

Center for Constitutional Rights

A NON-PROFIT LEGAL/EDUCATION ORGANIZATION COMMITTED TO THE CREATIVE USE OF LAW AS A POSITIVE FORCE FOR SOCIAL CHANGE.

September 13, 2002

Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re.: Request for Comment on First Amendment Issues, Docket No. 02N-0209

Dear Sirs:

Enclosed please find an eleven page document, which is the submission of the Center for Constitutional Rights and the Center for Medical Consumers in response to the FDA's "Request for Comment on First Amendment Issues," Docket No. 02N-0209.

An electronic version of this document in Microsoft Word format was submitted on the date of this letter (which is the submission deadline) as an attachment to an email sent to the email address provided on the FDA web site's dockets page.

Please feel free to contact me at (212) 614-6438 if I can be of any further assistance.

Yours sincerely,



Shayana Kadidal, Esq.

02N-0209

CONTINUING THE LEGACY OF THE NATIONAL EMERGENCY CIVIL LIBERTIES COMMITTEE

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September 13, 2002

**STATEMENT OF THE CENTER FOR CONSTITUTIONAL RIGHTS AND THE
CENTER FOR MEDICAL CONSUMERS IN RESPONSE TO FDA'S "REQUEST
FOR COMMENT ON FIRST AMENDMENT ISSUES"**

Docket No. 02N-0209

Statement of Interest

The Center for Constitutional Rights ("CCR") is a national non-profit legal, educational and advocacy organization dedicated to advancing and protecting the rights guaranteed by the United States Constitution. Founded in 1966 during the Civil Rights Movement, CCR has a long history of litigating cases on behalf of medical self-determination. *See Monell v. Dept. of Social Services*, 436 U.S. 658 (1978) (invalidating forced leave with loss of seniority for pregnant workers); *NOW v. Terry* (1988) (establishing concept of "buffer zones" for abortion clinic protestors). As part of its advocacy and litigation on behalf of those whose civil and constitutional rights have been violated, CCR has litigated numerous landmark cases under the First Amendment of the United States Constitution. *See Dombrowski v. Pfister*, 380 U.S. 479 (1965) and *Carmichael v. Selma* (anti-sedition prosecutions of civil rights activists chilled First Amendment rights); *Kinoy v. District of Columbia*, 400 F.2d 761 (D.C. Cir. 1968) (free speech rights in congressional hearing room); *Soglin v. Kauffman*, 418 F.2d 163 (7th Cir. 1969) (upholding rights of students expelled for lawful protest); *Capitol Police v. Jeannette Rankin Brigade*, 409 U.S. 972 (1972) (right to demonstrate on Capitol steps); *People v. Mandel* (1975) (introducing concept of rape shield motions); *Texas v. Johnson*, 491 U.S. 397 (1989) (flag burning during political protest is protected speech).

The Center for Medical Consumers, founded in 1976, is a non-profit advocacy organization active in both statewide and national efforts to improve the quality of health care. It is entirely supported by private donations, newsletter subscriptions, and the generous support of the Judson Memorial Church. The Center has been committed to broadening the public's awareness about the quality problems that pervade the American health care system. The Center participates in a number of New York State task forces and workgroups charged with improving the quality of healthcare. As part of this commitment, the Center has led efforts to ensure that healthcare institutions and professionals are held responsible for the quality of care they provide through strong enforcement of laws and regulations, to open up public access to all information available about doctor and hospital-specific performance, to hold medicine to the highest standard of scientific evidence that what it does is safe and effective, to critique misleading drug ads directed at physicians and consumers, to push for a greater consumer voice in decision-making that affects the quality of care, and to require that medical decisions made by managed care organizations can be appealed by consumers to independent medical experts.

