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Legal and Constitutional Perspectives on Tobacco Marketing Restrictions

Policy interventions for tobacco control have moved increasingly toward strong limitations on tobacco marketing. Steps in this direction include legislative and regulatory efforts by governmental agencies in the United States and other countries and a comprehensive ban on tobacco advertising, promotion, and sponsorship incorporated into the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC). This chapter explores the legal and constitutional issues presented by such restrictions, highlighted by discussions of controls imposed by the U.S. Federal Cigarette Labeling and Advertising Act, regulatory efforts by agencies including the U.S. Food and Drug Administration and Federal Trade Commission, and attempts at widespread promotional bans in Canada and the European Union.

Constitutional protection of commercial speech in the United States has been a major impediment to enacting a complete ban on tobacco advertising and promotion, and implementation of the WHO FCTC is subject to the constitutional frameworks of countries that are parties to the treaty. Nonetheless, the scope of such restrictions has continued to grow and evolve, with future limits remaining a matter of continuing legal and policy debate.

Introduction

This chapter examines the legal and constitutional issues affecting regulatory efforts aimed at tobacco marketing and promotion. Such efforts have expanded over time in response to public health concerns about the content and outcomes of tobacco product marketing and have become an important component of tobacco control policy interventions. As the scope of marketing restrictions broadens, important questions arise about balancing the public's interest with the right to free speech and about the allowable scope of regulatory and legislative efforts. This chapter explores these issues within the framework of existing protections for commercial speech, the efforts of regulatory agencies, and legal precedents in the United States and elsewhere.

Chapter 3 examines the arguments for increased regulation of tobacco marketing and promotion. These issues include the health consequences of tobacco use, deceptive or misleading promotional tactics, the failure of tobacco industry efforts to self-regulate its marketing practices, and the ineffectiveness of partial restrictions on tobacco advertising and promotion. Effective global policies that respond to these concerns must consider the legal and constitutional framework of each country involved.

In response to the global health impact of tobacco promotion, the World Health Organization (WHO) called on countries to undertake a comprehensive ban of all tobacco promotion, in accordance with each country's respective constitution, as part of the Framework Convention on Tobacco Control (FCTC). This chapter focuses on the United States but also illustrates and summarizes relevant regulatory actions and legal rulings in Canada, due to its proximity to the United States, and in the European Union (EU) because of the importance of regional developments taking place there.

Constitutional, Statutory, and Regulatory Perspectives

In the United States, constitutional and statutory provisions have impeded efforts to restrict tobacco advertising. First, there is a strong tradition of protecting free speech. The First Amendment to the U.S. Constitution prohibits the government from “abridging the freedom of speech.”¹ Since the mid-1970s, the U.S. Supreme Court has increasingly interpreted this provision to include “commercial” speech, meaning speech solely intended to sell products or services. Although the Supreme Court initially afforded commercial speech a low level of constitutional protection, in recent years it has imposed strict limits on governmental interference with advertising.

Other constitutional and statutory constraints have similarly impeded efforts to warn consumers about the health hazards of smoking and to limit advertising. The Federal Cigarette Labeling and Advertising Act (FCLAA),² which requires cigarette packs to contain specific health warnings, also contains language preempting state and local governments from imposing additional warnings on cigarette packs. The enactment by Congress of the FCLAA was also one basis for the Supreme Court's conclusion that the U.S. Food and Drug Administration (FDA) lacks jurisdiction to regulate tobacco products. Finally, even when the government has had some authority to regulate advertising, such as the Federal Trade Commission's (FTC's) mandate to prohibit false and misleading advertising, political and other pressures appear to have limited the exercise of that authority.³

This chapter describes legal constraints, both constitutional and statutory, on the

regulation of tobacco advertising and promotion in the United States, compares them to constraints on advertising restrictions in selected other countries, and discusses approaches that would more likely be consistent with current legal doctrine.

The First Amendment Framework

Evolution of Commercial Speech Protection

The First Amendment to the U.S. Constitution provides that “Congress shall make no law ... abridging the freedom of speech, or of the press.”^(n.1) 1 The First Amendment constrains the federal government from suppressing speech by private citizens, even if the subject matter is factually wrong or offensive.⁴ (The same constraints are placed on states through the Fourteenth Amendment.) While government may, consistent with the First Amendment, exert some control as to the physical and temporal attributes of speech—so-called time, place, and manner restrictions^(n.2) 5—it generally may not prohibit communications on the basis of their content.⁶ The general prohibition on content-based restrictions of speech applies equally to speech concerning matters of public health. In other words, the potentially detrimental effect of a particular communication on the health of an individual or population in and of itself is not considered a legitimate basis for government suppression.⁷

Several rationales are offered for such broad protection of free speech. Freedom of expression is thought to advance the values of (1) individual self-fulfillment, (2) attainment of the truth, (3) societal participation in social and political decision making, and (4) maintaining a balance between stability and change within society.⁸ The second value, that of truth, has been encapsulated in the metaphor

of a “marketplace of ideas.”^{5,9,10} In his 1919 dissent in *Abrams v. United States*, Justice Oliver Wendell Holmes, citing John Stuart Mill, states that

when men have realized that time has upset many fighting faiths, they may come to believe ... that the ultimate good desired is better reached by free trade in ideas—that the best test of truth is the power of the thought to get itself accepted in the competition of the market.^{10(p.630)}

