'd in part, rev'd in part on other grounds, 238 F.3d 1090 (9th Cir. 2001), aff'd sub nom. Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002), the Government argued that advertisements for compounded drugs were "inherently misleading" since they suggested that compounded drugs not approved by FDA have therapeutic value. The court disagreed, observing that "Defendants themselves presumably believe that compounded drugs have therapeutic value in some cases; otherwise, they would prohibit the unapproved use of such drugs altogether." 69 F. Supp.2d at 1299. Similarly, the court rejected the claim that banning advertisements for compounded drugs served the public health; noting that the FDAMA provisions at issue allowed pharmacists to initiate discussions about a compounded drug once a patient presented a prescription for another drug, the court found it "difficult to see how the communication of the same information can both serve and undermine the public health,

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Conf. Rep. No. 105-399 (Nov. 9, 1997), 1997 WL 703162 (Leg. Hist.), *97.

depending on which party initiates the contact or the method used to communicate it." Id.

In WLF I, the court rejected the theory that manufacturer-disseminated journal articles or textbooks discussing off-label uses were inherently misleading. Among other things, the court noted that FDA allows manufacturers to disseminate such materials in response to unsolicited requests, holding that "the exact same journal article or textbook reprint cannot be inherently conducive to deception . . . when it is sent unsolicited, yet of significant clinical value when mailed pursuant to a request." WLF I, 13 F. Supp.2d at 67.

In short, the Government's own statements and policies recognize that information on off-label uses (including information disseminated by manufacturers) can be valuable and important to good medical practice -- and the caselaw precludes speech prohibitions premised on the conflicting theory that such information is inherently misleading.

Second, an entire category of speech cannot be banned as "inherently" misleading if the information can also be communicated in a non-misleading fashion. Even where the speech at issue is potentially misleading, a broad prophylactic ban cannot be justified if the potential for deception is curable rather than inherent.

In In re R.M.J., 455 U.S. 191 (1982), the Supreme Court rejected the claim that certain forms of legal advertising could be banned on prophylactic grounds, holding that:

> Misleading advertising may be prohibited entirely, but the States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive. . . . [T]he remedy in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation. . . . Although the potential for deception . . . is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.

Id. at 203 (emphasis added). See also, e.g., Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 111 (1990) ("[t]he Commission's concern about the possibility of deception in hypothetical cases is not sufficient to rebut the constitutional presumption favoring disclosure over concealment"); Edenfield v. Fane, 507 U.S. 761, 777 (1993) ("[b]road prophylactic rules in the area of free expression are suspect") (quoting NAACP v. Button, 371 U.S. 415, 438 (1963)); Revo v. Disciplinary Bd. of the Supreme Ct. of New Mexico, 106 F.3d 929, 933 (10th Cir. 1997) ("[f]or a particular mode of communication to be inherently misleading, it must be incapable of being presented in a way that is not deceptive"); Pearson v. Shalala, 130 F. Supp.2d 105, 118 (D.D.C. 2001) (where FDA failed to show that the allegedly misleading aspects of a health claim could not be cured through disclaimers, "its decision to classify the [claim at issue] as inherently misleading is therefore erroneous"); WLF I, 13 F. Supp.2d at 67 ("[a]lthough the Government argues that health claims that have not been FDA approved are inherently misleading . . . at least some can be presented in a non-misleading

fashion") (quoting Nutritional Health Alliance v. Shalala, 953 F. Supp. 526, 529 (S.D. N.Y. 1997), aff'd in part, vacated and dismissed in part on other grounds, 144 F.3d 220 (2nd Cir. 1998)); Metpath, Inc. v. Myers, 462 F. Supp. 1104, 1109 (N.D. Cal. 1978) (advertisements for clinical laboratory services directed at the lay public could not be banned as "inherently misleading" based on the public's lack of technical expertise and the often-technical nature of advertising by clinical labs, where the plaintiff's ads were not technical and the court could "imagine an infinite number of advertisements of equal simplicity" that would not mislead a lay audience).

These principles preclude the position that information about off-label uses can be banned as inherently misleading, as the Supreme Court's Western States decision illustrates. There, the Government itself did not contend that advertisements for compounded drugs - - which have not been approved by FDA as safe and effective for any use - - are inherently misleading.[16] However, the dissent suggested that the ban on advertising compounded drugs might be justified by concerns that patients would be confused about their risks. The majority disagreed, holding that:

> Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive means of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.

Western States, 122 S. Ct. at 1508.

[16] As noted earlier, the Government did advance this argument unsuccessfully in the district court; however, the argument was not pursued on appeal.

If the potential for misleading patients by exposing them to pharmacists' advertisements for unapproved drugs can be dealt with through succinct disclaimers, any potentially misleading aspects of professional publications or seminars directed to a professional audience can plainly be dealt with through similar means. FDA itself has recognized that this kind of scientific and medical information on off-label uses can be reliable; that undue restrictions on this information could have adverse health consequences to patients; and that a manufacturer's involvement in disseminating such information does not automatically taint the information and render it "inherently misleading."

