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Critical Legal Issues: WORKING PAPER SERIES

PROPOSED LIMITS ON PRESCRIPTION DRUG ADS: A CONSTITUTIONAL ANALYSIS

by
Bert W . Rein
John F. Kamp
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Wiley, Rein & Fielding

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 110
July 2002

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INTRODUCTION

The national debate over rising health care costs has prompted questions about direct-to-consumer ("DTC") advertising for prescription drugs. Congressional skeptics claim that DTC advertising is wasteful and increases what they feel are already excessive prescription drug costs. Also, in something of a contradiction, they assert that DTC advertising is too effective and prompts consumers to pressure their physicians into prescribing unnecessary high cost "pioneer" drugs when available generics or the passage of time would be equally therapeutic. Leaving aside the merits of these concerns, the restrictions being proposed to remedy them raise serious constitutional issues — particularly after the Supreme Court's April 2002 decision in *Thompson v. Western States Medical Center,* _U.S._, 122 S. Ct. 1457(Apr. 29, 2002), which set aside on First Amendment grounds explicit

legislative restrictions on DTC advertising of so-called "compounded" drugs.

Proposals to restrain DTC advertising by prescription drug manufacturers are unlikely to imitate the frontal assault struck down in *Western States.* Rather, DTC critics contemplate imposing handicaps on DTC advertising by, for example, limiting its deductibility under the Internal Revenue Code or by disfavoring DTC advertising-supported drugs in government-sponsored benefit programs such as Medicaid or proposed new benefits under Medicare. These indirect restraints would coerce, but not require, prescription drug manufacturers to curtail DTC advertising. If such schemes were enacted, supporters no doubt would argue that they further speech-neutral government objectives such as increasing tax revenue or reducing the cost of benefit programs.

Western States principally focused on applying the well-established First Amendment standard of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980) and its progeny to restrictions on compounded drug DTC advertising, but the new decision also has a message for those seeking to impose indirect restraints on prescription drug DTC advertising. The restraint at issue in *Western States* did not set forth the terms of an immediate law violation. Rather, as explained further below, the restraint operated by denying a pharmacist who advertised a specific compounded product directly

to consumers the benefit of an exemption from possible sanction for violating the new drug approval process established under the Federal Food, Drug and Cosmetic Act ("FDCA"). Neither the majority nor dissenting Justices in *Western States* had any difficulty in subjecting this DTC advertising restraint to First Amendment scrutiny.

Even the facts of *Western* States cast an ironic light on the prescription drug DTC controversy. The advertising in *Western States* concerned tailored doses of drugs that pharmacists mix pursuant to a doctor's prescription, which the U.S. Food and Drug Administration ("FDA") traditionally has chosen (as a matter of enforcement discretion) not to subject to its new drug approval process. The prescription drugs spotlighted in DTC advertising, in contrast, are subject to exacting government scrutiny. FDCA, 21 U.S.C. § 301 *et seq.*, and its implementing regulations require that the drugs prepared by pharmaceutical manufacturers be tested for safety and effectiveness. Furthermore, the FDCA requires that DTC advertisements for these drugs comply with regulatory mandates for accuracy and balance. 21 U.S.C. § 352(n). Given this extensive government oversight, it seems fair to say that prescription drug DTC advertising contains speech of high integrity.

Consumers certainly find it so. Since advertisements of name-brand drugs have become commonplace on television and in the print media, studies

indicate that consumers find the messages helpful in learning more about medical conditions that may affect them.[1] Even former FDA officials who once fiercely contested even the application of the First Amendment to the agency's regulatory scheme now concede that DTC advertisements provide "a lot of educational benefit."[2]

Nevertheless, DTC opponents are unlikely to be persuaded of the merits of prescription drug advertising. Thus, it is likely that they will advance proposals designed to economically coerce pharmaceutical manufacturers into terminating or curtailing DTC advertising by putting access to government incentives (*e.g.*, deductions under the Internal Revenue Code) or benefits (*e.g.*, sales opportunities under a new Medicare drug benefit) out of reach of DTC-supported drugs. Advised by *Western States*, however, proponents are likely to mask their suppressive intent in the rhetoric of cost reduction and program management and to accompany their proposals with solemn declarations that any incidental impact on DTC advertising is a matter for manufacturers to

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[1] *See, e.g.,* Office of Medical Policy Division of Drug Marketing, Advertising, and Communications, U.S. Food & Drug Administration, *Attitudes and Behaviors Associated with Direct-to-Consumer (DTC) Promotion of Prescription Drugs: Main Survey Results*, available at http://www.fda.gov/cder/ddmac/dtcindex.htm (updated by FDA Jan. 11, 2002); John E. Calfee, Ph.D., *What the FDA Survey Showed About Direct-to-Consumer Prescription Drug Advertising*, 2 ECONOMIC REALITIES IN HEALTH CARE POLICY 10, 11-13 (June 2001) (summarizing 1999 FDA survey).

[2] Raja Mishra, *Ex-FDA Chief Recants on Drug Advertising: Kessler Tells Industry He Was Wrong to Resist*, BOSTON GLOBE, Apr. 17, 2002, at A2 (former FDA commissioner David Kessler publicly stated "I think I was wrong" in barring DTC advertising in 1990s).

determine.

Such indirect attacks on prescription drug DTC could not avoid First Amendment scrutiny. As demonstrated below, where Congress seeks to silence a speaker by making silence the price of access to a government benefit or privilege, the intent and effect of its actions will be evaluated under the First Amendment. While not every government action which has possible economic consequences for commercial speech (*e.g.*, a broad change in corporate income tax rates) raises First Amendment concerns, existing case law provides useful guidance on where such effects are likely to warrant constitutional review. The first section of this WORKING PAPER addresses the constitutional reviewability of indirect speech suppressions. The second section discusses the legal standard that courts are likely to apply in performing that First Amendment oversight. The final section examines how the four-prong *Central Hudson* test would apply to certain proposals that would effectively suppress, or significantly burden, DTC prescription drug advertising.