Introduction

This statement is a response to the FDA's open-ended call for comment, *Request for Comment on First Amendment Issues*, 67 Fed. Reg. 34942 (May 16, 2002), in the wake of the Supreme Court's decision in *Thompson v. Western States Medical Center*, 535 U.S. ---, 122 S. Ct. 1497, 70 U.S.L.W. 4275 (Apr. 29, 2002). In the call for comment, the FDA states that "[t]he Supreme Court has increasingly recognized the value of" commercial speech in case law that "presents a challenge to FDA." The call for comment states that, given this trend in the case law and the opinion in *Western States* in particular, the "FDA seeks to ensure ... that its regulations, guidances [sic], policies and practices comply with the First Amendment." Several specific inquiries follow, asking, *inter alia* (1) may the FDA argue that certain speech is "inherently misleading" unless it complies with regulations, (6) does the First Amendment allow greater latitude over product labels than over advertisements, (8) are there appropriate non-speech restrictions that could accomplish the same goals as advertising restrictions, and (9) "[a]re there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?" These queries appear to evidence self-doubt on the part of the FDA with regard to the breadth of its powers to regulate advertising of drugs. For the reasons stated below, we feel this reaction to *Western States* is unwarranted.

The *Western States* decision

In a recent letter to Senator Jack Reed's office, an FDA official indicated that *Western States* was "of particular concern ... because of the potential breadth of the Supreme Court's rationale." (Letter from Dr. Lester M. Crawford, Deputy FDA Commissioner, to Sen. Jack Reed, Aug. 12, 2002, at 1) "The Court held that although the government interest underlying the statutory provision was substantial, it was not permissible under the First Amendment for FDA to pursue that interest by imposing advertising restrictions because non-speech-restrictive alternatives were available."

One must be careful in extrapolating from a precedent that was decided in part based on what the parties *failed* to argue. First, the government did "not attempt to defend the [the challenged statute by] argu[ing] that the prohibited advertisements ... would be misleading." 122 S. Ct. at 1504. Rather, the government argued that the statute met the requirements set forth for regulation of commercial speech (that is not misleading or related to unlawful activity) in the Supreme Court's seminal opinion on the topic, *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980): that the speech restrictions be motivated by a "substantial" government interest, that they "directly advance" that interest, and that they be "narrowly tailored" to serve that interest (that is, that the restrictions be no more extensive than is necessary to serve the interest). As our analysis in the next section attempts to show, it may be possible for the FDA to argue that much regulated drug advertising is in fact "inherently misleading" when considered in context and in light of consumers' reactions to it. As the majority opinion in *Western States* points out, the government had the opportunity to argue that "patients who see [compounded drug] advertisements will be confused about the drugs' risks," but

failed to do so. 122 S. Ct. at 1508. As the government failed to properly raise and develop this argument, the majority held that it could not consider it.¹

The majority found that none of the interests the government actually asserted during the litigation met the “substantial interest” prong of the *Central Hudson* test. However, the government did not raise the argument that “an interest in prohibiting the sale of compounded drugs to ‘patients who may not clearly need them’” might meet the constitutional standard, and so the majority was foreclosed from even considering it. 122 S. Ct. at 1507 (“Nowhere in its briefs, however, does the Government argue that this interest motivated the advertising ban.”). Although the majority did go on to say, in dicta, that this interest in prohibiting unnecessary drug sales would be insufficient to justify the government “preventing the dissemination of truthful commercial information,” *id.*, it is unclear whether this “substantial interest” analysis (step two in the *Central Hudson* test) would have been reached had the government asserted that the speech in question was misleading to consumers.

Furthermore, there is the possibility that even the “substantial interest” analysis would have been conducted differently had the government asserted that the speech in question could potentially mislead consumers into pursuing unnecessary prescriptions. Several members of the court have expressed unease with the mechanistic aspects of the *Central Hudson* test, *see Western States*, 122 S. Ct. at 1504, and would prefer a more holistic approach to analysis of commercial speech, which to some extent has been reflected in recent majority opinions: “The four parts of the *Central Hudson* test are not entirely discrete. All 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. United States*, 527 U.S. 173, 183-84 (1999). If the government had made a stronger argument that the advertisements in *Western States* were misleading, the Court might have applied the narrow tailoring requirement more liberally.

