Developments in Policy: The FDA's Tobacco Regulations

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Developments in Policy:
The FDA's Tobacco Regulations

I. INTRODUCTION: RECENT DEVELOPMENTS IN TOBACCO REGULATION

A. The FDA Regulations

On August 9, 1995, the Commissioner of the Food and Drug Administration (FDA), David Kessler, announced the agency's intention to regulate tobacco products as delivery devices for the drug nicotine. His plan was outlined in a set of proposed rules entitled, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents." As the title indicates, the rules focused heavily on restricting the availability and advertising of cigarettes to minors and included the following provisions: the creation of a federal law criminalizing the sale of cigarettes to minors; a requirement that tobacco companies spend $150 million on an educational campaign to discourage young people from smoking; and bans on all of the following: pictures or color print in cigarette advertisements in magazines with a youth readership of 15% or more; all billboard advertising of cigarettes within 1000 feet of schools and playgrounds, and pictures and color print on billboards elsewhere; the display of tobacco product brand logos in sports or music events sponsored by tobacco companies; cigarette vending machines; mail-ordering of tobacco products; cigarette brand-names on promotional items such as hats or T-shirts; and "kiddie packs" containing fewer than 20 cigarettes.

Kessler's announcement provoked an immediate and ongoing storm of controversy. In the commentary period that followed the issuance of the proposed rules, the FDA received over 700,000 letters of both approval and protest. The agency spent a year reviewing comments and revising its

2. See id. at 41,322.
3. See id. at 41,326-28.
4. See id. at 41,335-36.
5. See id. at 41,334-35.
6. See id. at 41,336-38.
7. See id. at 41,324.
8. See id. at 41,325-26.
9. See id. at 41,336.
10. See id. at 41,324-25.
proposals; the final rule was announced on August 23, 1996.\textsuperscript{12} There were modest revisions in the final rule: It revokes the specific requirement of a $150 million contribution toward an educational campaign, and replaces it with a more general requirement of cooperation in developing such a campaign;\textsuperscript{13} it exempts "adult" establishments from the vending machine ban;\textsuperscript{14} and it withdraws the proposed ban on mail-order sales. For the most part, however, the final regulations are substantially similar to the proposed ones. The rules are scheduled to take effect anywhere from six months to two years from August 28, 1996 (the date of publication in the Federal Register), depending on the difficulties involved in satisfying the particular provision.\textsuperscript{16}

\textbf{B. Previous Regulatory Efforts}

The furor over the current regulations obscures the fact that tobacco products have long been a target of lawsuits and regulatory efforts in the United States.\textsuperscript{17} This history is hardly surprising, since smoking's negative effects on health have been suspected for at least a century.\textsuperscript{18} Attempts by government to regulate the industry, however, have generally proven problematic.\textsuperscript{19} One reason for this, of course, is the political strength of the tobacco industry, which has long been able to resist regulation due to its significant financial resources and political influence. The tobacco industry has effectively used lobbying, political contributions, and legal challenges to block or delay regulatory efforts.

\textsuperscript{13} See id. at 44,538-39.
\textsuperscript{14} See id. at 44,448-52.
\textsuperscript{15} See id. at 44,459.
\textsuperscript{16} See id. at 44,542.
\textsuperscript{17} For an exhaustive history of "Big Tobacco" in the United States, see RICHARD KLUGER, ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS (1996). For a briefer history that concentrates on litigation against tobacco companies, see Robert L. Rabin, A Sociolegal History of the Tobacco Tort Litigation, 44 STAN. L. REV. 853 (1992).
\textsuperscript{18} Luther Burbank, an American botanist, announced in the early 1900s that smoking was "nothing more or less than a slow, but sure, form of lingering suicide." The Tobacco Wars, MOTHER JONES, May/June 1996, at 40 (citing KLUGER, supra note 17). Epidemiological studies published in the 1950s offered confirmation that smoking presented major health risks. See, e.g., Richard Doll & A. Bradford Hill, A Study of the Aetiology of Carcinoma of the Lung, 2 BRIT. MED. J. 1271 (1952); Ernest L. Wynder & Evarts A. Graham, Tobacco Smoking as a Possible Etiologic Factor in Bronchiogenic Carcinoma: A Study of Six Hundred and Eighty-Four Proved Cases, 143 J. AM. MED. ASSN'N 329 (1950). In 1964, Surgeon General Luther Terry issued a report that put an official stamp on the growing body of scientific research. USDHEW, Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service, Public Health Service Publication No. 1103 (1964).
\textsuperscript{19} Private lawsuits to recover damages for smoking-related illnesses have been even less successful. See generally Rabin, supra note 17. There have been two major waves of litigation: one in the 1950s, triggered by new scientific data on smoking's carcinogenic effects, and one in the 1980s, probably spurred by the asbestos litigation of the 1970s. During the first period, tobacco companies successfully argued that they themselves had been unable to foresee the health risks of smoking. See id. at 860-61. During the second period, they prevailed by arguing that individual plaintiffs had not proven that smoking caused their illnesses, see, e.g., Galbraith v. R.J. Reynolds Tobacco Co., No. SB 14417 (Cal. Super. Ct. filed Feb. 10, 1983), that smokers generally assumed any risk, see, e.g., Paugh v. R.J. Reynolds Tobacco Co., 834 F. Supp. 228 (N.D. Ohio 1993) (holding that harm caused by tobacco is common knowledge); Brisboy v. Fibreboard Corp., 418 N.W.2d 650 (Mich. 1988) (holding that risk
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“Big Tobacco” lobby in America. In 1995, the tobacco industry gave over one million dollars directly to politicians, and “soft money” (unrestricted donations to party organizations) totaled $2,793,496 last year.20 The industry is also central to the economies of many tobacco-producing states.

To the extent that government has regulated the tobacco industry, the results have been mixed at best. The main governmental initiatives were the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA),21 which required that cigarette packages and print advertisements carry health warnings, and the Public Health Cigarette Smoking Act of 1969,22 which banned television and radio advertising. Neither provision worked wholly to the industry’s disadvantage. The health warning labels served as a shield against tort liability;23 and when television advertising ceased, so did the anti-smoking messages that broadcasters were previously required to air under the Fairness Doctrine.24

Recent regulatory efforts, which have moved increasingly to the local level, have also produced mixed results. In response to proposed local ordinances that would seriously cut back on the marketing of tobacco products, tobacco companies have, in some instances, pursued a strategy of anonymously backing state anti-tobacco legislative proposals, which are considerably less harsh and which explicitly preempt local ordinances.25

of developing lung cancer is within risk assumed by consumer), and that the Federal Cigarette Labeling and Advertising Act (FCLAA), which mandated warning labels, preempted claims based on failure to warn, see infra note 23; see also Hite v. R.J. Reynolds Tobacco Co., 578 A.2d 417 (Pa. 1990) (failure to warn claim preempted by FCLAA); Forster v. R.J. Reynolds Tobacco Co., 437 N.W.2d 655 (Minn. 1989) (same). In both eras, a major factor in the industry’s success was its remarkable “no-compromise” litigation strategy; tobacco companies did not offer to settle in a single case, and they exhausted the plaintiffs’ financial resources with protracted deposition and discovery, financed by a virtually unlimited budget. See Rabin, supra note 17, at 857-59; see generally William E. Townsley & Dale K. Hanks, The Trial Court’s Responsibility to Make Cigarette Disease Litigation Affordable and Fair, 25 CAL. W. L. REV. 275 (1989) (calling for enhanced judicial management of litigation against tobacco industry). 20. Figures are from Glenn Frankel, Tobacco Industry Switches Brands; Political Donations Shift to Republicans After Favoring Democrats, WASH. POST, Mar. 15, 1996, at A1.


24. See infra text accompanying notes 196-199.

25. Tobacco companies succeeded in passing state preemptive anti-smoking legislation in Michigan and Maine, and are currently backing similar measures in Massachusetts, New York, Pennsylvania, Ohio, Missouri, Kansas, Nebraska, Colorado, and Arizona. Interestingly, the strategy failed in Minnesota when a leaked memorandum publicly revealed the role of tobacco companies in supporting the bill. See Jeanne Brokaw, The War in the States, MOTHER JONES, May/June 1996, at 56, 57.
C. Recent Developments

The current FDA regulations, however, emerge against a new and importantly altered backdrop. In 1988, the Surgeon General issued a report detailing the addictive properties of nicotine. The following years saw continuing scientific confirmation of this conclusion. More dramatic were the confessions of a few former tobacco company officials and the leaking of voluminous documentation indicating that cigarette manufacturers withheld internal research about the health hazards of smoking, and that they have long known about, concealed, and capitalized on the addictive properties of nicotine.

The growing body of evidence that nicotine is physically addictive—and that the tobacco industry knew this fact—opened up a new option for the FDA, which may regulate products intended by their manufacturers to alter the structure or function of the body when used. In 1994, the FDA began examining whether nicotine would qualify as a drug. The 1995 proposed regulations were the result of this inquiry.

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26. The emphasis placed on revelations about nicotine in this and other accounts should not mislead readers into thinking that this is the only impetus for the FDA's actions. In fact, several factors have breathed new life into anti-tobacco efforts in the past few years. The primary factor may be the increasing health-consciousness of our society, paired with the growing acceptance—based on the cumulative weight of scientific evidence—that the health risks of smoking are fact, not hypothesis. See, e.g., J. AM. MED. ASS'N, July 19, 1995 (issue devoted to negative health effects of smoking).


28. The first and best known of these is Jeffrey Wigand, the former head of research at Brown & Williamson; others followed. See Sheryl Stolberg, Defectors Helping to Crack Wall Around Tobacco Firms, L.A. TIMES, Apr. 3, 1996, at A1.

29. A paralegal at Brown & Williamson copied over 4000 documents and sent them to Stanton A. Glantz, a researcher and long-time tobacco foe at the Medical School of the University of California, San Francisco. The University published an annotated compilation of the documents. See STANTON A. GLANTZ ET AL., THE CIGARETTE PAPERS (1996).

30. For a discussion of whether tobacco products actually meet this definition, see infra Part II.C.

31. The discovery that tobacco companies had withheld information fueled a new spurt of litigation as well. Although Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), held that claims based on failure to warn were preempted, it left open the possibility of suing for intentional fraud and misrepresentation. Two major class actions were certified, a nation-wide suit based in Louisiana and a state-wide suit in Florida. See Castano v. American Tobacco Co., 889 F. Supp. 904 (E.D. La. 1995); R.J. Reynolds Tobacco Co. v. Engle, 672 So. 2d 39 (Fla. App. 3d Dist. Jan. 31, 1996). The federal court of appeals in New Orleans decertified the Louisiana suit on May 23, 1996, on the basis that the federal district court failed to consider how variations in state law would affect predominance and superiority. See Castano v. American Tobacco Co., 84 F.3d 734 (5th Cir. 1996).

Also of interest (although not directly related to the nicotine revelations) are the many lawsuits brought by state Attorneys General, acting on behalf of the taxpayers, to recoup Medicaid expenditures for smoking-related illnesses. Mississippi was the first state to initiate such a suit; see Mississippi Sues Tobacco Firms, CHI. TRIB., May 24, 1994, at 15. To date, sixteen states have followed Mississippi's example. In Florida, the legislature passed legislation specifically enabling the lawsuits, which were otherwise preempted by existing products liability laws, Fla. STAT. ANN. ch. 409.910 (Harrington Supp. 1995). In Texas, the state is proceeding under criminal racketeering charges as well. See Wendy Benjaminson, Morales Fighting Tobacco Industry with Racketeer Law, HOUSTON CHRON., Apr. 7, 1996, at 1.
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D. The Response of the Tobacco Companies

Within days of the FDA's announcement, five major tobacco companies filed a joint lawsuit to enjoin the FDA from promulgating its rules.32 Their arguments are manifold; among issues of copyright and takings, they argue that the FDA lacks jurisdiction to regulate tobacco products, and that the advertising restrictions infringe on their First Amendment rights. Although the United States District Court for the Middle District of North Carolina is attempting to expedite the proceedings, most observers expect the legal battle over these issues to be long and costly. Certainly, the tobacco industry has shown no sign of capitulating.33 If anything, the industry has been given new hope by Kessler's announcement of his imminent resignation.34 Although the regulations will remain in force after his departure, they will lose what many believe to be their most ardent and effective backer.35

Nor are the tobacco companies without strategic resources. Since the FDA's jurisdiction is over products "intended to affect" the human body, the issue of how much the companies knew about nicotine may be material.36 If recent developments in other tobacco-related lawsuits are any indication, tobacco companies will try to ensure that minimal information on this question is available to the courts. This can be done (and has been done) in two ways. The first is by discouraging whistleblowers. In November 1995, CBS shelved a piece on tobacco (later leaked to the press) because an insider source had signed a nondisclosure agreement with Brown & Williamson that might open

33. To date, only one tobacco company has broken ranks and settled out of court: Liggett Group, Inc., the tobacco division of Brooke Group. The company settled with five state Attorneys General in March of 1996. See John Schwartz, Tobacco Firm Agrees to End Lawsuits Filed by Five States: Pact Creates Fund Based on Liggett Group's Profits, WASH. POST, Mar. 16, 1996, at A2. Liggett is the fifth largest producer of tobacco products; even so, it controls only two percent of the market, and it has been argued that the settlement was simply a "little-to-lose gambit by Wall Street tycoons trying to take control of R.J. Reynolds" (the settlement included an incongruous provision that the plaintiffs, currently suing RJR Nabisco, would not contest an RJR Nabisco breakup). Richard Kluger, A Peace Plan for the Cigarette Wars, N.Y. TIMES, Apr. 7, 1996, § 6 (Magazine), at 28, 30; see also Marc Levinson, Smoke and Fire: The Inside Story of Why One Cigarette Company Struck a Bargain with Opponents of Smoking, NEWSWEEK, Mar. 25, 1996, at 38. However, many provisions of the settlement are of interest. For example, for 25 years, Liggett will pay 2.5% of its annual pre-tax profits into a fund to be distributed among the five original settling states; an additional 5% will be paid into a fund for states that choose to settle in the future. Importantly, Liggett also agreed to withdraw its objections to the FDA regulations.
36. Whether or not this is material depends on the interpretation of "intent," an issue discussed infra at Part II.C.
up the network to a breach-of-contract suit. Such a suit was in fact brought by Brown & Williamson against whistleblower Jeffrey Wigand that same month.