I. APPLICATION OF THE FIRST AMENDMENT

Courts have experience in dealing with government regulations that, in their operation, suppress or burden protected rights without overtly addressing them: "The Constitution 'nullifies sophisticated as well as simple-minded modes' of infringing on constitutional protections." *U.S. Term Limits Inc. v.*

Thornton, 514 U.S. 779, 829 (1995) (citation omitted). With respect to freedom of speech, the Supreme Court has on several occasions explained that "[w]hat the First Amendment precludes the government from commanding directly, it also precludes the government from accomplishing indirectly." *Rutan v. Republican Party*, 497 U.S. 62, 77-8 (1990).

The proposed restrictions on DTC prescription drug advertising would confront a long line of precedent limiting the government's power to use speech-based distinctions as conditions that limit eligibility for generally available benefits. For decades, the Supreme Court has made clear that

> even though a person has no 'right' to a valuable government benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests — especially his interests in freedom of speech. For if the government could deny a benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to 'produce a result which (it) could not command directly.'"

Perry v. Sindermann, 408 U.S. 593, 597 (1972) (citation omitted). Not surprisingly, this line of reasoning has had particular force when the facts contain a flavor of government coercion with respect to the messages being suppressed. The principle can be seen in cases involving content-based

conditions on eligibility for public employment, *see, e.g., Pickering v. Board of Education*, 391 U.S. 563 (1968) (conditioning teaching post on non-criticism of school board); *Keyishian v. Board of Regents*, 385 U.S. 589 (1966) (conditioning teaching post on non-membership in Communist Party); *Shelton v. Tucker*, 364 U.S. 479 (1960) (conditioning teaching post on disclosure of all organizational affiliations); and tax exemptions, *Speiser v. Randall*, 357 U.S. 513 (1958) (conditioning exemption on pledge not to advocate overthrow of government).

The FDA previously has contended, however, that this general rule should not apply to the regulation of speech concerning prescription drugs. In *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.DC. 1998), *extended sub. nom. Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C 1999), *dismissed and vacated in part*, 202 F.3d (D.C. Cir. 2000) (subsequent history omitted), FDA argued that its efforts to restrict the circulation by prescription drug manufacturers of peer-reviewed publications concerning "off-label" (*i.e.*, not FDA approved) uses of prescription drugs were designed to foreclose unlawful marketing rather than to limit speech. FDA contended that speech suppression for the purpose of keeping manufacturers within the boundaries of a comprehensive regulatory scheme was not cognizable under the First Amendment. Not surprisingly, FDA's contention was

rejected by the District Court and largely abandoned on appeal. *See* 13 F. Supp. at 59; 56 F. Supp. at 85; 202 F.3d at 335. Nevertheless, because FDA's abandonment of the challenged restrictions effectively mooted the case, the litigation might have left some lingering doubt about the First Amendment's applicability to the promotion of heavily regulated prescription drugs. 202 F.3d at 335-37 & n.7.

If any such doubt were legitimate, *Western States* settled the question once and for all. There, the Supreme Court held that First Amendment protection applies even to less-than-direct restrictions on drug advertisements and promotions that arise from complex regulatory schemes — and that such restraints will be invalidated if they cannot satisfy the well-established commercial speech evaluation standard set by *Central Hudson* and fleshed out in later cases.

As noted above, the benefit at issue in *Western States* was woven into the federal drug approval process set forth in the FDCA, which generally requires that FDA review and approve any "new drug" before it can be introduced into the marketplace. This broad requirement is in some tension, however, with the traditional pharmacist service of compounding drugs to administer approved active ingredients in new formulations tailored to special patient needs.

Compounding is legal under state laws; many jurisdictions require that pharmacists have such skills. FDA, recognizing that the expense and delay of its approval process would effectively eliminate compounding, traditionally sought to resolve this tension by not challenging limited compounding operations. Congress, wishing to preserve this compromise, later enacted an express FDCA exemption: pharmacists would not be required to either seek FDA approvals for compounded drugs or to risk sanctions on the condition that, *inter alia*, they limited advertising messages about their compounding — specifically, as long as the pharmacist refrained from mentioning "any particular drug, class of drug, or type of drug" in an advertisement. *Western* States, 122 S. Ct. at 1502 (quoting 21 U.S.C. § 353a(c)). The statute did not expressly bar pharmacists from advertising that they compounded "particular drugs" — but if a pharmacist did so, he or she would be denied the benefit of the exemption and therefore run the risk of product seizure and criminal penalties.

The government contended that this indirect suppression of pharmacist speech was necessary to protect its drug approval regime and, ultimately, the public health. According to the government's theory, the use of advertising signals an effort to mass-market pharmaceuticals. Allowing pharmacists to advertise compounded drugs by name, therefore, might allow them to attract sufficient demand to produce unapproved drugs on a mass scale. That, in turn,

could endanger public health, precisely the concern at the heart of the FDCA. The government argued that the speech-suppressing effect of the exemption scheme was an incidental one that furthered an important non-speech policy goal. The Supreme Court agreed that protecting the drug approval process was a valid objective, but no member of the Court believed that this purpose exempted the advertising restraint from First Amendment scrutiny.

If safeguarding a pervasive regulatory regime is not itself sufficient to insulate indirect speech restraints from First Amendment scrutiny, proponents of DTC advertising restrictions still might contend that constitutional review is unnecessary because consumers could obtain the information in any repressed advertisement through another source — such as through their physicians, through FDA-approved labeling, and through the Physicians Desk Reference, a widely available publication.