Few would advocate a repeal of the 1962 amendments to the FDCA, or a wholesale deregulation of information about off-label uses of approved products. But responsible reforms that promote the exchange of truthful and non-misleading information on scientific and medical developments are essential to align FDA's current policies with its legal obligations and public health commitment.

II. DIRECT-TO-CONSUMER ADVERTISING

DTC advertising of prescription drugs has been a prominent topic in the public debate initiated by FDA, which produced a wide variety of comments on the legal issues surrounding DTC ads and the empirical evidence regarding their effects. We have focused here on one discrete aspect of the DTC debate. Several commentators emphasized the possibility of DTC ads increasing health care costs (i.e., the potential for DTC ads to result in increased utilization of high-cost drugs and/or price increases in the advertised drugs),[17] and FDA's Federal Register notice seemed to allude to this same issue without using the word "cost," asking whether its current approach to regulating advertising encourages "overprescription."[18] Because FDA may face pressure to use

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[17] See, e.g., July 30, 2002 comments of Community Catalyst, Health Care For All and Health Law Advocates (stating that "[a]ided in part by direct-to-consumer advertising, our nationwide prescription drug market continues to grow at a phenomenal rate, burdening an increasing number of consumers with the astronomical costs of brand-name drugs" and that reminder ads for drugs should be eliminated partly because they "may help account for the fact that in 2001 the 50 drugs with the largest price increases were brand-name options, and they showed disproportionately high increases in sales")(footnotes omitted); May 29, 2002 comments of the National Organization for Rare Disorders (a recent editorial in The Lancet "summarizes the negative effects of DTC advertising we have seen in the United States. Marketing expenses of pharmaceutical firms have risen from $860 million in 1997 to $2.5 billion in 2000. The impact of these expenses on drug costs to consumers is staggering"); May 13, 2002 comments of the BlueCross BlueShield Association (stating that "increases in the sales of the 50 drugs most heavily advertised to consumers in 2000 were responsible for almost half of the $20.8 billion (18.8%) one year increase in retail spending on prescription drugs" and that the "increased demand for prescription products raises the issue of whether patient requests for particular drugs represent the best available therapy. . . and whether DTC advertising may actually impair a physician's ability to prescribe the best available therapy by creating unrealistic consumer demands and preferences"); June 5, 2002 comments of Trigon BlueCross BlueShield (while DTC advertising has increased the use of prescription drug in appropriate patients, "it has also increased the use of expensive brand name drugs in place of more economical equivalent generic alternatives").

[18] 67 Fed. Reg. at 34943.

speech restrictions as a cost-containment measure (and perhaps has some sympathy for this approach), we believe it is important to address this strategy.

As an empirical matter, the evidence on whether DTC advertising increases health care costs is inconclusive. This is partly because the question involves a number of sub-issues. That is, DTC advertising might increase or reduce health care spending: (1) because it results in price increases; (2) because it increases drug utilization, or shifts treatment toward more expensive or less expensive therapies; or (3) because it prompts patients to discuss medical problems with their physicians, or improves patient compliance, and thus avoids the costs that might result from more delayed treatment or from noncompliance with the prescribed treatment regimen.

Whether DTC advertising results in price increases is unclear. While advertising could increase the prices of the advertised products (either because companies raise prices to cover these advertising costs, or due to increased demand) the empirical evidence on the issue is sketchy,[19] and advertising could also have the effect of reducing prices generally due to increased competition.[20] Whether DTC advertising causes

[19] As the FTC noted in its September 13, 2002 comments to FDA (at pp. 30-31):

> Extensive studies investigating the effect of DTC advertising on prices do not exist. In particular, the demand effects have not been extensively studied. The available evidence, however, suggests that any price effects from the costs of the advertising itself are likely to be small. . . .

[20] For example, the FTC's January 11, 1996 comments to the FDA responding to its request for comments on DTC advertising noted that:

> Although price effects cannot be definitively predicted a priori, we believe that DTC advertising may generally reduce drug prices. First . . . advertising can trigger competition among alternative therapies, which, in the long run, should result in lower average prices

increased utilization of costly treatment alternatives also is unclear. As a logical matter, one would not expect a pharmaceutical company to expend resources on DTC ads unless it believed they would increase sales, or to focus DTC ads on low-cost products; on the other hand, new drug therapies may provide an alternative treatment option for conditions that would otherwise require more costly treatments or increase hospitalizations.[21] Finally, the evidence available from consumer surveys suggests that DTC advertising can lead patients to ask their physicians about problems they had not previously discussed, and encourage patient compliance;[22] while both of these factors could potentially produce long-term savings, the magnitude of any such savings is speculative. In short, the question of whether DTC advertising increases or reduces health care costs raises a number of issues that undoubtedly will be the subject of further study, but the existing research is not sufficient to suggest a clear answer.

> for the therapeutic category, assuming all else (including quality) remains constant . . . .

http://www.ftc.gov/opp/advocacy/v960001.htm.