The second way to minimize the information available to the courts is to keep documents out of evidence. Tobacco companies have argued that many, if not most, of the internal documents subpoenaed in current litigation either fall under the attorney-client privilege or are privileged under the “attorney work product” doctrine. This argument has so far been rejected, either on public policy grounds (the public’s right to know about the health hazards of tobacco supersedes the work product rule), on the basis of the “fraud” exemption to the attorney product rule, or both. It is nonetheless an argument that the tobacco companies are still vehemently making.

Legal stonewalling, however, is not the only response that the tobacco companies can make. There are many serious substantive concerns that tobacco companies have raised about the FDA’s regulations. Among these are the questions of whether the FDA has jurisdiction over tobacco and tobacco products; whether a little-discussed corollary to the rules, the FDA’s announced intention to require tobacco companies’ cooperation in developing a campaign to warn young people of the dangers of smoking, unconstitutionally compels speech and/or association; and whether the advertising restrictions violate the protections accorded commercial speech under the First Amendment. In this issue of Developments in Policy, we will examine each of these three issues.

— Liza Goitein

II. DOES THE FDA HAVE JURISDICTION OVER NICOTINE?

Under the Federal Food, Drug, and Cosmetic Act (FDCA or the Act), the FDA has jurisdiction over “drugs” and “drug delivery devices,” terms which are defined in the Act. From the Act’s passage in 1938 until August 1995, the FDA had never claimed that “drugs” included nicotine or that “devices” included cigarettes or chewing tobacco. The expansion of these

42. Sackman v. Liggett Group, Inc., 920 F. Supp. 357 (E.D.N.Y. 1996) (also holding that documents were not in preparation for specific litigation).
43. See generally GLANTZ, supra note 29, at 235-47.
45. 21 U.S.C. §§ 321(g)(2), (h)(2).
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definitions was immediately challenged by five major tobacco companies, who filed suit in the United States District Court for the Middle District of North Carolina to enjoin the FDA from promulgating the Proposed Rule.\(^47\) One of the grounds upon which the companies sought the injunction was that the FDA did not have jurisdiction over tobacco, since the definitions of "drug" and "device" under the FDA's authorizing statute did not include nicotine and tobacco products.\(^48\)

A. Standard of Review

An initial question exists over what test a court should use to examine this issue. The standard a court uses to review an agency's interpretation of its statute was laid down in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*\(^49\) The Supreme Court set out a two-part test to review an agency's construction of a particular statute:

First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.\(^50\)

This deferential standard would allow the FDA leeway, but it is not clear that it is the proper approach. Commentators have debated whether *Chevron* should apply to agency interpretations of their jurisdiction, as opposed to interpretations of other statutes.\(^51\)

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121 (1996).

47. Coyne Beahm, Inc. v. FDA, No. 2:95CV00591 (M.D.N.C. filed Sept. 7, 1995). This suit had been on hold pending final issue of the new rules.

48. Hereinafter, unless otherwise stated, "nicotine" will also refer to cigarettes and smokeless chewing tobacco.


50. *Id.* at 842-43 (footnotes omitted).

51. Compare Quincy M. Crawford, Comment, Chevron Deference to Agency Interpretations that Delimit the Scope of the Agency's Jurisdiction, 61 U. Chi. L. Rev. 957 (1994) (arguing that courts should apply *Chevron* to agency interpretations of their jurisdiction), with Cass R. Sunstein, Law and Administration After Chevron, 90 Colum. L. Rev. 2071, 2097-101 (1990). Sunstein argues against deference in those cases in which "the issue is whether the agency's authority extends to a broad area of regulation, or to a large category of cases." *Id.* at 2100. The FDA's regulation of nicotine would seem to be just such a move.

The Administrative Procedure Act (APA) also requires that agency actions "in excess of statutory jurisdiction, authority, or limitation" be held unlawful. 5 U.S.C. § 706 (1994). However, it is unclear how much deference should be accorded under the APA. Obviously, if a court found that an agency exceeded its jurisdiction, it would be unlawful; but how the court conducts this inquiry is not answered by the APA.
The Supreme Court has not spoken dispositively on this question. Some Justices have argued that the distinction between jurisdictional and nonjurisdictional interpretations is untenable—simply by interpreting its own statute in a certain manner, an agency can expand or reduce its jurisdiction—and has not been used by the Court. Other Justices have claimed that this differentiation is critical. Thus, although this Part will use the *Chevron* framework to examine the question of the FDA's jurisdiction, its applicability in this context has not been definitively established. If *Chevron* deference is not appropriate, courts will still want to examine most of the factors that are examined herein, but would ultimately look at the FDA's action in a much less favorable light.

Even within the *Chevron* framework, a number of complicated questions exist about its application. Under *Chevron*, a court must first address the issue of explicit congressional intent. This examination is done using "traditional tools of statutory construction." The "starting point is the language of the statute," but "in expounding a statute, [a court] must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." If the language itself does not

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52. See Sunstein, supra note 51, at 2100.
53. See Dole v. United Steelworkers of America, 494 U.S. 26, 54-55 (1990) (White, J., dissenting) ("*Chevron* itself and several of our cases decided since *Chevron* have deferred to agencies' determinations of matters that affect their own statutory jurisdiction. The application of *Chevron* principles cannot be avoided on this basis." (citations omitted)); Mississippi Power & Light Co. v. Mississippi, 487 U.S. 354, 377 (1988) (Scalia, J., concurring). Scalia argues that deference is necessary in a jurisdictional inquiry as well:

[It] is plain that giving deference to an administrative interpretation of its statutory jurisdiction is both necessary and appropriate. It is necessary because there is no discernible line between an agency's exceeding its authority and an agency's exceeding authorized application of its authority. To exceed authorized application is to exceed authority. Virtually any administrative action can be characterized as either the one or the other, depending upon how generally one wishes to describe the "authority." And deference is appropriate because it is consistent with the general rationale for deference: Congress would naturally expect that the agency would be responsible, within broad limits, for resolving ambiguities in its statutory authority or jurisdiction.

Id. at 381-82 (citations omitted).
54. See Mississippi Power & Light, 487 U.S. at 383 (Brennan, J., dissenting, joined by Marshall and Blackmun, JJ.). These Justices argue,

[Statutes confining an agency's jurisdiction do not reflect conflicts between policies that have been committed to the agency's care, but rather reflect policies in favor of limiting the agency's jurisdiction that, by definition, have not been entrusted to the agency and that may indeed conflict not only with the statutory policies the agency has been charged with advancing but also with the agency's institutional interests in expanding its own power. . . . [W]e cannot presume that Congress implicitly intended an agency to fill "gaps" in a statute confining the agency's jurisdiction since by its nature such a statute manifests an unwillingness to give the agency the freedom to define the scope of its own power.

Id. at 387 (citations omitted). See also Adams Fruit Co. v. Barrett, 494 U.S. 638, 650 (1990) ("Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'" (quoting Federal Maritime Comm'n v. Seatrain Lines, Inc., 411 U.S. 726, 745 (1973))).
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clearly evidence intent, the other available tool is legislative history. However, in order for the examination to end at the first *Chevron* prong, this intent must be "unambiguously expressed." If a court does not find such intent, it must examine whether the agency's interpretation is a "reasonable one." Such a standard gives an agency broad discretion to determine its own policy in the absence of explicit congressional intent.

In this examination of the FDA's jurisdiction over nicotine, two overlapping questions are discussed: (1) whether the FDA's jurisdiction over nicotine has been addressed by the 1938 Act and (2) whether the meaning of "intended to affect" in the Act can encompass the behavior of cigarette manufacturers. The examinations of these questions employ similar methods of analysis, i.e., *Chevron* and its progeny.

B. The FDCA, Congress, and Nicotine

Nothing in the language of the FDCA speaks directly to the question of jurisdiction over nicotine. However, the absence of a positive declaration does not indicate whether FDA action is permitted or precluded. Evidence exists on both sides of this issue. The definitions used in the Act provide for an extremely broad reading of the FDA's jurisdiction, and courts have recognized this fact. However, Congress and the FDA alike have indicated in the past that jurisdiction over nicotine was lacking.

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494 U.S. at 35 (applying *Pilot Life* standard); *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989) (same). *But see Cardoza-Fonseca*, 480 U.S. at 452 (Scalia, J., concurring in judgment) ("If the language of a statute is clear, that language must be given effect—at least in the absence of a patent absurdity."


60. *Chevron*, 467 U.S. at 845.

61. This flexibility is something the Court deemed to be important: "We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations 'has been consistently followed by this Court . . . ." *Id.* at 844 (quoting United States v. Shimer, 367 U.S. 374 (1961)).

How much deference *Chevron* actually provides agencies has been a topic of significant debate. Some have viewed it as greatly expanding administrative authority, *see*, e.g., Harold H. Bruff, *Legislative Formality, Administrative Rationality*, 63 TEX. L. REV. 207, 224-25 (1984); Kenneth W. Starr, *Judicial Review in the Post-Chevron Era*, 3 YALE J. ON REG. 283, 283-84 (1986), while others have questioned whether it made a strong break with previous jurisprudence, *see*, e.g., Bloomberg, *Note, The Chevron Legacy: Young v. Community Nutrition Institute Compounds the Confusion*, 73 CORNELL L. REV. 113, 118.


63. Had Congress desired to preclude FDA jurisdiction, it could easily have done so by explicitly barring the FDA from exercising it. This technique has been used by Congress in other situations. *See*, e.g., Commodity Exchange Act, 7 U.S.C. § 1(a)(3) (1994) (defining areas where Commodity Futures Trading Commission has jurisdiction to include numerous products and "all other goods and articles, except onions." (emphasis added)).

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1. Evidence that Congressional Intent Does Not Preclude the FDA from Regulating Nicotine

The FDCA defines the term “drug” as “articles (other than food) intended to affect the structure or any function of the body of man or other animals” and the term “device” as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended to affect the structure or any function of the body of man or other animals.” The scope of this language makes it difficult to determine what Congress was precluding the FDA from regulating, and, at least on a cursory examination, nicotine and tobacco products would appear to fit under these definitions.

When Congress passed the FDCA in 1938, it sought to expand the jurisdictional authority of the FDA’s predecessor, the Bureau of Chemistry in the Department of Agriculture. The Pure Food and Drugs Act of 1906 defined drugs as “all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.” By abandoning its reliance on the medical profession’s definitions, Congress indicated its desire for enlarged jurisdiction.

Courts have interpreted the more open-ended definitions of the FDCA in extremely broad terms. As the Supreme Court explained:

Congress fully intended that the Act’s coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. . . . [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health . . . .

Following this logic, the language should encompass nicotine; the FDA is certainly acting in a manner that it believes will protect the public health.

64. 21 U.S.C. § 321(g)(1)(C).
65. 21 U.S.C. § 321(h), (h)(3). The discussion throughout this section will be on whether the FDA can regulate nicotine as a drug. However, whatever the answer is, the result will be the same for whether it can regulate tobacco products as nicotine delivery devices. This is because congressional intent and the meaning of “intended to affect” should be identical for both provisions of the FDCA.
68. It is not for courts to question whether the FDA is correct in believing that its policies will, in fact, benefit the public health. As the Court stated in Chevron, “[s]uch policy arguments are more properly addressed to legislators or administrators, not to judges.” 467 U.S. at 864 (footnote omitted).
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The FDA argues further that Congress's original intent actually encompassed nicotine in an indirect manner. One type of item that Congress was particularly concerned about regulating was weight management products. Accordingly, one claim the FDA makes in support of jurisdiction is that nicotine is widely believed to regulate weight gain in smokers. The view that smokers use cigarettes either to lose weight or to prevent weight gain could place nicotine into a traditional area of FDA control. However, the question remains whether the Act meant to include those products that were not explicitly advertised as regulating weight gain.

The FDA proposes an additional justification for regulation: the increase in knowledge about nicotine since 1938. At the time the Act was passed, the medical effects of nicotine were, at best, unclear. Since then, organizations such as the American Medical Association and World Health Organization have reported studies demonstrating the addictiveness of nicotine, and in 1988 the Surgeon General issued a report declaring that nicotine is addictive. Arguably, this new knowledge moves nicotine into the general area of regulation intended by Congress in 1938, even if Congress did not at that time recognize that nicotine fell within its purview. Chevron's deferential standard would allow such a reading as long as it was found that Congress's intent did not preclude the exercising of jurisdiction.