A line of First Amendment cases suggests that a restraint that simply channels messages by leaving open alternative avenues of communication does not abridge speech rights. For example, in ruling for the government in *Regan v. Taxation With Representation*, 461 U.S. 540, 548 (1983), the Court emphasized that a non-profit think tank effectively barred from lobbying by potential loss of its tax immunity could avoid that restriction by forming an affiliated lobbying entity. Similarly, in *Rust v. Sullivan*, 500 U.S. 173, 197

(1991), the Court upheld a restriction on clinics using federal funds which precluded them from advocating abortion for family planning because the clinics could conduct the same advocacy under a separate, affiliated program.

The alternative channels doctrine, however, requires not only that the listener have alternative access to the repressed information, but also that the speaker have an alternative means of communication. Thus, in *WLF*, the court was not dissuaded from First Amendment review by the fact that the enduring materials at issue were already published and merely being recirculated by prescription drug manufacturers. Similarly, in *FCC v. League of Women Voters of Cal.*, 468 U.S. 364 (1984), the Supreme Court struck down a ban on editorializing by noncommercial broadcast licensees because alternative channels for disseminating their views were unrealistic. Moreover, the Court has determined that further grounds for First Amendment scrutiny arises where a restriction invidiously discriminates among speakers on the basis of ideas or the nature of their commercial activity. *See TWR,* 461 U.S. at 548; *City of Cincinnati v. Discovery Networks, Inc.,* 507 U.S. 410 (1993) (invalid regulatory scheme discriminating between traditional fee-based newspapers and free commercial guides).

Finally, the courts accord the government First Amendment latitude when it promotes selected speech for public purposes and concomitantly accords

less support to other speech. For example, the government may select one advertising agency to promote military recruitment even through competing agencies are not similarly supported. Similarly in *NEA v. Finley*, 524 U.S. 569 (1998), the government's right as an arts "patron" to select specific projects for public funding was upheld. *Id*. at 662, n. 17. Promotional latitude, however, does not extend to restricting preferences of general applicability on the basis of speech activity or content. *See Ark. Writers' Project v. Ragland*, 481 U.S. 221 (1987) (state tax exemption policies subject to First Amendment review); *Rosenberger v. Univ. of Va.*, 515 U.S. 819 (1995) (administration of college student activity fund subject to First Amendment review).

Given this body of precedent, it is highly unlikely that any of the indirect restraints on DTC prescription drug advertising now under consideration, or any other Congressional action intended or reasonably likely to suppress DTC prescription drug advertising, could evade First Amendment review. While deductibility under the Internal Revenue Code is a matter of grace, denying deductibility for a selected class of speech has clear First Amendment implications under *Ragland*. Similarly, while the government has an undisputed right to seek to manage costs in the Medicaid or Medicare programs, suppressing commercial speech to achieve that result clearly implicates First Amendment values even if DTC advertisers are economically handicapped

within the programs rather than barred from them.[3] Thus, it is essential to evaluate these proposed restraints under substantive First Amendment precedent to determine whether the asserted non-speech interests supporting them could justify their expected and intended suppressive effects on pharmaceutical manufacturer speech.

II. APPLICABLE FIRST AMENDMENT STANDARD

The previous section demonstrated that *Western States* laid to rest contentions that proposed legislative efforts to suppress DTC advertising could avoid First Amendment scrutiny by operating in some indirect fashion, such as by denying manufacturers who advertise certain benefits under the Internal Revenue Code or Medicaid and Medicare programs. This section examines the legal standard that courts are likely to apply in performing that First Amendment oversight.

Because much of DTC prescription drug advertising is conventional product promotion, the four-prong framework for evaluating commercial speech restraints set out in *Central Hudson* ordinarily would apply.[4] *See Discovery*

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[3]It is no answer that the handicap is imposed via a higher co-payment by direct beneficiaries since the impact clearly falls on manufacturers. Nor can consumers be expected to pay for the benefits arising from DTC because those beneficiaries are conferred before drugs are chosen and because enhanced information flows benefit those who select alternative treatments as well as those taking the advertised drug.

[4]As most recently described by the Supreme Court in *Western States*, that test requires asking: "as a threshold matter whether the commercial speech concerns unlawful

Networks, 597 U.S. at 423 (Court has "characteriz[ed] the proposal of a commercial transaction as '*the test* for identifying commercial speech'") (internal citations omitted). Proponents of proposed DTC restrictions might argue that lawmakers should have greater constitutional latitude to fashion prescription drug advertising regulations because DTC advertising has less value to consumers than other product advertising — on the theory that physicians, rather than consumers, actually control the choice of the drug being purchased. However, *Western States* gave no indication that this different locus-of-decision had any constitutional significance. Indeed, the Court cited *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), involving advertisements of pharmacy pricing data that helped consumers choose where to fill their prescriptions, as the foundation for its *Central Hudson* analysis. *Western States*, 122 S. Ct. at 1503.