[21] See, e.g., U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Securing the Benefits of Medical Innovation for Seniors, The Role of Prescription Drugs and Drug Coverage (July 2002), http://aspe.hhs.gov/health/reports/medicalinnovation (noting that "[i]nnovations in medical science, especially pharmaceuticals, have shifted the focus of medicine from highly-invasive treatments and surgeries with potentially serious risks to less-invasive therapies focused on prevention and health maintenance. This shift has allowed many older Americans to . . . avoid[ ] long hospital or nursing home stays").

[22] For example, FDA's consumer surveys showed that roughly 20% of patients (27% in 1999 and 18% in 2002) reported that DTC ads had caused them to ask their physicians about a medical condition or illness they had not previously discussed with their physicians. Direct-to-Consumer Advertising of Prescription Drugs, Preliminary Patient Survey Results, Kathryn J. Aikin, http://www.fda.gov/cder/ddmac/DTCnational2002a/sld001.htm. For a discussion of the survey evidence suggesting that DTC ads improve patient compliance, see, e.g., John E. Calfee, What Consumer Surveys Show About Direct-to-Consumer Advertising of Prescription Drugs (May 7, 2001) 19-20.

By contrast, the situation on the legal front is clear. Even if the empirical evidence demonstrated that DTC ads increased health care costs, FDA could not restrict speech in order to "protect" patients from information that might lead them to seek high-cost or "unnecessary" medications. The First Amendment "directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good" -- a "teaching [that] applies equally to state attempts to deprive consumers of accurate information about their chosen products."[23]

The principle that Government cannot suppress truthful speech to prevent citizens from making the "wrong" decision has been recognized repeatedly in the commercial speech cases, beginning with Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 769 (1976). There, the State of Virginia argued that a ban on advertising prescription drug prices was necessary to prevent consumers from selecting pharmacies offering lower prices but lower-quality services. The Supreme Court rejected this rationale for the advertising ban, holding that:

> There is . . . an alternative to this highly paternalistic approach. That alternative is to assume that . . . people will perceive their own best interest if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . . Virginia is free to require whatever professional standards it wishes of its pharmacists . . . . But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering . . . [T]he justifications Virginia has offered for suppressing the

[23] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996).

> flow of prescription drug price information, far from persuading us that the flow is not protected by the First Amendment, have reinforced our view that it is.

Id. at 770.

Similarly, the court in WLF I rejected paternalism as a valid basis for restricting the dissemination of truthful information about off-label uses, holding that "[t]o the extent that the FDA is endeavoring to keep information from physicians out of concern that they will misuse that information, the regulation is wholly and completely insupportable." WLF I, 13 F. Supp.2d at 69. "If there is one fixed principle in the commercial speech arena," the court observed, "it is that 'a State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.'" Id. at 69-70 (quoting 44 Liquormart, Inc. v. Rhode Island, 517 U.S. at 497).

The Supreme Court re-emphasized this principle in Western States, rejecting the theory that an interest in "protecting" patients from truthful information could justify its suppression. There, the Court addressed the argument that FDAMA's ban on advertising compounded drugs could be sustained by an interest in preventing patients who do not need compounded drugs from seeking them, holding that:

> Even if . . . FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. Aside from the fact that this concern rests on the questionable assumption that doctors would prescribe

> unnecessary medications . . . [it] amounts to a fear that people would make bad decisions if given truthful information . . . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.

Western States, 122 S. Ct. at 1507 (emphasis added).[24]

Government agencies have a wide variety of tools to restrain health care costs generally, or to combat the perceived "overutilization" of specific products or services. For example, agencies that reimburse health care costs use mechanisms such as copayment requirements, coverage restrictions, and utilization reviews; agencies that purchase or reimburse health care products engage in aggressive negotiations to obtain discounts or rebates from product manufacturers; agencies often carry out educational campaigns to promote lower-cost treatment alternatives; and FDA itself has issued a series of public service announcements encouraging the use of generic drugs. All of these strategies are consistent with the First Amendment. What the First Amendment caselaw does preclude, however, is "speech-containment" strategies aimed at cost containment. Preventing citizens from asking their physicians about prescription drugs is not an interest that can justify restrictions on truthful advertising.

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[24] See also, e.g., Bates v. State Bar of Arizona, 433 U.S. 350, 374-75 (1977) ("[t]he argument assumes that the public is not sophisticated enough to realize the limitations of advertising and . . . is better kept in ignorance than trusted with correct but incomplete information. We suspect that the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefits of public ignorance"); Linmark Associates, Inc. v. Township of Willingboro, 431 U.S. 85, 96 (1977) (striking down a local ordinance because "the Council has sought to restrict the free flow of [the information at issue] because it fears that otherwise homeowners will make decisions inimical to what the Council views as the homeowners' self-interest and the corporate interest of the township").

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FDA's initiative to conform its regulatory activities to First Amendment standards has the potential to produce legally-defensible policies that facilitate the diffusion of valuable medical information and advance FDA's public health objectives. We hope that FDA will be successful in this important endeavor, and appreciate the opportunity to comment on these issues.

Sincerely,

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Daniel J. Popeo
Chairman and General Counsel

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Richard A. Samp
Chief Counsel