2. Evidence that Congressional Intent Precludes the FDA from Regulating Nicotine

At the same time, evidence exists that Congress did not intend for the FDA to possess jurisdiction over nicotine, and, at least until 1995, both Congress and the FDA believed that jurisdiction was lacking. Under the old Bureau of Chemistry, nicotine would not have fallen under the definition of a drug. In fact, the Bureau specifically stated that "tobacco and its preparation which are

69. See H.R. REP. No. 75-2139 at 3 (1938). See also Action on Smoking and Health v. Harris, 655 F.2d 236, 238 (D.C. Cir. 1980) ("The limited scope of [the 1906] definition made it difficult to control such substances as ... fraudulent remedies for obesity.").
71. For further discussion on the issue of whether a product is "intended" to have an effect only if advertised as such, see infra Section C.
not so labeled and are used for smoking or chewing or as snuff and not for medical purposes are not subject to the provision of the [1906] act.\textsuperscript{74}

Moreover, the position that jurisdiction over nicotine does not exist has been repeatedly stated to Congress by the FDA itself.\textsuperscript{75} For example, in 1972, FDA Commissioner Charles Edwards stated to Congress that “the regulation of cigarettes is to be the domain of Congress . . . [and] labeling or banning cigarettes is a step that can be taken only by the Congress. Any such move by the FDA would be inconsistent with congressional intent.”\textsuperscript{76} Congress also acted as if jurisdiction did not exist, as evidenced by repeated initiatives to give the FDA such authority. Bills were introduced in 1956,\textsuperscript{77} 1963,\textsuperscript{78} 1964,\textsuperscript{79} 1977,\textsuperscript{80} 1978,\textsuperscript{81} 1979,\textsuperscript{82} 1987,\textsuperscript{83} 1989,\textsuperscript{84} 1992,\textsuperscript{85} and 1993\textsuperscript{86} to provide the FDA with jurisdiction over tobacco; none of them passed. These bills seem to indicate Congress’s belief that positive action was required to provide the FDA with the authority to regulate tobacco. In other words, the 1938 Act had failed to provide it.\textsuperscript{87}

However, neither the statements of the FDA nor congressional attempts to provide jurisdiction can be seen as dispositive. Agencies can change their interpretation of a law, and, unless congressional intent is clearly to the contrary, may do so if the new interpretation is still a rational one and the

\textsuperscript{74} Bureau of Chemistry, Service and Regulatory Announcements, No. 13 (1914). Of course, this statement raises two separate issues: first, whether the nicotine in tobacco is actually used for a medicinal purpose, and second, whether such a purpose can legitimately be attributed when the product is not labeled to that effect. The first question is answered in the affirmative by the FDA, which cites the use of nicotine to fulfill an addiction and to prevent weight gain. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314, 41,453 (proposed Aug. 11, 1995). The second question is discussed below. See infra Section C.

\textsuperscript{77} See, e.g., Action on Smoking & Health v. Harris, 655 F.2d 236, 241 (D.C. Cir. 1980); Whatley, supra note 46, at 122-23.


\textsuperscript{79} H.R. 11280, 84th Cong. (1956).

\textsuperscript{80} H.R. 5973, 88th Cong. (1963); S. 1682, 88th Cong. (1963).

\textsuperscript{81} H.R. 2248, 89th Cong. (1965).


\textsuperscript{83} S. 3317, 95th Cong. (1978).

\textsuperscript{84} H.R. 279, 96th Cong. (1979).

\textsuperscript{85} H.R. 3294, 100th Cong. (1987).


\textsuperscript{87} In 1975 the D.C. District Court ruled that the FDA had jurisdiction over tobacco under the Federal Hazardous Substances Act (FHSA). American Public Health Association v. Consumer Product Safety Commission, C.A. No. 74-1222 (D.D.C. Apr. 23, 1975), vacated as moot, No. 75-1863 (D.C. Cir. June 15, 1976). Congress immediately reported bills that eliminated jurisdiction under the FHSA. S. REP. No. 94-261 (1975); H.R. REP. No. 94-325 (1975). These bills became part of the Consumer Product Safety Improvements Act. 90 Stat. 503 (1976). Although this law does not deal with jurisdiction under the 1938 Act, it does provide some indication of Congress’s view about FDA jurisdiction over nicotine.
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change is “amply justified . . . with a ‘reasoned analysis.’”88 Nevertheless, less deference is accorded to an agency that propounds inconsistent positions.89

Furthermore, subsequent congressional behavior does not clearly prove what the intent of the 1938 Act was. In large part, the congressional initiatives to grant jurisdictional authority were a response to the failure of the FDA to act.90 The converse situation, in fact, has occurred with current congressional bills that attempt to strip the FDA of jurisdiction.91 Certainly the sponsors of these bills would not support the assertion that the bills indicate that jurisdiction currently exists. Thus, while attempted legislation subsequent to the 1938 Act provides some evidence as to the intent of Congress, it is by no means dispositive in either direction.

C. The Meaning of “Intended to Affect”

The previous Section examined whether Congress had a clear desire regarding the regulation of nicotine by the FDA. Without this “unambiguously expressed intent,”92 it would appear that the open-ended language of the statute would permit the FDA to reasonably interpret its mandate to include nicotine regulation. However, those opposed to regulation have a secondary argument which focuses on a particular clause in the definition of drug.

According to the Act, a drug is a substance “intended to affect the structure or any function of the body of man.”93 Even if Congress is silent on the specific question of nicotine regulation, if “intent” has a certain, narrow meaning, regulation is precluded. The FDA argues that the Act’s language does not refer to explicit (i.e., claimed) intent but rather objective intent (as explained below). Those opposed to tobacco regulation, on the other hand, claim that Congress wanted the language to refer to manufacturers’ explicit

88. Rust v. Sullivan, 500 U.S. 173, 187 (1991) (quoting Motor Vehicle Mfrs. Ass'n., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983)). See also Chevron, 467 U.S. at 862 (rejecting argument that agency’s interpretation “is not entitled to deference because it represents a sharp break with prior interpretations”); Action on Smoking and Health v. Harris, 655 F.2d 236, 242 n.10 (D.C. Cir. 1980) (“Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representation thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action.”).

89. See Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (“[T]he consistency of an agency’s position is a factor in assessing the weight that position is due.”); see also Immigration and Naturalization Serv. v. Cardoza-Fonseca, 480 U.S. 421, 446 n.30 (“An agency interpretation of a relevant position which conflicts with the agency’s earlier interpretation is ‘entitled to considerably less deference’ than a consistently held agency view.” (quoting Watt v. Alaska, 451 U.S. 259, 273 (1981))).

90. See Whatley, supra note 46, at 122-23.


92. Chevron, 467 U.S. at 843.


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representations. In order to determine which construction is correct (or, at least, permissible), once again it is necessary to apply the *Chevron* test.

1. **Intent as an Objective Standard**

   The FDA argues that tobacco manufacturers intend that their products have "addictive and significant pharmacological effects" because a reasonable person would recognize that such effects would occur.\(^94\) This approach moves a tort standard into the legislative language and makes a company intend anything that is "reasonably foreseeable." The evidence that nicotine has certain effects on the body is fairly well substantiated,\(^95\) but whether the Act permits such a tort-style reading of intent is uncertain.

   The FDA argues that this broader reading of intent is correct for two related reasons. Both rely on the fact that the FDCA is a public welfare statute. First, courts have generally interpreted "intent" in public welfare statutes to mean objective intent. For example, in *United States v. Focht*,\(^96\) the Third Circuit found that the language of the Federal Hazardous Substances Act (FHSA)\(^97\) that applied to the shipping of components "intended for use in illegal fireworks" implied an objective intent standard.\(^98\) In another case,\(^99\) a court found that rattles were a toy under the FHSA, noting that "[t]he only rational interpretation of the word 'intended' in the statute calls for an objective test of intent: whether a reasonable person would believe that the object is a toy or article intended for use by children."\(^100\) Just like the FHSA, the FDCA is a public welfare statute, and the same meaning of "intent" should apply.

   Second, courts have also given stronger and broader interpretations to other language in regulatory public welfare statutes and, in particular, to the FDCA itself. In criminal prosecutions under the FDCA, for example, strict liability can be imposed.\(^101\) Thus, when a criminal statute serves a regulatory public welfare purpose, the mens rea requirement that is normally required for criminal liability can be waived. Producers of pharmaceutical products, for example, must act at their peril or face criminal sanctions. As Justice

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95. See id. at 44,701-39.
96. 882 F.2d 55 (3d Cir. 1989).
98. *Focht*, 882 F.2d at 58. In this case, however, no question existed about whether the FHSA covered fireworks; it explicitly did.
100. Id. at 231. However, the court believed that Congress intended for the FHSA to require an objective interpretation of intent. Id. at 232.
101. See, e.g., United States v. Park, 421 U.S. 658, 670-72 (1975) (allowing for criminal prosecution under 21 U.S.C. § 331(k) without awareness of wrongdoing); United States v. Dotterweich, 320 U.S. 277, 280-81 (1943) (same). Courts in cases such as these have differentiated between criminal laws that punish acts that are bad in themselves, such as murder, and those that punish acts, such as the distributing of unlabelled medication, merely for regulatory purposes.
Frankfurter wrote: "In the interest of the larger good [the Act] puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." Allowing strict liability—which is frequently employed in tort—in this criminal situation provides support for a tort-style intent standard for nicotine.

2. Intent as a Subjective Standard

Even though the FDA has argued in favor of an objective intent standard, they arguably could prevail using a subjective standard as well. While objective intent requires that manufacturers should have foreseen the result, the FDA has presented evidence that cigarette manufacturers knew that nicotine would have a "body-altering" effect.

Although cigarette manufacturers do not advertise their products as affecting the structure and function of the human body, the companies are nevertheless well aware of that particular property of nicotine. The tobacco industry has conducted numerous studies that have informed it of these addictive effects and has acted to create products that will provide the dose of nicotine that smokers require. Not only should tobacco companies be well aware of the effect of their product; according to the FDA, they are extremely well informed about this result.

3. Intent as Based on Manufacturers' Representations

The argument made by cigarette manufacturers and previously employed by the FDA is that jurisdiction only exists when a positive representation is made by manufacturers regarding the health effects of nicotine: "Congress has been made repeatedly aware that the FDA cannot assert jurisdiction over cigarettes absent health claims made by manufacturers or vendors." This is a higher standard than even the subjective test discussed above: Even if manufacturers actually knew about nicotine's body-altering effects, jurisdiction does not exist unless the manufacturer made representations about them.

During congressional hearings on legislation to expand the jurisdiction of the Bureau of Science, the head of the Food and Drug Administration testified before Congress that the "jurisdictional analysis would focus upon the existence of representations made by the manufacturer." He further testified that

102. Dotterweich, 320 U.S. at 281.
104. See id; see also Glantz, supra note 29.
105. Action on Smoking and Health v. Harris, 655 F.2d 236, 241 (D.C. Cir. 1980) [hereinafter ASH].
106. In fact, even if the products do not have such effects, but the manufacturer claims that they do, the FDA can exert jurisdiction.
107. ASH, 655 F.2d at 238 (citing Food, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce, 73d Cong. (1934)).
jurisdiction would be lacking absent such advertising, even if a device were used to cure certain ills. 108

Several court decisions have restricted jurisdiction by using this representation-based reading of "intent." The case of Federal Trade Commission v. Ligget and Myers Tobacco Co. 109 appears to support such a reading. In that case, the FTC attempted to regulate cigarettes as a drug. The agency made two arguments that it claimed enabled it to exert jurisdiction. The first claim was that the tobacco company was making actual representations in its statements that its cigarettes were "soothing." 110 The court spent little time in dismissing this argument, and it has no application to the current FDA decision.

The FTC also argued that the cigarettes were an irritant to the body and that this was the type of effect that allowed for jurisdiction. In finding that such jurisdiction did not exist, the court began by observing that the FTC's definition of "drug" is identical to the FDA's. 111 The court then noted that

[anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article "intended to affect the functions of the body of man". 112

The court concluded that "the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be." 113 Instead, the stated intent of the manufacturer was to serve as a limitation.

However, two factors make this analysis inapposite to the current situation. First, a significant difference exists between the FTC's reliance on "irritation" caused by cigarettes and the FDA's reliance on cigarettes' addictive properties. Cigarettes do not simply irritate the body, they alter its response to other stimuli and produce addiction. Second, the court's interpretation of the statutory language, given its broadness, runs counter to Chevron. Since the Chevron standard provides significant deference to agency interpretations of their authorizing statute, and the statutory language is where the examination of any statute begins, 114 the use of open-ended language would provide greater leeway. Without additional information, the court's finding the very

108. See id.
110. See id. at 576. The advertisement read that "Chesterfield cigarettes can be smoked by any smoker without inducing any adverse affect upon the nose, throat and accessory organs of the smoker." Id. at 573.
111. See id. at 576-77.
112. Id. at 576.
113. Id.
broadness of the statute to demand a narrow reading runs counter to standard approaches of the interpretation of agency statutes.

The only case that has specifically addressed the issue of FDA jurisdiction over nicotine, Action on Smoking and Health v. Harris (ASH), appears to indicate that FDA jurisdiction is lacking without actual representations of body-altering effects on the part of the cigarette manufacturers. In arriving at this conclusion, the D.C. Circuit relied on testimony during the 1934 hearing, actions by the FDA since 1938, and Congress’s recognition that the FDA lacked the necessary authority. However, this case provides limited support, at best, for the absence of jurisdiction. Most importantly, the factual situation was extremely different from the one at issue now. ASH was an attempt by an anti-smoking group to force the FDA to assert jurisdiction over nicotine. While the court’s ruling rested on several grounds, the critical portion of the decision, and one that the FDA today would not question, is the claim that “the construction and application of a statute by those charged with its administration is entitled to substantial deference.” In particular, an agency’s decision not to act receives even greater deference.