On the other hand, there are significant arguments that certain manufacturer communications relating to prescription drugs, including at least some DTC prescription drug advertising, should receive a higher level of constitutional protection than *Central Hudson* affords. For example, FDA policy

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activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, we next ask 'whether the asserted governmental interest is substantial.' If it is, then we 'determine whether the regulation directly advances the governmental interest asserted,' and, finally, 'whether it is not more extensive than is necessary to serve that interest.' Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional." Slip op. at 9 (internal citations omitted).

recognizes a category of "help seeking" advertisements which FDA exempts from the side-effect disclosure requirements of Section 352(n) because the advertising assists consumers in recognizing treatable conditions without identifying any specific treatment. Although these advertisements identify the sponsoring company and are motivated by a commercial interest, a strong argument can be made that the messages do not "propose a commercial transaction" and thus fall outside the constitutional boundaries of commercial speech. *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). Indeed, from the point of view of the listener, help-seeking advertisements convey scientific and technical information of a type ordinarily accorded the highest level of constitutional protection.[5]

To date, the Supreme Court has not squarely addressed the issue of whether the content of the message or the identity and motive of the speaker should provide the foundation for constitutional classification of speech as worthy of "strict scrutiny," the highest level of constitutional review, or the lesser "intermediate scrutiny" review accorded to commercial speech. The classification issue is likely to come to the Court's attention shortly. In *Kasky v. Nike, Inc.*, 2002 WL 827173 (Cal. May 2, 2002), the California Supreme Court held by a vote of 4-3 that issue advertisements by Nike addressing labor

[5] *See, e.g., Keyishian v. Board of Regents*, 385 U.S. 476, 484 (1957); *Board of Trustees of Leland Stanford Junior University v. Sullivan*, 773 F. Supp 472, 474 (D.D.C. 1991).

conditions in its foreign shoe-production plants were due only the constitutional protection afforded commercial speech, *id*. at *11-16, even though comparable, contrary advertisements by Nike's critics would benefit from the high level protection provided for political speech. *Id.* at *25 (Chin, J., dissenting); *id.* at *26 (Brown, J., dissenting). The *Nike* decision has attracted sharp criticism, beginning with the dissenting California justices, and observers expect that a *certiorari* petition to the U.S. Supreme Court will come in due course.[6] The case therefore may be the vehicle for resolving what appears to be some relevant inconsistency in existing case law.

The challenged speech in *Nike* involves a variety of company communications — including traditional issue advertisements and also letters to newspaper editorial pages and to universities that purchase athletic footwear — that rebutted critics' claims about conditions in Nike factories abroad. One critic brought suit under California law, alleging that Nike made false statements of fact actionable under state unfair competition and false advertising statutes. Whether the state laws applied at all depended upon whether the challenged communications were commercial speech, and therefore subject to lesser constitutional protection.

By a bare majority, the California Supreme Court concluded that the Nike

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[6] *See also, e.g.,* Gary Young, *Boardrooms Fret over Nike Ruling; Will U.S. Supreme Court Hear the Appeal?*, NAT'L L.J., May 13, 2002, at A19.

communications were commercial speech. Although the California court recognized that Nike was engaged in a debate on issues of public interest and that the company's speech was intermingled with noncommercial speech, the majority established what it called "a limited purpose test" for identifying commercial speech that could sweep most corporate communications into its wake. *Nike*, 2002 WL 827173 at *11-12. Under the California test, speech would be deemed commercial if (1) the speaker were engaged in commerce, (2) the intended audience for the speech were "actual or potential buyers" of the speaker's goods or services, and (3) the speech were made for the purpose of promoting commercial transactions. The latter might include not only traditional claims about price and quality of goods but also statements about labor conditions and potentially any other assertion casting a favorable light on the corporate speaker. According to the California court, "[t]his broad definition … is necessary, we think, to adequately categorize statements made in the context of a modern, sophisticated public relations campaign intended to increase sales and profits by enhancing the image of a product or of its manufacturer or seller." *Id.*

In separate, sharply worded dissents, three California justices denounced the majority opinion as constitutionally unsound. The dissenters rejected the majority's conclusion that Nike should enjoy full First Amendment protection

only if its statements addressed globalization issues generally and omitted specific references to Nike products and production practices. Such reasoning, the dissenters pointed out, ignored the reality that Nike had become "the 'poster child' in the international campaign for labor rights and reform," *Nike*, 2002 WL 827173 at *21 (Chin, J, dissenting) (internal citation omitted), and could not defend itself from critical attack without necessarily discussing its own products and its business practices abroad. The dissent criticized the majority for stripping Nike of the same level of First Amendment protections that its "noncommercial" critics enjoyed — and emphasized that this inequitable treatment hurt not only Nike but the "public at large," which "has the right to receive information from both sides of this international debate." *Id.*

One of the California dissenters issued an explicit call for the U.S. Supreme Court to overturn *Nike*. In so doing, Justice Janice Brown stated, the high Court should "develop a more nuanced approach" to commercial speech "that maximizes the ability of businesses to participate in the public debate while minimizing consumer fraud." *Id.* at *27.

It is true that the U.S. Supreme Court has provided no clear guidance on the classification issue. Rather, its precedent identifies some relevant considerations that lack a unified framework. For example, the challenged speech in one of the seminal First Amendment cases of modern times, *New*

York Times v. Sullivan, 376 U.S. 254 (1964), appeared in the form of a paid advertisement which commercially benefitted the newspaper. Yet the Court had no difficulty affording *The New York Times* full First Amendment political speech protection against a libel verdict. Almost twenty years later, the Court identified three factors relevant in classifying speech as commercial: (1) whether the speech appears in the traditional form of an advertisement, (2) whether the speech mentions a product, and (3) whether the speech was prompted by economic motivations. *See Bolger v. Youngs Drugs Products Corp.,* 463 U.S. 60, 66-67 (1983). The Court in *Bolger* declined, however, to declare that any of these factors were necessary to commercial speech determination. It went on to conclude that a mailing that promoted contraceptives should be treated as commercial speech even though portions of the packet constituted purely informational, scientific speech. *See id.* at 67-68 (noting concern for loophole that might allow advertisers "to immunize false or misleading product information from government regulation simply by including references to public issues").