In short, the litigation tactics adopted by the government in the course of the *Western States* case had a significant impact on the manner in which the case was decided. This in turn should lead informed readers to restrain any expansive interpretations of “the ... breadth of the Supreme Court’s rationale.”

Government power to regulate misleading speech

Were all the advertisements prohibited by the statute at issue in *Western States* misleading? Even the dissenters were concerned that the law encompassed some nonmisleading speech, for example, that “this pharmacy will compound drug X.” *Western States*, 122 S. Ct. at 1514 (Breyer, J., dissenting). However, a tremendous amount of drug advertising may be misleading **in terms of how it is received** by the listener. Much of the behavior the *Western States* dissenters would hope to prevent

¹ The majority opinion goes on, in dictum, to state that “Even if the government did [so] argue ... this interest could be satisfied by [a] far less restrictive alternative” of labeling. As dictum, this statement lacks the force of law. More importantly, it misstates the vast body of existing precedent which holds that misleading commercial speech is not protected by the First Amendment, which means the second stage of the *Central Hudson* analysis—identifying a significant government interest—is never reached. *See Central Hudson*, 447 U.S. at 563. This point is elaborated further, below.

through regulation—for example, the situation where a patient demands a drug that he or she does not need—may be triggered by advertising making factual claims which are systematically misunderstood by typical consumers.² We believe that the power of the FDA to regulate such speech as **misleading** may in fact be much broader than the FDA currently believes.

a. Case law on misleading speech

According to the Supreme Court’s opinion in *Central Hudson*, the First Amendment protection of commercial speech is “based on the informational function of advertising,” and, consequently, “[t]he government may ban forms of communication more likely to deceive the public than to inform it.” 447 U.S. at 563. (If a form of speech is categorized outside the line marking “commercial” speech, then content-based regulation is prohibited.) Where speech is deceptive, the First Amendment “‘poses no barrier to any remedy ... reasonably necessary to the prevention of future deception’ by the use of commercial speech.” *Accountants Soc’y of Virginia v. Bowman*, 860 F.2d 602, 605 (4th Cir. 1988), quoting *Harry & Bryant Co. v. FTC*, 726 F.2d 993, 1001-02 (4th Cir. 1984).

Most of the case law concerning misleading commercial speech deals with regulation governing advertising by attorneys. The Supreme Court has held that “advertising for professional services” may be prohibited “when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse.” *In re R.M.J.*, 455 U.S. 191, 203 (1982). In defining “misleading” for the purpose of the regulation of commercial speech, the Supreme Court has explained that when the possibility of deception is self-evident, the government need not survey the public or otherwise produce an exhaustive empirical foundation for its conclusions about the misleading nature of certain types of statements. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 652-53 (1985); see also *Accountants Soc’y of Virginia*, 860 F.2d at 606 (state need not produce an “elaborate evidentiary showing ... to establish the misleading nature of regulated speech”); *Kraft, Inc. v. FTC*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993) (rejecting argument that First Amendment required extrinsic proof of consumer reaction to advertisements in question, relying on *Zauderer* in finding that the ads made “facially apparent” implied claims). *Zauderer*, a lawyer who represented Dalkon Shield tort plaintiffs, had advertised that “no legal fees” would be owed unless the clients received compensation. The Court held this statement misleading because it believed that the general public would be unfamiliar with the important distinction between his attorney’s fees, and court and other costs. The importance of this line of cases is precisely that they deny the need for the government to conduct an extensive survey (much like that which will be produced in response to this call for comment) of empirical data in order to justify the finding that certain speech is misleading.

² Much of the regulation governing the disclosures required in clinical trials turns on similar concerns, for example, mandatory disclosures designed to avoid the “therapeutic misconception” by which subjects typically expect they are being “treated” by entering a trial even when there is a substantial chance they will be randomized into a placebo group.