Thus, the situation in ASH was the converse of the current one in which the FDA is attempting to assert jurisdiction. While the D.C. Circuit provided some evidence that congressional intent did not allow for the exercising of jurisdiction in the absence of manufacturer representations, the key question there was whether congressional intent required the exercising of jurisdiction over nicotine. The FDA is not now claiming that such action is mandated but instead that a reasonable interpretation of the 1938 Act allows it to exercise such authority. In fact, in terms both of a general claim of jurisdiction over nicotine and of the meaning of “intent,” the ASH case provides minimal support for the anti-jurisdiction side while also supporting a claim of deference to the interpretations of administrative agencies.

D. Conclusion

Some significant evidence exists that Congress did not desire the FDA to obtain jurisdiction over nicotine and that “intent” was limited to actual representations. However, if Chevron is applicable, it is unclear whether this

115. 655 F.2d 236 (D.C. Cir. 1980).
116. See id. at 238-39; see also supra note 107 and accompanying text.
117. See id. at 239-41.
118. See id. at 241-43.
119. Id. at 237.
120. See, e.g., Heckler v. Chaney, 470 U.S. 821, 831 (1985) (upholding FDA decision not to take action against drugs used in lethal injections. “Refusals to take enforcement steps generally involve precisely the opposite situation [from those in which specific guidelines do exist], and in that situation we think the presumption is that judicial review is not available.”).
121. See ASH, 655 F.2d at 238-39.
evidence demonstrates the “unambiguously expressed intent of Congress” that *Chevron* requires. Once the second step of the *Chevron* test—examining whether an agency has acted based on a permissible construction of the statute—is reached, it appears unlikely that the FDA will be denied jurisdiction over nicotine.

Of course, another factor also increases the likelihood of judicial deference to the FDA’s action—its claim that the rules protect the public health. Laws that serve such a purpose usually receive broad readings. This reliance on a public health purpose underlies the FDA’s claims that it has jurisdiction over nicotine and that objective intent is the proper standard. Whether this one factor is enough to answer both questions is an issue the courts must examine, but the burden is on those opposed to regulation to demonstrate congressional intent in order to succeed.

—Gregory S. Chernack

III. DOES THE PROPOSED EDUCATION CAMPAIGN CONSTITUTE COMPELLED SPEECH AND/OR ASSOCIATION UNDER THE FIRST AMENDMENT?

In its August 1995 proposed regulations, the FDA included a provision requiring tobacco manufacturers to “establish and maintain an effective national public educational program to discourage persons under 18 years of age from using cigarettes and smokeless tobacco products.” This regulation, which was proposed pursuant to section 520(e) of the Federal Food, Drug, and Cosmetic Act, was not included in the agency’s August 1996 final rule. However, the FDA made clear in its comments that it does not intend to abandon this requirement. Instead of pursuing the program under its section 520(e) regulatory authority, the FDA “intends to pursue implementation

122. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314, 41,374 (proposed Aug. 11, 1995) [hereinafter Proposed Rule]. In establishing this requirement, the FDA sought “to combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products.” *Id.* at 41,326. Under the requirement, tobacco manufacturers would contribute $150 million per year to fund the educational campaign, with each contributing an amount proportionate to its share of the total advertising and promotional expenditures of the tobacco industry.

123. Under section 520(e) of the Federal Food, Drug, and Cosmetic Act, the FDA “may by regulation require that a device be restricted to sale, distribution, or use (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or (B) upon such other conditions as the [Commissioner] may prescribe in such regulation, if, because of its [harmful potential], the [Commissioner] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.” 21 U.S.C. § 360j(e) (1994) (emphasis added).


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of [a national] education campaign” under the direct statutory authority of section 518(a).\textsuperscript{125}

The FDA has not yet issued an order prescribing the scope and content of an educational campaign, but the 1995 proposed regulations hinted at its contours.\textsuperscript{126} The initiative likely will require tobacco manufacturers to disseminate FDA-approved anti-smoking messages through prime-time television programming targeted at youth between the ages of twelve and seventeen.\textsuperscript{127} Indeed, according to one report following the agency’s announcement of the final rule, “the FDA will require six companies that it says have attracted the largest percentages of underaged customers to run a campaign—including television spots—that will warn children and adolescents about the dangers of tobacco.”\textsuperscript{128} An FDA order of this sort clearly implicates First Amendment protections against government-compelled speech and association.

The Supreme Court has consistently held that the First Amendment protects “both the right to speak freely and the right to refrain from speaking at all.”\textsuperscript{129} Recently, in *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, the Court affirmed that “one important manifestation of the principle of free speech is that one who chooses to speak may also decide ‘what not to say.’”\textsuperscript{130} *Hurley* upheld the exclusion of gay, lesbian, and bisexual Irish-Americans from a privately organized St. Patrick’s Day parade, arguing that “the communication produced by the private organizers would be shaped by all those protected by the law who wished to join in with some expressive demonstration of their own. But this use of the State’s power violates the fundamental rule of protection under the First Amendment, that a speaker has the autonomy to choose the content of his own message.”\textsuperscript{131}

\textsuperscript{125} Id. at 44,538. According to the FDA, section 518(a) gives the agency more explicit authority than section 520(e) to compel tobacco manufacturers to fund an educational campaign. See id. Under section 518(a), if the FDA finds that a device “presents an unreasonable risk of substantial harm to the public health,” that “notification . . . is necessary to eliminate [such] risk,” and that “no more practicable means is available . . . to eliminate such risk,” then the agency may issue an order “to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk.” 21 U.S.C. § 360h(a) (1994).

The FDA has indicated that “it could make the findings required by section 518(a) . . . and so could order tobacco manufacturers to notify young people about the substantial health risks that tobacco products present in a form appropriate to eliminate the risk.” Rule, 61 Fed. Reg. at 44,538.


\textsuperscript{127} See id. at 41,327 (“The program would be national in scope and could require that the companies purchase certain times and places on television programming . . . .”).


\textsuperscript{129} Wooley v. Maynard, 430 U.S. 705, 714 (1977) (invalidating New Hampshire criminal statute requiring citizens to display motto “Live Free or Die” on state license plates); see also West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 633 (1943) (holding that school children with religious objection to saluting flag have constitutional right to be free from “compulsion . . . to declare a belief”).

\textsuperscript{130} 115 S. Ct. 2338, 2347 (1995) (citation omitted).

\textsuperscript{131} Id.
A. Compelling Corporations to Speak

In invoking this line of cases to challenge the proposed regulations, tobacco manufacturers might find a persuasive analog in Pacific Gas & Electric v. Public Utilities Commission (PG&E),132 in which the Court determined that a state utilities commission violated the First Amendment rights of a privately owned utility company by requiring it to include in its billing envelopes speech of a third party with which it disagreed. For decades the utility had included "political editorials, feature stories on matters of public interest, [and] tips on energy conservation" in the extra space of its monthly billing envelope.133 A ratepayers' advocacy group asked the commission to forbid the utility from using the extra space for political editorials "on the ground that the [utility's] customers should not bear the expense of [the utility's] own political speech."134 The state utilities commission responded by ordering the utility to permit the ratepayers' advocacy group to use the extra space four times a year, "plac[ing] no limitation on what [the group] could say in the envelope, except that [the group] is required to state that its messages are not those of [the utility]."135 In striking down the order, a plurality of four Justices held that "[c]ompelled access like that ordered in this case both penalizes the expression of particular points of view and forces speakers to alter their speech to conform with an agenda they do not set."136

PG&E may present difficulties for an FDA-mandated educational program in at least two ways. First, PG&E affirmed that the government has no more authority to compel speech by corporations than it has to compel speech by individuals: "For corporations as for individuals, the choice to speak includes within it the choice of what not to say. . . . [S]peech does not lose its protection because of the corporate identity of the speaker. Were the government freely able to compel corporate speakers to propound political messages with which they disagree, this protection would be empty . . . ."137 Second, the state utilities commission in PG&E was not permitted to compel a private company to publish third party views with which it disagreed, even where the third party was required to disclaim the company's adherence to those views. Arguably, a mandatory educational campaign would require tobacco manufacturers not only to fund the dissemination of anti-smoking views, but also to identify themselves with those views. This goes one step

132. 475 U.S. 1 (1986) [hereinafter PG&E].
133. Id. at 5.
134. Id.
135. Id. at 7.
137. PG&E, 475 U.S. at 16.
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further than the regulations struck down in *PG&E*. Such coercion frustrates the "individual freedom of mind" protected by the First Amendment. 138

On a closer analysis, however, one might plausibly argue that *PG&E* does not determine the constitutionality of the FDA's proposed educational campaign. *PG&E* involved non-commercial, political speech, which receives the highest degree of First Amendment protection. Government regulation of such speech must be narrowly tailored to achieve a compelling state interest. 139 It is not clear whether the content of the educational program envisioned by the FDA would qualify as political speech as opposed to "commercial speech," which is subject to an intermediate degree of First Amendment scrutiny, 140 or "government speech," which is subject to only minimal scrutiny when its vehicle is ordinary legislation or regulation. 141 The proper

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138. West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 637 (1943); see *Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 234-235 (1977) ("[A]t the heart of the First Amendment is the notion that an individual should be free to believe as he will, and that in a free society one's beliefs should be shaped by his mind and his conscience rather than coerced by the State."); see also *PG&E*, 475 U.S. at 15 n.12 (state may not "require corporations to carry the messages of third parties, where the messages themselves are biased against or are expressly contrary to the corporation's views"); Central Ill. Light Co. v. Citizens Utility Bd., 827 F.2d 1169, 1173 (1987) ("companies can[not] be made into involuntary solicitors for their ideological opponents").


140. See infra Part IV (discussing definition and standard of review applicable to commercial speech set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980)).

141. The term "government speech" is applied to a wide array of government-sanctioned, government-funded, and government-mandated speech. See generally Steven Shiffrin, *Government Speech*, 27 UCLA L. REV. 565 (1980); Mark G. Yudof, *When Governments Speak: Toward a Theory of Government Expression and the First Amendment*, 57 TEX. L. REV. 863 (1979). Here, "government speech" will refer to expressive activities undertaken by the government in the course of furthering a public policy goal—for example, "warning of the dangers of cigarette smoking or drug use, praising a career in the armed services, or offering methods for AIDS prevention." *United States v. Frame*, 885 F.2d 1119, 1131 (3d Cir. 1989). Government speech of this sort is typically funded by general tax revenues and implemented through ordinary legislation or regulation. It need not implicate the free speech rights of taxpayers compelled to support the government any more than other government expenditures for programs with which taxpayers may disagree. See infra text accompanying notes 144-146.

While the government clearly may use public funds to pursue policies that run counter to the views of some or many citizens, it may not compel adherence by individuals to a particular view. This limitation on government speech is stated in *Barnette*: "[N]o official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." 319 U.S. at 642. See also *Wooley v. Maynard*, 430 U.S. 705, 713 (1977) (forbidding state from "requir[ing] an individual to participate in the dissemination of an ideological message by displaying it on his private property"); *Abood*, 431 U.S. 209 (invalidating state laws authorizing agreements between teachers' unions and boards of education requiring public school teachers to pay union service charge used to advocate political views unrelated to collective bargaining). In addition, the government may not monopolize the "marketplace of ideas," *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 390 (1969), or drown out or suppress competing private speech contrary to the government's own positions. See *Linmark Ass'n v. Township of Willingboro*, 431 U.S. 85, 86 (1977) (invalidating municipal ordinance prohibiting "the posting of 'FOR SALE' or 'SOLD' signs" despite municipality's objective of preventing flight of white homeowners); *Police Dep't. of Chicago v. Mosley*, 408 U.S. 92 (1972) (holding prohibition of picketing, except peaceful picketing involving labor disputes, makes impermissible distinctions between types of picketing based on content);
standard of constitutional review depends on which type of speech is at issue.

B. Political vs. Commercial vs. Government Speech

On this question, United States v. Frame may be instructive. The court in Frame examined the constitutionality of the Beef Promotion and Research Act of 1985, enacted by Congress to strengthen the nation's lagging beef industry. Under the Act, cattle buyers and producers were required to pay an assessment of one dollar per head of cattle to fund a national information campaign designed to increase beef consumption. Frame, a cattle producer, refused to pay the assessment "because it compel[led] him to participate administratively and financially in the promotion of a cause (an advertising campaign 'to strengthen and preserve the position of beef and beef products in the marketplace') and a message (the consumption of beef is 'desirable, healthy, nutritious') with which he disagree[d]."

In its decision, the Third Circuit affirmed a basic principle of government speech doctrine. It asserted that "citizens do not have the right to refuse to support financially government programs with which they disagree, even if that program involves expressive association." Citing Justice Powell's concurrence in Abood v. Detroit Board of Education, the court recognized that "[c]ompelled support of a private association"—which the state sought to require in PG&E, for example—

is fundamentally different from compelled support of government. Clearly, a local school board does not need to demonstrate a compelling state interest every time it spends a taxpayer's money in ways the taxpayer finds abhorrent. . . . [T]he reason for permitting the government to compel the payment of taxes and to spend money on controversial projects is that the government is representative of the people.

However, the court went on to conclude that the advertising campaign did not actually fall within the realm of government speech. In contrast to imposing general taxes for the support of public schools, the government in Frame singled out a particular group to support its beef promotion campaign. Recognizing this "coerced nexus between the individual and the specific expressive activity," the court concluded that the advertising campaign was

142. 885 F.2d 1119 (3d Cir. 1989).
143. Id. at 1129.
144. Id. at 1131.
146. Frame, 885 F.2d at 1131 (quoting Abood, 431 U.S. at 259 n.13 (Powell, J., concurring)).
147. Id. at 1132.
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“not properly characterized as ‘government speech.’” The court explained that “[w]hen the government allocates money from the general tax fund to controversial projects or expressive activities, the nexus between the message and the individual is attenuated. In contrast, where the government requires a publicly identified group to contribute to a fund earmarked for the dissemination of a particular message associated with that group, the government has directly focused its coercive power for expressive purposes.”