Five years later, the Court returned to characterizing the traditional "proposal of a commercial transaction" as "the test for identifying commercial speech." *Board of Trustees of the State University of New York v. Fox*, 492 U.S. 469, 473-74 (1989) (nonetheless rejecting argument that co-mingled

commercial and noncommercial speech were inseparable)

This lack of clarity on the proper approach for classifying commercial speech has left lower courts struggling. At least one illustration of these difficulties comes from the FDA realm. The District Court in *WLF,* 13 F. Supp. 2d 51, followed and extended the *Bolger* line. It held that reprints of peer-reviewed medical journal articles and textbook excerpts were commercial speech when circulated by prescription drug manufacturers though they were clearly scientific speech when originally published. 13 F. Supp. 2d at 62-64. The issue was not reached on appeal.

The decisions in *Nike* and *WLF* cannot be reconciled with the Supreme Court's increasing recognition of the important role commercial speakers play in national discourse. If, as the Court has stated, "the general rule is that the speaker and the audience, not the government, assess the value of the information presented," *Edenfield v. Fane*, 507 U.S. at 767, and the Court adheres to its view in *Western States* that speech suppression should be a last, rather than first, resort in effecting public policy, then affording maximum protection to speech by content classification seems most appropriate. If the ultimate beneficiary of First Amendment safeguards is the body politic which entered into the constitutional compact, then audience rights should be paramount and classification should depend on the information that the

audience is receiving, rather than the origin of the message.

The classification issue has real significance for the proposed DTC prescription drug advertising restrictions now under discussion. As currently conceived, those proposals sweep in all DTC prescription drug advertising without discrimination. If some DTC advertising is constitutionally classified as scientific speech so that its suppression would be subject to strict scrutiny, *Keyishian*, 385 U.S. 476, then the proposals are virtually certain to be overbroad even if otherwise sustainable. As emphasized in *Western States*, prohibitions which reach "useful speech" as well as potentially suppressible speech are particularly troublesome. *Western States*, 122 S. Ct. at 1509.

In sum, while the bulk of DTC prescription drug advertising falls within the parameters of conventional commercial speech, there are DTC communications which cannot readily be classified as something other than scientific speech. Legislative restrictions which indiscriminately burden all DTC prescription drug advertising thus may encounter substantial constitutional problems if the included scientific communications are appropriately protected under a strict scrutiny standard.

III. EFFORTS TO LIMIT DTC ADVERTISING FAIL FIRST AMENDMENT TEST

The previous two sections established that First Amendment review

would apply to certain legislative proposals to suppress direct-to-consumer advertising of prescription drugs by denying manufacturers who advertise their products a benefit under various government programs. At the very least, such legislative schemes would be subject to the "intermediate scrutiny" standard set by *Central Hudson* and increasingly invigorated by its progeny, including the Supreme Court's most recent commercial speech decision, *Western States*, 122 S. Ct. 1497 (invalidating statutory restrictions on DTC advertising of so-called "compounded" drugs).

This final section examines how the four-prong *Central Hudson* test would apply to certain proposals that would effectively suppress, or significantly burden, DTC prescription drug advertising. As we explained above, some DTC critics contemplate imposing handicaps on DTC advertising by limiting its deductibility under the Internal Revenue Code. Others suggest that government-sponsored benefit programs such as Medicaid or proposed new benefits under Medicare should disfavor DTC advertising-supported drugs by, for example, establishing a prescription drug reimbursement plan that would differentiate between advertised and non-advertised drugs.

The first prong of the *Central Hudson* analysis raises the threshold issue of whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. *Central*

Hudson, 447 U.S. at 566. Although it is possible that an individual DTC advertisement might be shown to be misleading or to step outside the boundary of claims officially approved by FDA, the potential for occasional enforcement cases is no basis for making a broad legislative determination that all DTC prescription drug advertising is outside constitutional protection. In fact, such DTC advertising generally is more reliable, from the consumer standpoint, than essentially any other type of commercial speech. FDA already closely monitors pharmaceutical manufacturers' claims for adherence both to the government-approved uses of the drug and to regulatory mandates requiring "fair balance" in disclosure of possible side effects and contraindications.[7] A manufacturer who promotes unapproved uses would risk violating prohibitions in FDCA against both "unauthorized sale" and "misbranding," thereby subjecting the advertised drug to seizure and the manufacturer to substantial penalties. *See WLF*, 202 F. 3d at 335, citing Appellant's Brief at 34-35. Failure to maintain fair balance is another substantive violation that again would risk substantial penalty under FDCA. *See* 21 C.F.R. § 202.1 (d)(5)(ii); 21 U.S.C. § 355(n). Against these facts, lawmakers would have no arguable basis for determining that all

[7]The pharmaceutical products themselves have met a standard of rigorous governmental review that the vast majority of products and services sold in the United States never face. Each drug is approved for use only on the basis of "substantial evidence" derived from two "adequate and well controlled" studies. 21 U.S.C. § 355(d). Whether the statutory fair balance requirement governing prescription drug advertising, 21 U.S.C. § 352(n), is constitutional is beyond the scope of this paper.

DTC prescription drug advertising concerns unlawful activity or is inherently misleading. Hence, any across-the-board legislative suppression would clearly invade an area of protected speech.

Once the truthful, non-misleading nature of the constitutionally-protected DTC speech is established, the remaining three prongs of *Central Hudson* focus on (2) the government's goal in imposing restrictions on it, (3) the degree to which the regulations directly advance the goal, and (4) the precision used in fashioning the restrictions. The analysis is not a formal balancing process, but the Supreme Court recently explained that the four prongs "are important and, to a certain extent, interrelated: Each raises a relevant question that may not be dispositive to the First Amendment inquiry, but the answer to which may inform a judgment concerning the other three." *Greater New Orleans Broad. Ass'n. v. U.S.* 173, 183-84 (1999). Given the existing government oversight of the accuracy of DTC messages, lawmakers intending to restrict them must demonstrate that their goals require depriving consumers of access to very valuable information.