“[S]peech that may be merely likely to deceive the public” may be “regulated or banned.” *Discovery Network, Inc. v. Cincinnati*, 946 F.2d 464, 469 (6th Cir. 1991) (emphasis added). Whether it may be banned or merely regulated depends on whether it is found to be “inherently”³ or merely “potentially” misleading. This distinction is a subtle one, but extremely important, and we will address it at some length below. The Court gave some guidance as to the distinguishing factors in two attorney advertising cases, *In re R.M.J.*, 455 U.S. 191 (1982), and *Peel v. Attorney Registration and Disciplinary Committee of Illinois*, 496 U.S. 91 (1990).

In *In re R.M.J.*, an attorney had advertised his services and included the phrase “Admitted to Practice Before THE UNITED STATES SUPREME COURT” in his advertisements, which was in violation of Missouri’s rules. The Court, however, held the Missouri rule unconstitutional. The Court, citing *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977), stated that regulation was permissible “where the particular advertising is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive.” 455 U.S. at 202. The Court in *R.M.J.* essentially found that the advertising was merely “potentially” misleading, and therefore that regulation of it must be limited. Writing for a unanimous Court, Justice Powell wrote, “States may not place an absolute prohibition on certain types of potentially misleading information, e.g., a listing of areas of practice, if the information also may be presented in a way that is not deceptive.” 455 U.S. at 203. The Court further stated that restrictions upon potentially misleading advertising “may be no broader than reasonably necessary to prevent the deception.” *Id.* In practice, courts have allowed regulations forcing advertisers to add mandatory disclaimers to such statements, but few other restrictions have passed the “no broader than reasonably necessary” test.

To some extent, the Court in *R.M.J.* and similar cases have (circularly) defined the “potentially misleading” category of advertisements as those where the Court’s preferred remedy happens to be mandated additional speech, such as disclaimers. *Cf. Bates*, 433 U.S. at 372-75 (finding advertising there not inherently misleading, essentially, because the Court concludes as a matter of policy that “[i]f the naivete of the public will cause advertising by attorneys to be misleading, then it is the bar’s role to assure that the populace is sufficiently informed as to enable it to place advertising in its proper perspective”). However, advertisements for the professions carry a special risk of deception: “The public’s lack of knowledge, the limited ability of the professions to police themselves, and the absence of any standardization in the product renders advertising for professional services especially susceptible to abuses that the [government has] a legitimate interest in controlling.” *R.M.J.*, 455 U.S. at 202. Where these factors combine to make advertised information too complex to be processed by the general public, such that additional “counter-speech” would not help eliminate any confusion engendered by advertising, then that advertising ought to be subject to regulation beyond mere mandatory disclaimers—that is, it should fall into the category of “inherently” misleading commercial speech.

If *R.M.J.* and *Bates* show that the Court has been circular in deciding that certain speech is potentially misleading, *Peel* demonstrates that the Court can be confused in its

³ The Court also often refers to “actually” misleading commercial speech, which obviously falls on the same side of the regulatory equation as “inherently” misleading commercial speech, and will not be described as distinct from the latter here in order to avoid confusion.

line drawing between “inherently” and “potentially” misleading speech. In *Peel* the Court splintered on the question of the inferences that might be drawn from an attorney’s letterhead statement that he was a “Certified Civil Trial Specialist by the National Board of Trial Advocacy [NBTA].” While four justices found the statement not misleading, two justices thought that it was “potentially misleading” and three justices found it “inherently misleading.” See 496 U.S. at 118 (White, J., dissenting, surveying positions).

The *Peel* plurality believed that some consumers would have inferred from Peel’s certification advertisement that his qualifications were greater than those required for mere admission to the bar. However, the four justices also felt that the NBTA was a bona fide organization with clear standards, and therefore concluded that this inference on the part of consumers was not inaccurate. There was no evidence that consumers inferred government sanction from the ad, and the plurality was satisfied that “the consuming public understands” that many private organizations issue licenses on their own standards, *id.* at 103, stating “[w]e reject the paternalistic assumption that the recipients of petitioner’s letterhead are no more discriminating than the audience for children’s television.” *Id.* at 105.