While arguing successfully that the advertising program was not government speech, the defendant in Frame “concede[d] that the compelled speech at issue here qualifies as ‘commercial speech.’” One might therefore expect the court to have applied the intermediate scrutiny of Central Hudson’s four-part standard for evaluating commercial speech regulation. However, the case was not decided on this basis. Instead, the court employed a higher standard of review because the defendant had asserted not only a free speech but also a free association claim. Frame alleged a violation of his First Amendment associational rights on the ground that he “[had] no desire to participate in [the advertising] program, disagree[d] with its message and methods, and want[ed] no part of any association, express or implied[,] with this government created trade association.” The court in Frame, relying on Roberts v. United States Jaycees, noted that the right to be free from compelled association deserves the full protection of the First Amendment. Thus, in the language of strict scrutiny, the court promised to “sustain the constitutionality of the... Act only if the government can demonstrate that the Act was adopted to serve compelling state interests, that are ideologically neutral, and that cannot be achieved through means significantly less restrictive of free speech or associational freedoms.”

Yet, even under this exacting standard, the court ultimately determined that the government’s interest in “preventing further decay of an already deteriorating beef industry” was sufficiently compelling, and that the advertising campaign’s incursion on First Amendment rights was “slight” since it was limited to the non-political purpose of “promot[ing] the product that the

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148. Id.
149. Id.
150. Id. at 1133. At a minimum, “commercial speech” encompasses speech that proposes a commercial transaction (e.g., the sale of beef). See Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 637 (1985), cited in Frame, 885 F.2d at 1133.
152. Frame, 885 F.2d at 1129 (quoting appellants’ answer and counterclaim).
154. Frame, 885 F.2d at 1134.
155. Id.
defendant himself has chosen to market.”156 The contested provision of the Act was therefore upheld.

Four years later, in a similar case, the Ninth Circuit applied Frame’s analytic framework to reach a different result. In Cal-Almond, Inc. v. USDA,157 the federal government issued an Almond Marketing Order requiring almond handlers (1) to pay an assessment to fund a generic pro-almond public relations program conducted by the government, or alternatively (2) to spend a comparable amount on “creditable advertising” that met federal regulations.158 Several almond handlers claimed that the order violated their rights to free speech and free association. In a direct analogy to Frame, the court in Cal-Almond held that both prongs of the marketing program, independently and in combination, implicated the almond handlers’ First Amendment rights. In selecting the proper standard of constitutional review, the court determined that Central Hudson’s intermediate scrutiny applied to the extent that the program involved commercial speech,159 but that the more stringent standard of Roberts applied to the extent that the program interfered with freedom of association.160 In contrast to Frame, where the court upheld the beef advertising program even under the more rigorous level of review, the court in Cal-Almond invalidated the almond marketing program under the less exacting Central Hudson standard.161

Although they reached different results, Frame and Cal-Almond provide some guidance for analyzing the constitutionality of the FDA’s proposed educational campaign. Because the FDA—like the government in Frame and Cal-Almond — would “require[] a publicly identified group to . . . disseminate[e] . . . a particular message associated with that group,”162 the speech at issue cannot constitute government speech. The FDA’s regulations would therefore be subject to something higher than the minimal level of judicial scrutiny that government speech receives.

On the other hand, to the extent that the educational campaign conveys information concerning the health risks of tobacco consumption, it does not “necessarily implicate a broad range of ideological, moral, religious, economic,

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156. Id. at 1136.
157. 14 F.3d 429 (9th Cir. 1993).
158. See id. at 433.
159. See id. at 436 & n.5.
160. See id. at 436 (citing Roberts, 468 U.S. at 623).
161. See id. at 437-40. In particular, the court found that, although the USDA sought to advance a substantial government interest, it “failed to meet its burden [under Central Hudson] of showing that the overall almond marketing program ‘directly advances’ its stated goals of selling more almonds and increasing returns to producers.” Id. at 439. Moreover, because the USDA did not carefully consider advertising alternatives that imposed a lesser burden on First Amendment freedoms, the court decided that the USDA failed to prove, as it must under Central Hudson, “that the regulations are no more extensive than necessary to serve the interest of increasing almond sales.” Id.
162. Id. at 435 (quoting Frame, 885 F.2d at 1132) (emphasis in Cal-Almond).
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and political interests”\textsuperscript{163} that would trigger the rigorous constitutional protections applicable to non-commercial, political speech. The primary purpose of the educational program is “to combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products.”\textsuperscript{164} Speech that aims to provide truthful information about a commercial product, even if it decreases sales, could lie within the current legal conception of commercial speech.\textsuperscript{165} Moreover, the fact that the informational campaign would occur in a highly political context would not alone alter its status as commercial speech. For example, the Court has held that “advertising which ‘links a product to a current public debate’ is not thereby entitled to the constitutional protection afforded noncommercial speech.”\textsuperscript{166}

However, although the educational campaign could conceivably be characterized as commercial speech, it is nevertheless unlikely that its constitutionality would be determined by Central Hudson’s intermediate standard. Like the cattle producers in \textit{Frame} and the almond handlers in \textit{Cal-Almond}, the tobacco manufacturers here would likely allege not only a free speech violation but also an infringement on their right to free association. The claim would be that the educational campaign forces a tobacco company, against its volition, to associate with the FDA and other companies in the coordinated dissemination of a message that runs counter to its interests. It is well-settled that “[f]reedom of association . . . plainly presupposes a freedom not to associate,”\textsuperscript{167} and a claim of compelled association would require the FDA to show that the educational program was “adopted to serve compelling state interests, unrelated to the suppression of ideas, that cannot be achieved through means significantly less restrictive of associational freedoms.”\textsuperscript{168} Thus, it is probable that the educational campaign would be subject to the most rigorous standard of constitutional review.

\begin{footnotesize}
\begin{itemize}
\item[163.] \textit{Frame}, 885 F.2d at 1136.
\item[164.] Proposed Rule, 60 Fed. Reg. at 41,326.
\item[165.] As defined by the Supreme Court, commercial speech is speech that proposes a commercial transaction. \textit{See Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico}, 478 U.S. 328, 340 (1986); \textit{Ohralik v. Ohio State Bar Ass’n}, 436 U.S. 447, 455-56 (1978). The definition of “transaction” is not limited to a simple sell. It is the fact of being within “the stream of commercial information” (Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 771-72 (1976)), rather than the effect of that information on commerce, that makes speech “commercial” and therefore deserving of certain protections and regulations.
\item[168.] \textit{Id.}
\end{itemize}
\end{footnotesize}
C. Application to the FDA Regulations

The key question, then, is whether the FDA program would survive such scrutiny. An examination of Frame and Cal-Almond together cannot yield one answer to this question, considering that the two courts reached different results in quite similar cases. However, Frame provides helpful insights into what factors would be taken into account by a court more sympathetic to regulation, while Cal-Almond indicates how the analysis might proceed if undertaken by a court more wary of regulation. The FDA's rules will likely be examined by more than one court; since one cannot ignore the individual court's predilections in imagining the outcome, it is helpful to see how the FDA regulations would fare under either scenario.

Frame suggests that the regulations might survive strict scrutiny. The government's interest in "discourag[ing] young people from using cigarettes and smokeless tobacco products"\(^{169}\) may fairly be regarded to be at least as compelling as the "primarily economic" interest advanced in Frame.\(^{170}\) Arguably, the FDA has demonstrated a close fit between means and ends by offering substantial evidence that the concerted dissemination of anti-smoking messages leads to reduced cigarette consumption.\(^{171}\) Additionally, in evaluating whether "the extent of the interference here is no more than necessary to further the government's interest," Frame determined that the Beef Promotion Act avoids "a significant incursion on Frame's constitutional rights" insofar as it "expressly prohibits spending for political activity" and furthers an "ideologically neutral" purpose.\(^{172}\) Similarly, the FDA's proposed educational campaign does not seek to enforce adherence to a particular ideology nor to influence legislation or government policy. However, in contrast to the Beef Promotion Act, the FDA's program aims to discourage rather than encourage consumption of the product manufactured by the entities compelled to support the campaign. To the extent that a mandatory educational campaign would require the tobacco industry to promote messages opposed to its commercial interests, a court may find the campaign's interference with First Amendment rights to be particularly burdensome.

Moreover, the invalidation of the marketing order in Cal-Almond casts further doubt on the constitutionality of the FDA's educational campaign. Applying an intermediate standard of review, the court in Cal-Almond required the USDA's marketing program to be "no more extensive than necessary to
serve the interest of increasing almond sales." Where, as here, the most stringent constitutional review applies, the fit between means and ends must be even tighter than what Cal-Almond required: The FDA must show that its interest in curbing youth smoking "cannot be achieved through means significantly less restrictive of associational freedom." If the intermediate "no more extensive than necessary" standard was problematic for USDA's marketing order in Cal-Almond, then the more rigorous "least restrictive means" test surely will be problematic for the FDA's educational campaign. The agency may argue persuasively that an educational program is an effective means of reducing tobacco use. However, it must also explain why such a program must be funded and implemented by tobacco manufacturers. Indeed, it is not clear why an alternative program conducted directly by the FDA and funded by general tax revenue would not be equally effective. Such an approach would impose few, if any, restrictions on First Amendment rights. The FDA faces the difficult task of arguing why its proposal is necessary in light of this and perhaps other alternatives.

D. "Corrective Advertising"

Finally, the FDA cites Warner-Lambert Co. v. FTC to argue for the constitutionality of an educational campaign on a separate theory of "corrective advertising." In Warner-Lambert the Federal Trade Commission ordered a mouthwash manufacturer to stop advertising that its product, Listerine, prevented or alleviated the common cold, since that claim contradicted scientific evidence. In addition, the order required Warner-Lambert to disclose in future advertisements that "Listerine will not help prevent colds or sore throats or lessen their severity." In upholding the order under precedents governing commercial speech regulation, the court determined that "corrective advertising" was a permissible remedy where "the accumulated impact of past

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173. Cal-Almond, 14 F.3d at 439 (applying Central Hudson's intermediate standard). The court explained that "this standard is not as strict as a 'least restrictive means' test." Id. Under Central Hudson, the fit between means and ends must be "not necessarily perfect, but reasonable; . . . not necessarily the best disposition but one whose scope is in proportion to the interest served; . . . not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective." Id. (quoting Board of Trustees v. Fox, 492 U.S. 469, 480 (1989)).


175. See supra note 161 and accompanying text.

176. It is important to note that reliance on existing warning label requirements would not be considered a meaningful alternative for achieving the FDA's goal of reducing tobacco use by teenagers. The Surgeon General's warning is not directly targeted at youth; moreover, teenage smoking has increased, rather than decreased, during the time since warning labels were first mandated.


178. Id. at 752.
advertising . . . necessitates disclosure in future advertising." The court explained that

under certain circumstances an advertiser may be required to make affirmative disclosure of unfavorable facts. One such circumstance is when an advertisement that did not contain the disclosure would be misleading. . . . Affirmative disclosure has also been required when an advertisement, although not misleading if taken alone, becomes misleading considered in light of past advertisements.

When applied to the context of tobacco advertising, the rationale of Warner-Lambert conceivably could support the constitutionality of the FDA's proposed education campaign. Evidence exists indicating that "cigarette advertising and promotion play an important role in encouraging young people to start smoking, to sustain their smoking habit, and to increase consumption," and that past advertising has generated a misleading association between tobacco use and an active, glamorous, even athletic lifestyle. Throughout its comments on the 1995 proposed regulations, the FDA makes clear that the mandatory educational program is intended to be "corrective."

Nevertheless, the First Amendment circumscribes the scope of a corrective remedy. In National Commission on Egg Nutrition v. FTC, the court upheld an FTC order prohibiting false and misleading advertising by an egg industry trade association whose ads denied the well-substantiated relationship among eggs, cholesterol, and heart disease. However, it struck down a part of the order requiring the association to include in future advertisements "the further statement that many medical experts believe increased consumption of dietary cholesterol, including that in eggs, may increase the risk of heart disease." The court declared that "[t]he First Amendment does not permit a remedy broader than that which is necessary to prevent deception or correct the effects of past deception." The court was careful to distinguish Warner-Lambert on the ground that the evidence in Egg Nutrition "does not show a long history of deception which has so permeated the consumer mind that the 'claim was believed by consumers after the false advertising had ceased.'"

179. Id. at 761 (emphasis in original).
180. Id. at 759-60.
182. See id. at 41,329-34.
183. See, e.g., id. at 41,327 (educational program "would correct and combat the effects of the pervasive positive imagery in advertising"); id. at 41,328 (referring to "corrective educational program").
184. 570 F.2d 157 (7th Cir. 1977).
185. Id. at 164.
186. Id.
187. Id. (quoting Warner-Lambert, 562 F.2d at 771).
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Thus, whether the proposed educational program will survive on a theory of corrective advertising depends largely on the fit between the corrective remedy and the degree to which consumers have been misled by prior advertising. In Warner-Lambert, where the misleading claim had persisted for over fifty years, the order upheld by the court required the manufacturer to maintain its corrective disclosure until it had spent an amount equal to its average annual advertising budget (approximately $10 million). Here, in its 1995 proposed regulations, the FDA indicated that it would seek $150 million per year from tobacco manufacturers to fund a mandatory educational program, a figure that reflects roughly half the amount that would be spent on anti-smoking advertisements under the Fairness Doctrine if that doctrine were still in effect. Notably, this figure also reflects a mere 2.4 percent of the $6.2 billion spent by the tobacco industry on advertising, promotion, and marketing of cigarettes and smokeless tobacco in 1993. The latter comparison suggests that the corrective remedy proposed by the FDA does not impose an excessive burden, at least financially, on the tobacco industry.