The second prong of the analysis requires the government to come forward with a "substantial" non-speech interest to justify restraints. *Western States*, 122 S. Ct. at 1504 (citing *Central Hudson*, 447 U.S. at 566). Based on congressional rhetoric, there appear to be only three possible justifications for suppressing DTC prescription drug advertising: (1) enhancing safety by foreclosing consumers from cajoling physicians into prescribing drugs which consumers do not need and which may even harm them, (2) containing costs in government benefit programs such as

Medicaid and Medicare, and (3) increasing tax revenues by limiting advertising deductions.

Government assertion of a public safety interest, as a general matter, would typically receive a respectful hearing. However, the government would have to demonstrate that there are advertising-generated patient pressures on physicians which threaten sound prescribing practices. Proving that this safety interest even exists, much less stands as a "substantial" one, seems an insurmountable burden for the government — as a factual matter and in the wake of *Western States*.

From the factual perspective, a number of recent studies show that physician-patient relationships are not harmed, but rather enhanced, by DTC prescription drug advertising.[8] Both patients and physicians report that DTC advertisements help to educate consumers about symptoms that may indicate the existence of a serious

[8] *See* U.S. Food & Drug Admin. Div. of Drug Mktg., Adver. & Communications, Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results (April 18, 2002), available at http://www.fda.gov/cder/ddmac/DTCnational2002a/sld001.htm ("2002 FDA Survey"); U.S. Food & Drug Admin. Div. of Drug Mktg., Adver. & Communications, *Attitudes and Behaviors Associated with Direct-to-Consumer (DTC) Promotion of Prescription Drugs* (1999), available at http://www.fda.gov/cder/ddmac/dtctitle.htm ("1999 FDA Survey") (both accessed May 31, 2002). *See also, e.g.*, Market Measures Interactive L.P., The *DTC Monitor* 2001: A Competitve Evaluation of DTC Advertising Campaigns (June 2001); Prevention Magazine, *Fifth Annual Survey of Consumer Reaction to Direct-to-Consumer Advertising of Rx Medicines*, March 2002 ("Prevention DTC Study"); Market Measures/Cozint, *Doctors Say Direct-to-Consumer Advertising of Rx Medicines Improves Physician/Patient Relationship* (press release dated Feb. 14, 2001 (summarizing study based on physician reports of over 400 office visits where patients initiated a discussion about a prescription drug) (Market Measures/Cozint DTC Study"); Sharon Allison-Ottey, et al., *"To Do No Harm": Survey of the Physicians of the National Medical Association Regarding Perceptions on DTC Advertisements*, 2001 (survey of 886 NMA member physicians) ("NMA Physician Survey").

health condition.[9] Patients and physicians also report that the advertising prompts consumers to seek out additional information from their doctors — and that nearly twenty percent of these patients ask questions about a condition for the first time.[10] Recent data also indicate that DTC advertisements actually help to improve patient compliance with treatment regimens.[11] For their part, a majority of physicians recently told researchers that DTC advertisements led patients to ask appropriate questions that led to more thorough discussions on subjects such as suitable products, efficacy, and side effects.[12] Most doctors said they feel little or no pressure to prescribe a drug simply due to a patient query; in fact, research indicates that in response to such questions, a physician is likely to prescribe another drug, prescribe no drug at all, or counsel the patient on lifestyle changes.[13] In short, no real problem with improper prescribing appears to exist.[14]

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[9] *See, e.g.*, 2002 FDA Survey; 1999 FDA Survey; NMA Physician Survey at 11-12. There is little dispute that under-treatment of conditions is a significant problem; for example, data indicates that fewer than half of Americans with heart disease or its precursors are receiving proper treatment, only about half of American with diabetes are even aware of their illness, and less than 25 percent of Americans with serious depression receive proper care. *See* U.S. Centers for Disease Control, National Health and Nutrition Examination Survey III, 2001, available at http://www.cdc.gov/nchs/nhanes.htm (accessed May 31, 2002). The data indicates that minority populations disproportionately suffer the effects of under-diagnosis and -treatment.

[10] 2002 FDA Survey (18 percent); *see also* 1999 FDA Survey (27 percent).

[11] RxRemedy Information Services, *Impact of DTC Advertising Relative to Patient Compliance*, June 2001; Prevention DTC Study.

[12] Market Measures/Cozint DTC Study; NMA Physician Study at 12.

[13] *See* 1999 FDA Survey, 2002 FDA Survey; *see also* NMA Physician Survey at 12.

[14] As a general matter, FDA itself recently acknowledged that drug advertising can play a key role in delivering critical health information to both health care professionals and

Western States greatly increases the difficulties the government would face in substantiating this asserted safety interest. The speech restraint in *Western States* operated by effectively limiting what a pharmacist could say in DTC advertisements about specific "compounded" drugs, *i.e.,* tailored doses of drugs that pharmacists mix pursuant to a doctor's prescription, which traditionally are not reviewed by FDA for safety and effectiveness.

Tellingly, the government in *Western States* did not even attempt to argue that DTC compounded drug advertisements might "put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway," *Western States*, 122 S. Ct. 1497, 1499, but the Court still considered the notion before firmly rejecting it. The good sense of consumers and the skills of licensed physicians, the Court concluded, were sufficient to ensure that compounded drugs would be prescribed safely notwithstanding the advertising:

> 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…. If it is appropriate for the [FDCA] to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them, it is not clear why it would not also be appropriate to rely on

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lay persons. *See* Dep't of Health & Human Serv., Food & Drug Admin., *New Drugs and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible*, 67 Fed. Reg. 37988, 37992-93 (May 31, 2002) (rejecting call for sweeping advertising restrictions on drugs intended to address harms created by chemical, biological, radiological or nuclear substances). The agency explained that "[a] prohibition on advertising could limit health care providers' and public health and emergency preparedness officials' awareness of the products approved under this rule. Limiting awareness of these products, which are intended to reduce or prevent life-threatening or disabling toxicity, does not seem desirable or appropriate."