Justice Marshall, concurring in the judgment, found the advertisements “potentially” misleading. Surveying older cases, he stated that “inherently” misleading speech included information imparted by a method “inherently conducive to deception and coercion” (in-person solicitation being one example), and “speech that is devoid of intrinsic meaning,” especially where such speech “historically has been used to deceive the public.” *Id.* at 112. Justice White agreed with Justice Marshall but dissented as to proper outcome. The other three dissenters (O’Connor, Rehnquist, and Scalia) stated that advertising was “inherently” deceptive “‘where [it] is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive.’” They found Peel’s letterhead “‘inherently likely to deceive,’” 496 U.S. at 121,—and therefore “inherently” deceptive—because an “ordinary consumer with a ‘comparative lack of knowledge’ about legal affairs” should be able to assess the validity of the claims therein, and here it was simply too difficult for laypersons to determine what the NBTA was and what its “certification” meant. *Id.* at 121-22.

Peel demonstrates how subjective and fact-specific⁴ any attempt to differentiate and categorize “inherently” and “potentially” misleading speech will be. One commentator has stated that “the Court [has] failed to set forth in any detail the distinctions between” these sub-categories of misleading speech, and in particular has “merely react[ed] in a visceral fashion” in distinguishing speech as “either ... inherently misleading or potentially misleading.” Michael E. Rosman, *Ambiguity and the First Amendment*, 61 Tenn. L. Rev. 289, 342 (1993). Nonetheless, a laundry list of elements from the cases provides helpful guideposts: “Inherently misleading” speech has included speech that is delivered in a fashion that is inherently coercive, speech that is inherently devoid of meaning, speech that has been empirically found to be deceptive in practice, speech that has historically been regarded as deceptive, speech that can only be understood with esoteric knowledge available to professional insiders (*Peel* dissent), speech making general claims about professional services that are inherently individualized (as to both appropriateness for the consumer and quality of the provider,

⁴ Despite this, the *Peel* plurality held that the determination that an advertisement was inherently deceptive is a matter of law, over which the Court would exercise de novo review. See 496 U.S. at 108.

see *Bates, R.M.J.*), and, finally, speech where common sense indicates that there is a good chance of confusion (*R.M.J., Zauderer*).

Under these rough guidelines, much of the commercial speech traditionally regulated by the FDA would arguably fall into the “inherently misleading” category. Advertising claims about the appropriateness of particular drugs for particular patients are obviously making general claims about professional services that should be tailored to an individual’s needs by an expert professional. Drug claims have been archetypical targets of deceptive advertising regulation over history. And where the FDA has concrete empirical evidence of deceptive effect of certain claims in practice, such claims obviously qualify as “inherently deceptive.” Although this short list does not exhaust the arguments for finding speech “inherently misleading” (many further normative criteria exist as well; see below), it is plain that much existing FDA regulation of speech may be justified merely based on established precedent.

b. Normative arguments: what should be legally considered misleading speech?

Notwithstanding what the Court has said, what should the proper test for “inherently” misleading speech be? Commentators have opined that the “false or misleading” exception ought to be extended to “information understood by recipients to be factual”—that is, that the “recipient’s interpretation” ought to govern the analysis. Randall P. Bezanson, *Institutional Speech*, 80 Iowa L. Rev. 735 (1995). Courts have occasionally followed suit. See, e.g., *American Airlines, Inc. v. Edwards*, 1992 U.S. Dist. LEXIS 21063 at *5 n.2, *6 (S.D.N.Y. 1992) (where an advertisement “could be perceived as encouraging” a misleading interpretation of terms of sale, it falls outside of the sphere of First Amendment protection). Similarly, Congress, in § 3604(c) of the Fair Housing Act, has regulated housing advertisements to ban the exclusive use of Caucasian models as sending a message that minorities are not wanted, and courts have upheld this as a regulation of speech “deceptive” to the “ordinary reader.” See *Ragin v. New York Times Co.*, 923 F.2d 995, 1002-03 (2d Cir. 1991), *cert. denied*, 502 U.S. 821 (1992). Where professional expertise is necessary to evaluate advertising claims, especially general claims related to personal health, the government should be especially sensitive to the sort of misperceptions that ordinary consumers may overlay onto otherwise factual claims.