Additional questions remain, however, as to whether an educational campaign is an appropriate corrective remedy for past cigarette advertising. For instance, it is not clear in what sense an educational campaign emphasizing the addictiveness and health risks of youth smoking would be a "correction" for the pervasive positive imagery of glamour and social desirability cultivated through prior advertising. In addition, while the FDA had contemplated an educational campaign with "major reliance on television messages," one might question whether anti-smoking spots on television would be a fitting remedy given the fact that pro-smoking advertisements on television and radio have been banned for twenty-five years.

More fundamentally, it is arguable whether tobacco advertising has been "misleading" in a way that would justify the imposition of a corrective remedy. In Egg Nutrition and Warner-Lambert, private entities had made

188. See Proposed Rule, 60 Fed. Reg. at 41,328.
189. Before Congress decided to ban cigarette advertisements from television and radio (see infra note 200 and accompanying text), the Fairness Doctrine required broadcasters to provide significant commercial air time for anti-smoking messages. Between 1967 and 1970, "one anti-smoking message appeared for every three or four industry-sponsored, pro-smoking advertisements," amounting to $75 million in 1970 dollars (or $290 million in 1994 dollars). See id. at 41,326-28; see also infra text accompanying notes 196-199.
190. See id. at 41,315.
191. Id. at 41,326.
192. One response to this concern might be that pro-smoking messages have still appeared on television to the extent that tobacco manufacturers have been prominent sponsors of televised concerts and sporting events. See text accompanying notes 202-203. In addition, television advertising of smokeless tobacco products, though a smaller market than cigarettes, has increased in recent years. See id. at 41,329.
193. For a description of what constitutes misleading advertising, see infra, text accompanying notes 231-233.
false claims about a product in the face of solid scientific evidence; in Warner-Lambert such claims had appeared in advertisements for half a century. Here, it is more difficult to identify the sense in which the imagery of glamour, sophistication, and social desirability "mischaracterizes" cigarettes and smoking. Certainly it is fair to say that cigarette advertising is misleading—and that a corrective remedy is justified—to the extent that such advertising portrays tobacco use as safe and healthful. However, the educational campaign as proposed seeks to combat the many other dimensions of cigarette advertising that give smoking its social and psychological appeal. In order to justify the program's broad sweep on a theory of corrective advertising, the FDA would face the difficult and somewhat peculiar task of showing that the tobacco companies' non-health-related claims about cigarettes are false or misleading and thus subject to a corrective remedy.

E. Conclusion

Invoking the direct authority of section 518(a) of the Federal Food, Drug, and Cosmetic Act, the FDA has declared its intention to enlist tobacco manufacturers in funding and implementing a nation-wide anti-smoking educational program targeted at youth. By requiring a particular group to engage in specific expressive activity, the program implicates First Amendment protections against compelled speech and association.

There is no precedent on the constitutionality of a government order requiring an industry to fund an independent publicity campaign opposed to its own commercial interest. However, related precedents yield some important insights. First, the compelled speech at issue here could perhaps qualify as commercial speech. Second, the intermediate standard of constitutional review applicable to commercial speech would nonetheless give way to a more rigorous standard if an additional claim of compelled association is asserted. Third, to survive the higher standard, the educational program must be the least restrictive means of achieving a compelling government interest. While the FDA's interest in eliminating youth smoking may be compelling, it is not obvious that the FDA cannot further this interest in a way that burdens First Amendment rights less than the current proposal.

Finally, the FDA might defend the educational program on a separate theory of corrective advertising. If past cigarette advertising has in fact created a misleading association between smoking and health, the FDA has a sound basis for pursuing a corrective remedy. However, that hypothesis is debatable, and the First Amendment restricts the remedy to the scope of past deception. In defining the substance and strategy of an educational program, the FDA must ensure a precise fit between the program and the past advertising it is intended to correct.
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—Goodwin Liu

IV. DO THE FDA'S RESTRICTIONS ON ADVERTISING VIOLATE COMMERCIAL SPEECH RIGHTS UNDER THE FIRST AMENDMENT?

A. History of Tobacco Advertising Regulation

The FDA has chosen to regulate tobacco primarily by regulating tobacco advertising. This approach is not a new one. Indeed, tobacco advertising has consistently been at the heart of attempts to regulate the industry.

In 1964, frightened by growing public concern over the health risks associated with tobacco and the potential for litigation, the tobacco industry attempted to regulate itself through advertising constraints. The manufacturers of over ninety-nine percent of domestic cigarettes adopted the Cigarette Advertising Code, which prohibited any advertising that was directed primarily to persons under twenty-one or that was located in scholastic media. The code also mandated that cigarette advertising not represent “smoking as essential to social prominence, distinction, success or sexual attraction.” However, this attempt at self-regulation failed. No fines for violating the code were ever enforced, and the code ended in November, 1970, after membership dwindled to only three cigarette manufacturers.

The government’s attempt to regulate advertising, occurring soon thereafter, was at least initially more successful. The Federal Communications Commission (FCC) applied the “Fairness Doctrine” to tobacco advertising in 1967. In general, the Fairness Doctrine required radio and television broadcasters to (1) “devote a reasonable percentage of broadcast time to the coverage of public issues” and (2) ensure that coverage was “fair in the sense that it provides an opportunity for the presentation of contrasting points of view.” As applied to the tobacco industry, the doctrine required broadcasters to air at least one anti-smoking message for every four cigarette commercials. The FCC justified its application of the Fairness Doctrine to tobacco advertising by stating that:

195. Id.
196. The FCC began the gradual development of the Fairness Doctrine as early as the 1940s, as a corollary principle to the rules on personal attack and political editorial (see 47 C.F.R. § 73.123 (1968)). In 1978, the FCC formally incorporated the principle into its rules. See Regulations of Radio and Television Broadcasting, 43 Fed. Reg. 45,842 (1978); 47 C.F.R. §§ 73.1910-1940 (1988).
The advertisements in question clearly promote the use of a particular cigarette as attractive and enjoyable. Indeed, they understandably have no other purpose. We believe that a station which presents such advertisements has the duty of informing its audience of the other side of this controversial issue of public importance—that, however enjoyable, such smoking may be a hazard to the smoker’s health.199

Unsatisfied with increasing public smoking levels, however, Congress later enacted the Public Health Cigarette Smoking Act of 1969, which eliminated television and radio advertisements for cigarettes.200 The removal of electronic media advertising meant that tobacco companies were no longer subject to the Fairness Doctrine. Many observers believe that the tobacco companies actually increased their volume of sales following the ban as a direct result of the fact that broadcasters were no longer required to air anti-smoking ads.201 As for the tobacco companies’ own ability to promote their products on television, it was not so much curtailed as rechanneled. Tobacco companies began to sponsor major sporting events such as the Virginia Slims tennis tournament and the Winston Cup autoracing events. One source estimates that tobacco support of motor sports is approaching $200 million per year.202 While the electronic media ban prohibits companies from airing advertisements during scheduled commercial breaks, tobacco product logos and brand names are prominently displayed throughout the telecasts.203

After the elimination of direct tobacco advertisements on television, the government implemented additional regulations designed to strengthen the warning labels on cigarette packages.204 In 1984, the government amended the Federal Cigarette Labeling and Advertising Act to require a rotation of four warnings.205 The Federal Trade Commission later extended these warning to

199. 8 F.C.C.2d 381, 382 (1967).
203. See Holly Cain, Drag Race: Clinton vs. Cigs, TAMPA TRIB., Sept. 1, 1996, Sports, at 1. Dr. Alan Blum stated that during a 90-minute telecast of an Indy-car race in 1989, his Doctors Ought to Care (DOC) group documented 5,933 exposures of the Marlboro logo. Gary Mihoces, Anti-Smoking Leader Says Ban’s Too Late, USA TODAY, Sept. 11, 1996, at 3C. See also Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,534 (1996) (detailing comments that tobacco companies have circumvented advertising ban).
205. The warnings are: SURGEON GENERAL’S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy; SURGEON GENERAL’S WARNING: Quitting Smoking Now Greatly Reduces Serious Risk to Your Health; SURGEON GENERAL’S
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smokeless tobacco products and print advertising. However, despite the efforts of Congress, teenage use of tobacco products actually increased even while use by adults decreased.

B. The Current FDA Regulations

The current FDA regulations contain a variety of restrictions on tobacco advertising. These restrictions include the following: a ban on tobacco-product billboard ads within 1000 feet of schools and playgrounds; a requirement that tobacco ads in publications whose youth readership exceeds fifteen percent contain only black-and-white text and no pictures; a ban on publicity items bearing tobacco product names and logos; a ban on brand-name sponsorship of entertainment and sporting events, including sponsorship of individual cars and teams; and a ban on color imagery in billboard ads except in adults-only areas such as bars and nightclubs, provided that the image cannot be seen from the outside and cannot be removed easily. The restrictions clearly reflect the FDA’s conclusion that “the most effective way to achieve ... a reduction [in the use of tobacco products by children and adolescents] is by limiting access to, and attractiveness of, cigarettes and smokeless tobacco to young people.”

C. First Amendment Jurisprudence on Commercial Speech

The tobacco companies, as well as numerous commentators, have argued that the above restrictions represent an unconstitutional encroachment of their First Amendment “commercial speech” rights. The Supreme Court has defined commercial speech as speech that proposes a commercial transaction

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207. See Elizabeth Gleick, Out of the Mouths of Babes, TIME, Aug. 21, 1995, at 33.


209. See id. at 44,502 (to be codified at 21 C.F.R. § 897.30(b)).

210. See id. at 44,513 (to be codified at 21 C.F.R. § 897.32). Questions persist as to how readership numbers will be measured.

209. See id. at 44,502 (to be codified at 21 C.F.R. § 897.30(b)).

211. See id. at 44,521 (to be codified at 21 C.F.R. § 897.34(a)-(b)).

212. See id. at 44,527 (to be codified at 21 C.F.R. § 897.34(c)).

213. However, the FDA has allowed vending machines sales in adults-only areas such as bars and nightclubs. See id. at 44,449-52. Likewise, mail order sales of tobacco products, which the FDA had originally sought to prohibit, are allowed under the final rule. See id. at 44,459.

214. Id. at 44,399.

and is "related solely to the economic interest of the speaker and its audience."\textsuperscript{216} That the FDA's regulations curtail the tobacco industry's freedom to engage in commercial speech is clear. Whether or not the curtailment is unconstitutional, however, is less clear, in light of the fact that the Supreme Court has held that the "Constitution... accords a lesser protection to commercial speech than to other constitutionally guaranteed expression."\textsuperscript{217}

The prevailing test for the constitutionality of restrictions on commercial speech was established in 1980 by \textit{Central Hudson Gas & Electric Corp. v. Public Service Commission}.\textsuperscript{218} In that case, the appellant utility challenged the constitutionality of a New York Public Service Commission regulation that ordered electric utilities in the state of New York to cease all advertising of electricity. The Court held that the Commission's complete ban of all advertising was more extensive than necessary to further the state's interest in energy conservation. In reversing the lower court's judgment for the commission, the Court formulated a four-part test:

\begin{quote}
At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and must not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.\textsuperscript{219}
\end{quote}

The four-prong \textit{Central Hudson} test has guided the Court in its subsequent commercial speech cases\textsuperscript{220} and remains the standard by which regulations such as the FDA's must be judged. However, the recent case of \textit{44 Liquormart v. Rhode Island}\textsuperscript{221} may cast a new light on how the Court intends to apply \textit{Central Hudson} in the future. \textit{Liquormart} involved a Rhode Island statute that prohibited advertising of the retail prices of alcoholic beverages. In holding that the statute failed to survive a \textit{Central Hudson} inquiry, the Court invoked a footnote within the \textit{Central Hudson} decision, cautioning that "although the special nature of commercial speech may require less than strict review of its regulation, speech concerns arise from 'regulations that entirely suppress commercial speech in order to pursue a non-speech-related policy.'"\textsuperscript{222} The Court made a clear differentiation between narrow regulation for the purpose

\begin{footnotes}
\item \textsuperscript{216} Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 561 (1980).
\item \textsuperscript{217} Id. at 557.
\item \textsuperscript{218} 447 U.S. 557 (1980).
\item \textsuperscript{219} Id. at 566.
\item \textsuperscript{220} See, e.g., Florida Bar v. Went For It, Inc., 115 S. Ct. 2371 (1995); Board of Trustees v. Fox, 492 U.S. 469 (1989).
\item \textsuperscript{221} 116 S. Ct. 1495 (1996).
\item \textsuperscript{222} Id. at 1506 (quoting \textit{Central Hudson}, 447 U.S. at 566 n.9).
\end{footnotes}
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of consumer protection and so-called “blanket bans” meant to effectuate government policies other than market regulation: “[W]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands.”[223] Liquormart also definitively rejected two commonly-made arguments in support of commercial speech restrictions: that the Rhode Island legislature’s greater power to regulate the sale of alcoholic beverages necessarily includes the lesser power to ban the advertising of alcoholic beverages;[224] and that products associated with vice or bad habits are less deserving of advertising protections.[225]

Certainly, there are differences between the circumstances attending the FDA regulations and the situation in Liquormart. Furthermore, no single part of the eight-part Liquormart decision was able to garner a majority, and so its predictive value is uncertain. It is reasonable to say, however, that the Liquormart decision may signal an increased level of skepticism on the part of the Court when assessing commercial speech restrictions. As we examine how the FDA's regulations might fare under a Central Hudson test, this should inform our analysis.