> doctors to refrain from prescribing compounded drugs to patients who do not need them in a world where advertising was permitted.

Western States, 122 S. Ct. 1497, 1507-08.

Indeed, *Western States* can be fairly read as yet another example of the Court rejecting government paternalism as a legitimate justification for commercial speech restrictions. Although the justices' disaffection for paternalism in this arena first surfaced in *Virginia Pharmacy*, the trend has gained considerable force since the mid-1990s. *See, e.g., 44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484 (1996). The latest manifestation is particularly striking, perhaps, because the drugs at issue in *Western States* were not reviewed and approved by the government for safety and effectiveness. Prescription drugs, on the other hand, do undergo such review — which suggests that *Western States* stands as a virtually insurmountable barrier to broad government suppression of DTC advertising on the basis of safety.

There also is doubt whether "cost containment" interest would be a cognizable interest under *Central Hudson.* All advertising involves some expenditures,[15] and the government purchases almost all goods and services available in the U.S. marketplace for some purpose. If cost containment were a "substantial" interest supporting suppression of advertising, potentially no advertisements would be immune from restrictive regulation. In fact, the balancing of interests required by

[15]This does not mean that drug costs for individual consumers necessarily go up. As an economic matter, however, expenditures on advertising may lead to expanded production that in turn reduces marginal costs — which, in a competitive market, would exert downward pressure on per-unit prices.

Central Hudson would be obliterated; one could argue that the complete suppression of advertising may be the only effective means of advancing the cost containment objective. Yet, while the government no doubt has authority to contain procurement costs by, for example, refusing to recognize self-congratulatory advertising as an eligible cost under cost-plus government contracts, see 48 C.F.R. § 31.205-1, there appears to be no precedential support for using cost containment as a substantial non-speech interest under prong two of *Central Hudson.*

Moreover, from a factual standpoint, the cost issue is not as simple as it may first appear. Recent economic studies indicate that improved health in the U.S. population over recent decades has provided benefits worth billions of dollars.[16] Much of this gain is due to the impact of healthier workers on productivity; estimates indicate that each year added to average life span adds approximately 4% to national output.[17] New drug treatments have been shown to be a factor in increasing worker productivity.[18] New drugs also can be more effective than older drugs in reducing or eliminating the need to turn higher cost alternatives such as hospitalization or nursing

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[16] *See* William Nordhaus, *The Health of Nations: The Contributions of Improved Health to Living Standards*, Cowles Foundation Discussion Paper No. 1355 (1999); Kevin Murphy & Robert Topel, THE ECONOMIC VALUE OF MEDICAL RESEARCH 1 (U. of Chicago 1999).

[17] David E. Bloom, David Canning & Jaypee Sevilla, *The Effect of Health on Economic Growth: Theory and Evidence*, Nat'l Bur. Econ. Research Working Paper Series No. 5 (2001).

[18] D. Walsh, *Costs of Illness in the Workplace*, in WORK HEALTH AND PRODUCTIVITY 217-40 (G. Green & F. Baker, eds., Oxford University Press 1991).

home care.[19] These cost trade-offs should have real significance in the overall calculus: The federal government as an employer has a direct interest in the productivity of more than 4.5 million civilian and military workers[20]; as a tax collector, it has an indirect interest in the entire U.S. workforce; and as a benefits provider, it has direct interests in holding down hospitalization and nursing home costs. In short, "containing" drug costs may provide no real fiscal benefits generally. Moreover, from a constitutional perspective, the facts cast doubt on whether the government would be able to satisfy its burden of showing that the purported concern is a "real" one. *Edenfield v. Fane*, 507 U.S. at 770-71.

Notwithstanding the frailty of an asserted safety or cost containment interest as substantial government goals, it is possible that lawmaker assertions that their proposed restrictions on DTC prescription drug advertising would serve to increase tax revenues might survive prong two scrutiny. The consequence of that would be to shift attention to prong three of the *Central Hudson* analysis, the determination of "whether the regulation directly advances the governmental interest asserted."

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[19] Provenzano, et al., *Delays in Nursing Home Placement for Patients with Alzheimer's Disease Associated with Treatment Donepezil May Have Healthcare Cost-savings Implications*, PHARMACOECONOMICS & OUTCOMES NEWS, May 2001.

[20] *See* U.S. Office of Personnel Management, *Trend of Federal Civilian On-Board Employment for Executive Branch (Excluding Post Office) Agencies*, available at http://www.opm.gov/feddata/exec2000.pdf (citing 1.7 million federal employees in 2000); U.S. Dep't of Labor Bur. Labor Stat., *Postal Service Workers*, available at http://www.bls.gov/oco/ocos141.htm (citing 860,000 postal employees in 2001); U.S. Dep't of Defense, DoD Active Duty Military Personnel Strength Levels, available at http://web1.whs.osd.mil/mmid/military/ms9.pdf (citing total of 1.3 million military employees in 2000); U.S. Dep't of Defense, Monthly Report of Federal Civilian Employment, available at http://web1.whs.osd.mil/mmid/civilian/fy2002/March2002/Consolid.pdf (citing 667,000 employed in March 2002) (all visited May 31, 2002).