The policy justifications for allowing such government regulation of misleading commercial speech are more numerous where the speech touches on areas involving scientific expertise and its communication to laypersons—areas classically regulated by the FDA. We usually rely on opposing speech to counter the effects of false or misleading speech, but in specialized areas of technical competence, false or misleading speech is less likely to provoke corrective counterspeech. The Court has acknowledged as much: “the truth of commercial speech ... may be more easily verifiable by its disseminator than, let us say, news reporting or political commentary, in that ordinarily the advertiser seeks to disseminate information about a specific product or service that he himself provides and presumably knows more about than anyone else.” *Virginia State Bd. of Pharmacy v. Virginia Citizens’ Consumer Council*, 425 U.S. 748, 772 n.24 (1976); see also Kathleen M. Sullivan, *Cheap Spirits, Cigarettes, and Free Speech: The Implications of 44 Liquormart*, 1996 Sup. Ct. Rev. 123, 156 (1996) (“the consumer is not expected to

have the competence or access to information needed to question the advertiser's claim, and the correction is not to be left to competitors and mere government counterspeech.")

The counter-speech model and indeed most of the classical laissez-faire free-speech marketplace are predicated on a market of free and equal consumers of speech, on an equal footing with the providers of information, and not in need of paternal assistance from expert advisors or the state. "There are many social settings, however, in which persons are neither equal nor free, but rather unequal and dependent. A paradigmatic example might be the reliance of a patient upon the advice of his doctor. The Court has sometimes used the misleading requirement to identify such circumstances and to deprive them of ... constitutional protection ... on the grounds that they 'pose dangers that the State has a right to prevent,' like 'uninformed acquiescence.'" Robert Post, *The Constitutional Status of Commercial Speech*, 48 U.C.L.A. L. Rev. 1, 38 (2000), quoting *Edenfield v. Fane*, 507 U.S. 761, 774-75 (1993) and *Ohralik v. Ohio St. Bar Ass'n*, 436 U.S. 447, 465 (1978). In such situations the Court has frankly acknowledged the paternalistic implications of its "misleading speech" doctrine. See, e.g., *In re R.M.J.*, 455 U.S. 191, 200 (1982) ("because the public lacks sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in legal advertising," quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 383 (1977))

"Used in this way, the misleading requirement refers not to the content of speech, but to the structural relationship between a speaker and her audience. Thus the Court has used the requirement to distinguish between 'in-person solicitation' and 'print advertising,' holding that the latter 'poses much less risk of overreaching or undue influence' because it is 'more conducive to reflection and the exercise of choice on the part of the consumer than is personal solicitation.' [*Zauderer*, 471 U.S. at 642.] In this context, the misleading requirement articulates the prerequisites for the public communicative sphere that underwrites the very constitutional category of commercial speech. It is therefore appropriate to use the requirement as a threshold precondition for First Amendment protection under the *Central Hudson* test." Post, 48 U.C.L.A. L. Rev. at 38. The doctrine is an acknowledgement that "state protections are necessary when the evaluation of commercial information requires unusual expertise, or when there are reasons to doubt the autonomy of consumers." *Id.* The FDA's traditional regulatory jurisdiction falls squarely within this zone where consumers of speech do not stand on an equal footing with advertisers, and merely mandating more speech will be an ineffective remedy in the face of this lack of autonomy.