1. Speech Must Be Legal and Non-Misleading

The first prong of the Central Hudson test requires that commercial speech must be legal and non-misleading if it is to receive First Amendment protection. Central Hudson held that “there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.”[226] However, “suppression of information concerning the availability and price of a legally offered product is . . . a covert attempt by the State to manipulate the choices of its citizens, not by persuasion or direct regulation but by depriving the public of the information needed to make a free choice.”[227]

While the first part of this prong—the question of whether the commercial transaction proposed by tobacco advertising is a legal one—may at first glance appear a foregone conclusion, the FDA argues that the activity in question is illegal. The reasoning is that tobacco ads propose a commercial transaction and that advertisers do not distinguish between adult and minor purchasers. Because selling cigarettes to minors is illegal in every state, “the undifferentiated offer

223. Id. at 1507.
224. See id. at 1512; see also infra, text accompanying notes 290 & 291.
225. See id. at 1513-14; see also infra, note 266.
227. Id. at 574-75.
to sell constitutes, at least in part, an unlawful offer to sell." Consequent-
ly, the FDA claims, tobacco advertising proposes illegal transactions. The FDA
also posits that even if tobacco advertising does not propose an illegal activity,
it does encourage the "purchase, possession, or use of tobacco products by
minors." More rigorously contested is the second part of the first Central Hudson
prong—the question of whether tobacco advertising is misleading or deceptive.
In asserting that misleading commercial speech receives no First Amendment
protection, the Central Hudson Court further solidified a proposition from
Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.:

Obviously, much commercial speech is not provably false, or even wholly false,
but only deceptive or misleading. We foresee no obstacle to a State's dealing
effectively with the problem. The First Amendment . . . does not prohibit the state
from insuring that the stream of commercial information flow cleanly as well as
freely.

What constitutes deceptive or misleading speech, of course, is not easily
defined. In assessing whether advertising is deceptive for the purposes of
regulation, the FTC examines whether deception is likely among a substantial
segment of the purchasing public. "Substantial" does not imply a majority.
In the past, a court has held that misleading advertising occurred when an
estimated ten to fifteen percent of the public was misled. The FTC has also
taken the position, upheld on appeal, that "an advertiser's failure to disclose
material facts" may be as deceptive as openly misleading statements. These
provisions make the definition of "misleading" open to a significant amount of
interpretation.

Proponents of tobacco advertising regulation argue that tobacco advertising
affirmatively misleads a substantial amount of the public through the
presentation of inaccurate images. As one commentator has written:

In the cigarette industry, advertising has actively stimulated demand for the
advertised brand by portraying cigarette smoking in general and the smoking of
advertised brands in particular as a satisfying, desirable, and attractive activity.
Such advertising has associated cigarette smoking with such positive attributes as
contentment, glamour, romance, youth, happiness, recreation, relaxation, comfort,
and sophistication, at the same time suggesting that smoking is an activity at least

229. Id.
232. See Firestone Tire & Rubber Co. v. FTC, 481 F.2d 246, 249 (6th Cir. 1973), cert. denied,
233. FTC STAFF REPORT, supra note 231, at 4-18 to -19 (citing Simeon Management Corp. v.
FTC, 579 F.2d 1137, 1145 (9th Cir. 1978)).
consistent with physical health and well-being. Furthermore, cigarette advertising has frequently intimated, without claiming outright, that smoking or smoking the advertised brand is innocuous or at least less hazardous than smoking other brands. Cigarette advertising has thus stressed the claim satisfactions of smoking while ignoring completely—or even attempting to negate—the dangers of the habit. 234

The defenses available to counter this accusation are twofold: the images presented are not inaccurate, and/or they are not likely to mislead a substantial segment of the population. Whether or not tobacco advertisements make something tantamount to affirmative assertions of smoking's healthfulness or innocuousness is arguable; but the same issue could be dealt with effectively by the claim that the advertisements withhold material negative information. The issue then becomes whether or not a substantial amount of the public is deceived into ignorance of smoking's negative health effects. A response by tobacco companies that may be viable is that the industry has been forced to dispel any misunderstandings about health risks through the required warnings on tobacco packages. 235 Consequently, any potentially misleading statements or omissions in the advertisements would be extinguished by the warnings. The industry has pointed out that the makers of other potentially harmful products, such as foods high in fat or sodium, do not even carry warning labels and still have not been found deceptive in their advertising. Of course, a potent counterargument to this is that while alcohol, sugar and other potentially dangerous products may endanger health, they are only dangerous when abused. 236 Therefore, a person who does not receive the impression from butter advertisements that butter is harmful is not necessarily deceived.

By far the strongest claim that tobacco advertising has withheld information in a way that deceived a substantial amount of the public can be made regarding to the industry's treatment of nicotine. The government made its official pronouncement of nicotine's addictiveness in 1988, when the Surgeon General published a full report on the subject. 237 The fact that a product can lead to a biochemical dependence seems to fall clearly within the realm of a "material fact," the omission of which would be seen to violate a prohibition against deceptive or misleading advertising under the FTC's standards. 238 It soon emerged, in a dramatic series of events, that tobacco companies could not plead ignorance of this material fact. First the former head of research at Brown & Williamson, then other tobacco company officials, came forward to attest to their prior knowledge and exploitation of nicotine's addictiveness.

235. See Ludwikowski, supra note 201, at 111.
238. See supra text accompanying notes 28 & 29.
Later, approximately 4000 documents supporting these confessions were leaked and published.²³⁹ These developments lend crucial support to claims that tobacco companies have successfully deceived the public, since there has arguably been inadequate public knowledge about nicotine to counteract the industry’s failure to disclose the information in its possession.

2. The Government Must Demonstrate a Substantial Interest

If the speech in question is legal and non-misleading, the government must demonstrate a substantial interest in support of the new regulations in order to meet the *Central Hudson* test for restrictions on commercial speech.²⁴⁰ Since *Central Hudson*, the Court has traditionally found that the asserted government interest was substantial in cases where the government was acting to safeguard the public health and welfare.

In *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*,²⁴¹ the operator of a gambling casino in Puerto Rico sought to overturn a Puerto Rican statute and other regulations that restricted the advertising of casino gambling to residents of Puerto Rico. The Puerto Rican legislature wanted to increase tourism, but believed that “[e]xcessive casino gambling among local residents . . . would produce serious harmful effects on the health, safety and welfare of the Puerto Rican citizens, such as the disruption of moral and cultural patterns, the increase in local crime, the fostering of prostitution, the development of corruption, and the infiltration of organized crime.”²⁴² In holding that the statute did not violate the First Amendment, the Supreme Court had “no difficulty in concluding that the Puerto Rico Legislature’s interest in the health, safety, and welfare of its citizens constitutes a ‘substantial’ governmental interest,”²⁴³ noting that Puerto Rico’s concerns were largely identical to those expressed by many other states in banning casino gambling.²⁴⁴

The Fifth Circuit accorded great weight to a similar governmental interest in *Dunagin v. City of Oxford*.²⁴⁵ In that case, a group of outdoor advertisers, newspapers, and television and radio stations brought suit alleging that Mississippi law, which banned liquor advertising by local, in-state media, violated their First Amendment rights. The Fifth Circuit determined, without hesitation, that the state had an interest in “safeguarding the health, safety and

²³⁹. See supra notes 14 & 15 and accompanying text.
²⁴⁰. *Central Hudson*, 447 U.S. at 569.
²⁴². Id. at 341.
²⁴³. Id.
²⁴⁴. See id.
²⁴⁵. 718 F.2d 738 (5th Cir. 1983).
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general welfare of its citizens by controlling the artificial stimulation of liquor sales and consumption created by the advertising of liquor.”

The Supreme Court has not yet addressed the issue of the governmental interest in protecting minors from tobacco, but a lower court has done so, and has upheld the government’s interest. In *Penn Advertising of Baltimore, Inc., v. Baltimore (Penn II)*, a billboard owner brought suit alleging that a city ordinance prohibiting cigarette advertising on billboards located in certain zones of Baltimore violated his First Amendment rights. The ordinance in question was designed to reduce the exposure of children to stimuli that would have the effect of encouraging them to purchase cigarettes and thus to engage in an illegal transaction. The court found the City’s interest in reducing the number of illegal transactions, as well as the underlying public policy interest in reducing the consumption of cigarettes by minors, to be substantial.

Moreover, courts are generally more likely to find a substantial interest in regulations designed to protect children. In *Anheuser-Busch, Inc. v. Baltimore (Penn I)*, the petitioners filed an action seeking to overturn a city ordinance that banned the billboard advertising of alcoholic beverages. While both parties in the case agreed that the “welfare and temperance of minors” are substantial governmental interests, the language of the court indicated that even if no agreement existed, it was prepared to rule in the government’s favor on the issue.

At the Supreme Court level as well, one can find the principle that the government has a special interest in protecting youth. To choose one example: *Federal Communications Commission v. Pacifica Foundation* concerned the determination by the FCC that the language used in a broadcast monologue was indecent and, thus, prohibited by statute. The Court held that although the monologue was not obscene, the language was indecent and was properly prohibited. In doing so, the Court reinforced the government interest in the “well-being of its youth,” and stated that “[t]he ease with which children may obtain access to broadcast material . . . amply justif[ies] special treatment of indecent broadcasting.”

Against this background, an evaluation of the government’s interest in tobacco regulation appears initially to pass muster. In proposing its regulations on tobacco, the government’s stated interest is protecting children from the

246. Id. at 747.
247. 862 F. Supp. 1402 (D.Md. 1994) [hereinafter *Penn II*].
248. See id. at 1406.
249. See id.
251. See id. at 818.
253. Id. at 749.
254. Id. at 750.
health effects of smoking. The FDA claims that the restrictions will decrease
the use of tobacco products by those who are "the most vulnerable to addiction
and perhaps the least capable of deciding whether to use the products.
Decreased use of these products will reduce the risk of tobacco-related illnesses
and deaths."\(^{255}\)

Judging by the numbers, the government's claim appears to be legitimate.
According to the FDA, tobacco use is the single leading cause of preventable
death in the United States.\(^{256}\) The amount of tobacco use by children is
significant; seventy-five percent of all adult smokers have reported that they
became addicted to tobacco before they were eighteen years old.\(^{257}\) The
government argues that these young smokers (if they live long enough) will
become old smokers. Decreasing the demand for tobacco products will reduce
deaths and disease, which would in turn reduce the need for Medicare and
Medicaid, the budgets for which are a matter of obvious governmental
concern.\(^{258}\)

The government also has a substantial interest in preventing the sale of
tobacco products to minors, which is an illegal activity.\(^{259}\) All states have
statutes that prohibit the sale of cigarettes to persons under eighteen years of
age.\(^{260}\) Limiting the exposure of young people to advertising might reduce the
number of young people attempting to procure an illegal sale of cigarettes. The
court in *Penn II* accepted the significance of the governmental interest in
promoting compliance with such state statutes.\(^{261}\)

However, while the precedents discussed above would support the
conclusion that the government's interest in regulating tobacco advertising will
be found substantial, *Liquormart* sounds a cautionary note. In Part IV of the
*Liquormart* decision, three Justices agreed that there was much reason to be
skeptical of any governmental motives "unrelated to the preservation of a fair
bargaining process."\(^{262}\) This part of the opinion seems to suggest that the
government should only consider *commercial* harms. In the words of the Court,

\(^{255}\) Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. 41,314, 41,354 (proposed Aug. 11, 1995).
\(^{258}\) For more on this angle of the argument, see LARRY C. WHITE, MERCHANTS OF DEATH: THE AMERICAN TOBACCO INDUSTRY 159 (1988). For a counter-argument, see Kluger, supra note 33, at 29 (pointing out that smokers die younger, thus collecting less in state benefits, and pay more in taxes than they cost in Medicaid expenditures).
\(^{260}\) See id. at 44,473.
\(^{261}\) See *Penn II*, 862 F. Supp. at 1406.
\(^{262}\) *Liquormart*, 116 S. Ct. at 1507.
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bans that target truthful, nonmisleading commercial messages rarely protect consumers from such [commercial] harms. Instead, such bans often serve only to obscure an ‘underlying governmental policy’ that could be implemented without regulating speech. In this way, these commercial speech bans not only hinder consumer choice, but also impede debate over central issues of public policy.\textsuperscript{263}

Thus, even when the underlying governmental policy is one directed at the public good, it should be viewed with skepticism. In fact, “[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”\textsuperscript{264} Of course, the Rhode Island statute in \textit{Liquormart} is distinguishable from the FDA regulations in that the former represented a total ban on price advertising rather than certain restrictions on the type of advertising allowed. The Court was careful to note a distinction between “complete speech bans” and “content-neutral restrictions on time, place, or manner of expression.”\textsuperscript{265} Also, the Rhode Island statute was not expressly designed for the protection of children. Nonetheless, \textit{Liquormart} casts doubt on what otherwise might seem a foregone conclusion: that the Court would find a legitimate substantial governmental interest in the FDA’s regulations.\textsuperscript{266}

3. \textit{The Regulations Must Directly Advance the Governmental Interest}

If the government demonstrates a substantial interest, then the \textit{Central Hudson} test requires the government to demonstrate a connection between the proposed restrictions and its substantial interest.\textsuperscript{267} In \textit{United States v. Edge Broadcasting Co.},\textsuperscript{268} the Court clarified the standard, holding that the government must show “an immediate connection between advertising and demand.”\textsuperscript{269} Although the test may appear strict, courts have until recently been relaxed in their interpretation of a direct link and have generally supported the link between advertising and consumption. The very fact that advertisers oppose advertising restrictions so vehemently has itself been seen as proof of this connection. As the Court stated in \textit{Central Hudson}, “[t]here is an immediate connection between advertising and demand for electricity.