Western States, 122 S. Ct. 1497, 1504 (citing *Central Hudson*, 447 U.S. at 566.) At this juncture, if not before, the proposed DTC restrictions inevitably would run into heavy seas. The burden of establishing direct advancement would fall on the government, and the Supreme Court has made it plain that this burden "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield v. Fane,* 507 U.S. at 770-71. A regulation "[cannot] be sustained if it provides only ineffective or remote support for the government's purpose," *id.,* or if there is "little chance" that the restriction will advance a legitimate goal, *Greater New Orleans*, 527 U.S. at 193. Per the Court, "this requirement [is] critical, otherwise a state could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 487 (1995) (citing *Edenfield v. Fane,* 507 U.S. at 771).

The somewhat circular interrelationship of the "substantial interest" and "direct advancement" prongs of *Central Hudson* is highlighted by at least two of the government objectives behind the current proposals for DTC restrictions. As discussed above, even if the government had a substantial interest in safeguarding physician prescribing practices from improper influences, there are no facts to show that restricting DTC advertising would directly advance that objective.

Similarly, even assuming that cost containment were a valid, non-speech

objective, we are aware of no evidence that DTC prescription drug advertising raises the "cost" experienced by the buyer — *i.e.,* the price charged by the manufacturer — as opposed to the cost incurred by the seller. Indeed, evidence available now suggests that there is no clear correlation between advertising dollars and price changes.[21] Furthermore, existing economic literature indicates market expansion through informative advertising may reduce unit costs by increasing production and, as a result, reduce unit prices.[22] Unless proponents of DTC restriction could demonstrate clear evidence linking advertising to increases in unit prices, they would be forced to define the interest in cost containment as reducing aggregate drug expenditures by reducing the number of patients seeking treatment. Presumably the proposed restrictions would directly advance the goal by keeping Medicaid and Medicare beneficiaries ignorant of drugs that their physicians, if prompted, would consider necessary and beneficial treatment options. That, in turn, resurrects a serious prong two issue: to assert that the government has a "substantial" interest in using information restriction to limit effective treatment under Medicaid or Medicare is to contradict the health care foundation of these programs.

The government could, of course, support a limitation on the deductibility of DTC prescription drug advertising by relying on the truism that any limitation on deductibility directly advances an interest in increasing tax revenue. That rationale,

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[21] *See* John E. Calfee, *Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs* 12-13 (American Enterprise Institute, April 26, 2002).

[22] *See e.g.,* J.H. Beales & T.J. Muris, *State and Federal Regulation of National Advertising* (AEI Press, 1993).

however, would support using the Internal Revenue Code to regulate any form of advertising by reference to its content. Such an effort would run squarely against a long line of precedent condemning invidious discrimination in dispensing government benefits, including tax exemptions and limitations. *See, e.g., Ark. Writers' Project,* 481 U.S. 221 (state tax exemption policies); *Rosenberger*, 515 U.S. 819 (college student-activity fund).

In short, given the existing body of knowledge on the price and health care effects of DTC prescription drug advertising, it is highly unlikely that any of the proposed restrictions now under discussion could survive to the final stage of the *Central Hudson* analysis. If any did, however, the fourth prong would obligate the government to demonstrate that its restraints were "not more extensive than is necessary to serve" its legitimate and substantial goal. *Western States,* 122 S. Ct. at 1504 (citing *Central Hudson*, 447 U.S. at 566). *Western States* indicates that prong four requires consideration of whether the challenged restriction suppresses potentially beneficial speech along with speech whose suppression furthers a legitimate goal. *Id.* at 1506. Prong four also requires determining whether the government could have used non-speech restricting alternatives to advance its valid objectives. *Id.* ("we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.")

There can be no quarrel that DTC prescription drug advertising messages usefully alert consumers to dangerous health conditions, such as depression, which

are vastly undertreated (particularly in minority populations). DTC advertising also can alleviate the stigma of seeking treatment for sexually transmitted diseases and mental illnesses, where affirmation that the problem is medically treatable is critically important to patients. Moreover, the evidence demonstrating that DTC advertising enhances doctor-patient communication and dosing regime compliance confirms that repressive measures would block a great deal of speech which offends no discernible government interest. Thus, the overbreadth of the proposed restrictions alone may cause them to fail prong four review.

In addition, the government plainly could advance its legitimate objectives without speech restrictions. For example, lawmakers have at their disposal numerous means of increasing tax collections for general revenue purposes that would not discriminate against DTC prescription drug advertising. These range from increasing tax rates to denying tax deductions for all advertising expenses. Similarly, overall cost containment in the Medicaid and Medicare programs could be achieved by a variety of non-discriminatory measures, including total dollar caps on prescription drug benefits or total patient benefits. Thus, the proposed restrictions on DTC prescription drug advertising could not be considered "narrowly tailored" to limit encroachments on protected speech while either raising revenues or containing costs.

The same is true with respect to the government's interest in avoiding unnecessary or unsafe prescribing by physicians under patient pressure. To the extent improper prescribing might take place within the Medicaid and Medicare

programs, it could be subjected to audit and regulation on the same basis that the programs deal with other excessive uses of medical resources, such as diagnostic tests. To the extent that physician need to better prepare to deal with patient inquiries, FDA could require manufacturers to alert physicians that DTC advertising is being used. As the Court emphasized in *Western States*, however, there is simply no basis to conclude that a well-informed physician would respond irresponsibly to patient inquiries generated by DTC advertising.

CONCLUSION

In sum, comprehensive analysis of current legislative proposals for restricting DTC prescription drug advertising demonstrates that the schemes would be cognizable under the First Amendment, subject to review under at least the "intermediate scrutiny" standard of *Central Hudson,* and incapable of withstanding constitutional challenge.