c. Conclusion: Much of the speech the FDA traditionally regulates is "inherently" misleading

The FDA, in sum, has broad leeway under existing law to regulate speech based on the misleading effect it may have on its intended audience. The FDA should be very careful to ensure that it is not giving up on regulating fields where commercial speech may arguably be categorized as "inherently misleading" rather than "potentially misleading." Where the FDA is capable of assembling empirical support for the proposition that a type of speech is likely to confuse consumers, it should certainly do so; however, as we have demonstrated, this is not a prerequisite for regulating advertising as

“inherently” misleading. Legally, the FDA’s power to regulate vast areas of advertising traditionally within its control as “inherently” misleading is unexplored territory, and there is both precedent and good normative support leading us to expect that much of the advertising falling within the traditional regulatory purview of the FDA will be held to constitute “inherently” misleading commercial speech. Nothing in *Western States* indicates that FDA’s powers in this regard are likely to be subject to sharp curtailment by the Court. We would encourage the FDA to invoke the “inherently misleading” exception aggressively in its regulatory and litigation strategy in the service of FDA’s legislative mandate.

Government power to regulate nonmisleading speech

Central Hudson puts forward a four-part test of the validity of commercial speech regulation. The first step is to determine if in fact the commercial speech is protected—for present purposes, to ensure that it is not misleading. “If the communication is neither misleading nor related to unlawful activity, the government’s power is more circumscribed.” 447 U.S. at 564. The state must (2) assert a substantial interest, and the regulation must be proportional to that interest, which is to say, (3) the regulation must “directly advance” the interest (i.e. it may not provide merely “ineffective or remote” support for it), and (4) the restriction must be “narrowly drawn”—that is, the state “cannot regulate speech that poses no danger to the interest” and cannot “suppress restrictions on expression when narrower restrictions on expression would serve its interest as well.” 447 U.S. at 565. This four-part test was applied in *Western States*, where the restriction on advertising drug compounding was held to fail the fourth “narrow tailoring” requirement.

However, the Supreme Court has also upheld a ban on nonmisleading speech (casino advertising) which the state justified by arguing that the public would be more likely to gamble if it received this speech (even though, notably, gambling was a legal activity). *Posadas De Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986) (statute banning advertising of casino gambling directed to Puerto Rico residents to prevent bad effects on morals of residents constitutional). *Posadas* is part of a line of cases allowing speech regulation in order to alleviate adverse effects following from advertising (see, e.g., *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447 (1978) (regulation banning in-person solicitation of accident victims for legal business because young victims may be coerced into hiring lawyer constitutional); *Young v. American Mini Theatres, Inc.*, 427 U.S. 50 (1976) (regulation setting different zoning regulations for pornographic theatres or bookstores to prevent neighborhood deterioration and crime increases constitutional)).

In recent years various members of the court have doubted the logical validity of this line of cases, but have failed to garner the requisite votes to overturn it. See *44 Liquormart*, 517 U.S. at 509 (critiquing *Posadas*’ conclusion that speech regulation was a valid “legislative choice” between suppressing advertising and corrective educational speech) (Part VI, Stevens, J., joined by Kennedy, Thomas, and Ginsburg, J.J.).⁵ Similarly,

⁵ It is true that Justice O’Connor’s opinion, for herself and Justices Souter, Breyer and Chief Justice Rehnquist, casts doubt on *Posadas*’ “legislative choice” theory, although not as explicitly as the Stevens

these four votes were the only ones willing to reject explicitly the “greater-includes-the-lesser” argument that since the state could ban alcohol sales or gambling, it could also a fortiori ban advertising encouraging those activities. *See id.* at 510-12. Thus, it is quite possible that this “paternalistic” line of cases might be extended to uphold some FDA speech regulation that attempted to shield the public from nonmisleading advertisements “for its own good.”