\begin{itemize}
\item \textsuperscript{263} Id. at 1508 (quoting \textit{Central Hudson}, 447 U.S. at 566 n.9) (citation omitted).
\item \textsuperscript{264} Id. at 1508.
\item \textsuperscript{265} Id. at 1507.
\item \textsuperscript{266} \textit{Liquormart} also laid to rest the idea that the Court favors governmental regulation of advertising when the advertising relates to a “vice” activity. Four Justices joined in agreeing that “a ‘vice’ label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity.” Id. at 1513-14.
\item \textsuperscript{267} \textit{Central Hudson}, 447 U.S. at 556.
\item \textsuperscript{268} 509 U.S. 418 (1993).
\item \textsuperscript{269} Id. at 434.
\end{itemize}
Central Hudson would not contest the advertising ban unless it believed that promotion would increase its sales."270

In Penn I and Penn II, the District Court of Maryland supported the proposition that advertising leads to increased consumption. The court in Penn II found such a link in examining a question identical to that posed by the FDA’s proposed regulations. By corollary, the court reasoned that if advertising increases the consumption of cigarettes, then a decrease in advertising would lead to a decrease in cigarette consumption.271 The counterargument, as advanced by Penn Advertising, is that the purpose of advertising is not to increase overall consumption but to increase the market share of a particular brand. However, the court rejected this counterargument, stating:

It is beyond our ability to understand why huge sums of money would be devoted to the promotion of sales of liquor without expected results, or continue without realized results. No doubt competitors want to retain and expand their share of the market, but what business person stops short with competitive comparisons? It is total sales, profits, that pay the advertiser; and dollars go into advertising only if they produce sales. Money talks: it talks to the young and the old about what counts in the marketplace of our society.272

The link between advertising and consumption is all the more convincing when the audience includes minors. The Court in Penn II noted that “if advertising increases consumption among the general population, it is also reasonable to accept the proposition that advertising increases consumption among youths. If anything, this statement may be more applicable to the youthful population than to the adult population due to the impressionable nature of youngsters."273

With reference to the “judicially recognized proposition that advertising increases consumption,”274 however, Liquormart again threatens to change the settled landscape. Far from accepting the relationship between advertising and demand as a reasonable given, the Court determined that the government must meet a high burden of proof to support such a claim in any given instance. The Court stated that “[a]lthough the record suggests that the price advertising ban may have some input on the purchasing patterns of temperate drinkers of modest means, the State has presented no evidence to suggest that

270. Central Hudson, 447 U.S. at 569.
271. See Penn II, 862 F. Supp. at 1410. Similarly, the Supreme Court in Posadas agreed with the Puerto Rico Legislature that advertising of casino gambling would increase the demand for gambling. See 478 U.S. at 341-42.
273. Id. at 1410.
274. Id.
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its speech prohibition will significantly reduce market-wide consumption.”

The Court continued:

[...]Any conclusion that elimination of the ban would significantly increase alcohol consumption would require us to engage in the sort of ‘speculation or conjecture’ that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the State’s asserted interests . . . . Such speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.

The need to present empirical proof is not necessarily fatal to the FDA’s case. However, it may mean that the FDA will have to rethink its approach to the proof issue. The FDA has argued that:

[It is not necessary for [the] FDA to establish by empirical evidence that advertising actually causes underage individuals to smoke, or that the restrictions on advertising will directly result in individuals that are under 18 ceasing to use cigarettes or smokeless tobacco. . . . Rather, the agency must show that the available evidence, expert opinion, surveys and studies, provide sufficient support for the influence that advertising does play a material role in children’s tobacco use.

If the Court does require a higher level of proof than this, as Liquormart suggests it will, the government may have a difficult time proving that tobacco advertising causes teens to smoke. The FDA cites studies of foreign countries that have restricted some forms of tobacco advertising and promotion in support of its argument on the relationship between advertising restrictions and reduced consumption. However, a study by the International Advertising Association examined eight communist countries where cigarette advertising had been banned for more than thirty years in each country. The evidence suggested that advertising bans had failed to achieve the effect that their proponents had hoped. “In all eight centrally planned economies per capita cigarette consumption grew from 1970 to 1981 by an average of 14%, and aggregate consumption increased by 25%.”

Tobacco companies present alternative theories, both for what their advertising achieves, if not increased consumption, and for what other factors correlate with increased consumption. They argue that cigarette advertising does not increase overall consumption but merely serves to distinguish brands

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275. Liquormart, 116 S. Ct. at 1509.
276. Id. at 1510.
278. Id. at 44, 490-92.
from each other and to encourage brand switching. They also argue that the single best predictor of whether a young person will smoke seems to be whether that young person has a best friend who smokes rather than how much exposure to advertising the young person has.

The FDA responds that while tobacco advertising is not the only factor that causes individuals to smoke, it does affect other smoking influences, such as peer group and social pressures. "To argue that smoking is influenced by peer pressures at school begs the question of where such pressures originate and who will benefit from them." The FDA continues that while "advertising may not be the most important factor in a child's decision to smoke[,] ... it is a substantial, contributing, and therefore material factor." The government relies substantially upon studies that, taken cumulatively, tend to demonstrate the influence of cigarette advertising on young people. However, the FDA concedes that none of the studies is individually sufficient to "(1) Establish that advertising has an effect of directly causing minors to use tobacco products; (2) determine directionality—that is, did advertising causes the observed effect, or are smokers more observant of advertising ...; or (3) define terms or disprove the influence of peer pressure in smoking behavior." Without such conclusive evidence, Liquormart suggests, the government could conceivably fail at this prong of Central Hudson.

4. The Regulations Must Be Narrowly Tailored

(a.) The meaning of the requirement. The final prong of the Central Hudson test requires that restrictions on commercial speech be narrowly tailored to meet the government's interest. While the requirement of narrow tailoring in the context of political speech implies that there be no less restrictive alternative, the requirement has been interpreted somewhat differently in the context of commercial speech.

In Board of Trustees v. Fox, the Court clarified the narrow tailoring test in Central Hudson:

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280. See Rule, 61 Fed. Reg. at 44,489 (noting tobacco industry comments claiming that because "advertising is ... directed ... to adults who already use tobacco, ... it is not proper subject for government regulation."). Critics point out that "It is curious that the only two categories of advertising that the [advertising] industry suggests do not increase consumption are also those threatened by legislation"—tobacco and alcohol. Tollison & Wagner, supra note 7, at 148.


282. Chapman, supra note 236, at 8.


284. Id.

285. See United States v. O'Brien, 391 U.S. 367, 377 (1968) (narrow tailoring requires that the restriction on speech "is no greater than is essential to the furtherance of [the government's] interest.").

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What our decisions require is a “fit between the legislature’s ends and the means chosen to accomplish those ends”—a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but, . . . a means narrowly tailored to achieve the desired objective. Within these bounds we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.287

“Reasonable fit” does not require that there exist no other regulatory options. In Penn II, the court determined that the restrictions on cigarette advertising were a sufficiently reasonable fit despite the existence of alternative means:

The mere suggestion of alternatives . . . does not conclusively establish that the City’s chosen means are not narrowly tailored; a reasonable fit is all that is necessary: ‘A judge need not agree with the decisionmaker as to the most appropriate method for promoting a governmental interest; as long as there is a reasonable fit between the restriction and the interest served, the manner of regulation is left to the decisionmaker.’ In other words, although consideration of alternatives is an element of ‘reasonable fit,’ it is not dispositive.288

However, whether a set of restrictions is a “reasonable fit” may be conditional on whether or not the restrictions allow for alternative means of expression. As the Court stated in Liquormart, “[i]f alternative channels permit communication of the restricted speech, the regulation is more likely to be considered reasonable.”289

Previously, the government has argued that if it has the authority to prohibit an activity, it also has the authority to take the lesser step of restricting advertising of that activity. The majority in Posadas found it strange to “concede to the legislature the authority to totally ban a product or activity, but to deny to the legislature the authority to forbid the stimulation of demand for the product or activity through advertising on behalf of those who would profit from such increased demand.”290 In Liquormart, however, the Court rejected the “greater-includes-the-lesser” argument it had previously endorsed in Posadas. The Liquormart Court reasoned that “banning speech may sometimes prove far more intrusive than banning conduct. . . . [W]e reject the assumption that words are necessarily less vital to freedom than actions, or that logic somehow proves that the power to prohibit an activity is necessarily ‘greater’ than the power to suppress speech about it.”291 Whether the government can

287. Id. (quoting Posadas, 478 U.S. at 341).
289. Liquormart, 116 S. Ct. at 1521.
prohibit tobacco consumption, therefore, has no bearing on the application of the reasonable fit test.

(b.) Are the FDA’s proposed restrictions a reasonable fit? One reason tobacco supporters believe that the proposed restrictions may be an unreasonable fit is that the restrictions will significantly affect adults as well as children. The regulations may:

(1) [s]ubstantially impair advertising of tobacco to adults; (2) deprive adults of useful information about products and services such as availability, price, and quality; (3) reduce the incentive and ability to market improved products; and (4) deprive adult smokers of the benefits of competition to provide a broad range of choice and to assure that tobacco products are provided at the lowest possible cost.292

Opponents of the regulations point out that “[t]obacco advertising in magazines is already low and has fallen drastically during the last decade. By restricting tobacco advertising in publications that have a fifteen percent or more youth readership, the government is effectively restricting the up to eighty-five percent adult readers of those magazines from receiving the information.”293

A similar issue arises in obscenity and indecency law, and its treatment there can provide some insight. The Court has granted obscenity and indecency a low level of speech protection. Nonetheless, in Butler v. Michigan,294 the Court found that the effect of Michigan’s obscene literature statute was to “reduce the adult population of Michigan to reading only what is fit for children. It thereby arbitrarily curtails one of those liberties of the individual, now enshrined in the Due Process Clause of the Fourteenth Amendment, that history has attested as the indispensable conditions for the maintenance and progress of a free society.”295 Yet, in Federal Communications Commission v. Pacifica Foundation,296 when ruling on a prohibition of “indecent” material during certain hours on radio broadcasts, the Court found that the incidental effects on adults were justifiable.297 The Court based its conclusion on the access concerns that were inherent to broadcasting.298 The Court’s holding was thus very narrow, and required any restrictions to take into account many variables, including the time of day and the anticipated audience. Nevertheless, the Pacifica holding stands for the Court’s willingness to tolerate a certain amount of carefully controlled intrusion into adult-accessible speech.

293. Ludwikowski, supra note 201, at 115.
295. Id. at 383-84. The Court in Sable Communications, Inc. v. FCC., 492 U.S. 115 (1989), followed the reasoning of the Butler Court in striking down provisions in which the rights of adults were limited to what was acceptable for children.
297. Id. at 750.
298. See id.
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in order to protect children when particularly accessible forms of media are involved.

In *Penn II*, the district court’s ruling paralleled *Pacifica* in that respect. The court noted the pervasive and uncontrollable nature of billboards in the community; consequently, the court supported the City’s reasoning in differentiating between billboards and other media forms. “[T]here is a legitimate justification relating to the City’s asserted interest for differentiating billboards from other types of media which are less accessible to children and to which parents can control their children’s exposure, media such as newspapers, magazines and signs inside stores which sell cigarettes.”

Whether the Court would find that the FDA’s restrictions deal sufficiently narrowly with special, highly youth-accessible media is a key question. The answer could well be different for different regulations, e.g., billboards surrounding school areas (to which parents might have great difficulty in restricting a child’s “access”) versus distribution of promotional items (which parents may be more able to monitor effectively.). Moreover, the Court could avoid reaching that inquiry if it determined that the FDA’s goals could be reached more effectively by means that were clearly less restrictive of speech. While “reasonable fit” leaves some room for alternative solutions to go untried, a restriction of commercial speech cannot survive if “[i]t is perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State’s goal . . .” If the Court believed that government counterspeech, for example, would be equally or more effective in negating the harm done by advertising, the FDA’s regulations would stand little chance.

E. Conclusion

Our *Central Hudson* analysis of the FDA’s tobacco advertising regulations reveals above all the complexity and malleability of the test itself. There are several points within each prong of the test on which either the FDA or the tobacco industry could legitimately prevail. Under the misleading/deceptive prong, the FDA can point to the concealment of nicotine’s effects; the tobacco industry can reasonably question whether the public has, in fact, received the wrong idea. Under the substantial interest prong, the FDA can rely on the time-tested governmental interest in children’s welfare; the tobacco industry, however, can invoke the specter of government policy masquerading as consumer protection. Under the prong that examines whether the FDA’s methods would further its interest, the FDA can summon general empirical


300. *See supra* text accompanying note 288.

301. *Liquormart*, 116 S. Ct. at 1510.
evidence as well as common sense; the tobacco industry can demand a higher level of empirical proof, as per Liquormart. And under the narrow tailoring prong, the field is wide open for debate as to the particular methods that the FDA has chosen.

Given the ambiguities inherent in the test and the compelling arguments that can be made on both sides, the mood of the Court may become the determining factor. If the recent decision in Liquormart augurs a permanent shift—a hypothesis at best, since no part of the decision garnered a clear majority—the FDA faces an uphill battle. Only one outcome of a Supreme Court analysis of the FDA's regulations can be predicted with certainty: Whatever decision the Court might embrace will have permanent implications, not just for the American tobacco industry, but for First Amendment jurisprudence itself.

— Melvin T. Davis