Finally, it is worth noting that *Western States* confuses the first step of the *Central Hudson* analysis: Justice O’Connor’s majority opinion, in dictum, appears to indicate that even if an advertisement were misleading, the subsequent three stages of the *Central Hudson* test must be passed. She states: “Even if the government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by [a] far less restrictive alternative” of labeling. *Western States*, 122 S. Ct. at 1508. As dictum, this statement lacks the force of law. More importantly, it misstates the vast body of existing precedent which holds that misleading commercial speech is simply not protected by the First Amendment, which means that the second stage of the *Central Hudson* analysis—identifying a significant government interest—is never reached. *See Central Hudson*, 447 U.S. at 563. Compare Justice O’Connor’s opinion in *Ibanez v. Florida Dept. of Bus. and Professional Regul., Bd. of Accountancy*, 512 U.S. 136, 150 (1994) (O’Connor, J., concurring) (correctly stating that “States may prohibit inherently misleading speech entirely”); *cf.* the majority opinion in *Ibanez*, 512 U.S. at 145 (“actually or inherently” misleading speech may be banned, but where “possible” deception is at issue we favor “disclosure over concealment”).

Conclusion

The FDA should not read the *Western States* decision as signaling a broad departure from precedent. In fact, the opinion in that case was shaped in large part by the government’s failure to raise certain available arguments in its defense. In particular, the government failed to argue that the advertisements in question would be misleading, and thus were forced to meet the “narrow tailoring” prong of the *Central Hudson* test. However, this hard-to-meet requirement would never be reached if the speech in question were held to be “inherently misleading.” This category is ill-defined but there is much support in the Supreme Court’s precedent for finding that, in areas of advertising traditionally within the FDA’s regulatory competence, regulated speech would be “inherently misleading” to medical consumers. Furthermore, it is logically consistent with First Amendment norms to regulate such areas of speech as “inherently misleading.” Information about the risks and benefits of drugs must be interpreted, with the benefit of professional expertise, in light of the consumer’s individual characteristics, and therefore many statements that might be considered true in a statistical, scientific sense when applied to the population in aggregate would be inherently misleading when directed at an inexperienced individual consumer. We urge the FDA to consider these factors in evaluating how best to comply with its obligations under the First Amendment.

opinion does. *See* 517 U.S. at 531; *see also Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 182 (1999).

Respectfully submitted,



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Company Food & Drug Administration
Address 5630 Fishers Lane **Wm, 1661**
to "HOLD" at FedEx location, partial FedEx address **We cannot deliver to P.O. boxes or P.O. ZIP codes**

City Rockville **State** MD **ZIP** 20852
Dept./Floor/Suite/Rm



0159317343

4a Express Package Service

FedEx Priority Overnight **FedEx Standard Overnight** FedEx First Overnight
Next business morning Next business afternoon Earliest next business morning delivery or select locations

4b Express Freight Service

FedEx 2Day* FedEx Express Saver* FedEx 1Day Freight* FedEx 2Day Freight FedEx 3Day Freight
Second business day Third business day Second business day Third business day Third business day

5 Packaging

FedEx Envelope/Letter* FedEx Pak* Other Pkg
*Declared value limit \$500 Includes FedEx Box, FedEx Tube, FedEx Custom Pkg

6 Special Handling

SATURDAY Delivery SUNDAY Delivery HOLD Weekday HOLD Saturday
Available only for FedEx Priority Overnight to select ZIP codes Available only for FedEx Priority Overnight to select ZIP codes Available only for FedEx Priority Overnight to select ZIP codes Available only for FedEx Priority Overnight to select ZIP codes

7 Payment Bill to:

Sender Recipient Third Party Credit Card Cash/Check
From: FedEx A/R No. or Draft Card No. below.

8 Release Signature

Signature Required Signature Not Required
Your liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

By signing you authorize the carrier to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from all claims, damages, losses, costs, expenses or call 1-800-GO-FedEx (800)465-3339 or call 1-800-GO-FedEx (800)465-3339
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