Under the marketplace rationale, permitting unfettered expression exposes false ideas to debate and rejection while permitting truth to be discovered. As Mill states,

the peculiar evil of silencing the expression of an opinion is, that it is robbing the human race; posterity as well as the existing generation; those who dissent from the opinion, still more than those who hold it. If the opinion is right, they are deprived of the opportunity of exchanging error for truth: if wrong, they lose, what is almost as great a benefit, the clearer perception and livelier impression of truth, produced by its collision with error.¹¹

Certain classes of speech have, however, been categorically excluded from First Amendment protection. The exclusions have come, not from the text of the First Amendment itself, but from Supreme Court interpretations thereof. In *Chaplinsky v. New Hampshire*,¹² the Court opines, “There are certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem.”^{12(pp.571–72)} The Court lists these categories as “the lewd and obscene, the profane, the libelous, and the insulting or ‘fighting’ words.”^{12(p.572)} From this and other cases, the following categories of speech have been historically excluded from First Amendment protection: (1) obscenity, (2) fighting words, (3) incitement, and (4) defamation.¹³ In contrast to political,

social, or artistic expressions, these excluded categories of speech are considered to constitute “no essential part of any exposition of ideas, and are of such slight social value as a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality.”^{12(p.572)} In *Texas v. Johnson*,¹⁴ however, the Court struck down a law prohibiting flag desecration, holding that such conduct could not be construed as fighting words.

Until relatively recently, the Supreme Court found that speech relating to commercial transactions and activities—what has become known as “commercial speech”—was also categorically excluded from First Amendment protection.^(n.3) In the 1942 case *Valentine v. Chrestensen*,¹⁵ which was decided shortly after *Chaplinsky*, the Court upheld an ordinance prohibiting the use of city streets for “commercial and business advertising matter.”^{15(p.53)}

The Supreme Court did not revisit the issue again for more than 30 years. In the 1975 case *Bigelow v. Virginia*,⁹ however, the Court struck down an ordinance that would have prohibited a newspaper from carrying an advertisement informing the public that abortions were legal in New York and offering assistance in obtaining abortion services. The Court held that “speech is not stripped of First Amendment protection merely because it appears”^{9(p.818)} in the form of a paid commercial advertisement. The Court limited the effect of *Chrestensen*, stating that the case did not provide “authority for the proposition that all statutes regulating commercial advertising are immune from constitutional challenge”^{9(p.820)} and “does not support any sweeping proposition that advertising is unprotected *per se*.”^{9(p.820)}

The *Bigelow* decision involved advertising solely for abortion services, which the Supreme Court viewed as speech that

“conveyed information of potential interest and value to a diverse audience—not only to readers possibly in need of the services offered.”^{9(p.822)} In the following year, however, the Court confronted head on the issue of “pure” commercial advertising. In *Virginia Pharmacy Board v. Virginia Citizens Consumer Council*,¹⁶ the Court struck down a Virginia law prohibiting pharmacists from advertising the prices of prescription drugs. The state argued that the restriction was necessary to protect consumers, since permitting price advertising would undermine the professionalism of pharmacists and jeopardize the customer-pharmacist relationship. By allowing pharmacists to compete as to price in advertising, the state feared that the quality of pharmacists’ service to customers would decline, to the customers’ detriment. The Court, after acknowledging that its holding in *Chrestensen* had “all but passed from the scene,”^{16(p.759)} formally recognized that commercial speech (i.e., speech that does “no more than propose a commercial transaction”)^{16(p.762)} is protected by the First Amendment. The Court noted the important interests furthered by commercial speech. “As to the particular consumer’s interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.”^{16(p.763)} With respect to pharmaceutical price advertising specifically, the Court noted that

those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs; yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent.^{16(p.763)}

Responding to the state’s concerns that consumers would choose low-cost, low-quality pharmacy services, the Court states

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.^{16(p.770)}

The Court concluded that the state could not suppress truthful information about a lawful activity solely because of its concerns about the effect of the information on the disseminators and the recipients of that information.

Notwithstanding its recognition of the value of commercial speech that warranted First Amendment protection, the Court nevertheless notes factors that distinguish commercial speech from other types of protected speech. First, whether commercial speech is truthful “may be more easily verifiable by its disseminator”^{16(p.772)} than other types of speech, since the advertiser is in a position to know about the product. Second, commercial speech is less likely to be stifled by government regulation because the speaker is motivated to speak by the opportunity for commercial profit. Thus, “the greater objectivity and hardness of commercial speech ... may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker.”^{16(p.772)}

Central Hudson Gas & Electric Corporation

Following the *Virginia Pharmacy Board* case, the Supreme Court considered commercial speech in a variety of contexts,^{17,18} including lawyer and other professional advertising.^{19–22} Through these cases, the Court formalized its commercial speech doctrine, which was articulated in the 1980 case *Central Hudson Gas &*

Electric Corporation v. Public Service Commission.²³

In *Central Hudson*, the Court laid out a four-part balancing test for determining whether a particular government restriction of commercial speech comported with the First Amendment. Under this test, a court must first determine whether the speech being restricted is misleading or concerns an unlawful activity.²³ Only speech that is truthful and relates to a lawful activity merits First Amendment protection.

Assuming this first criterion is satisfied, the second prong of the test imposes a burden on the government to demonstrate that it has a substantial interest in restricting the speech at issue.²³ Third, the restriction must directly advance the state interest involved. Restrictions that provide only “ineffective or remote support for the government’s purpose”^{23(p.564)} will not be upheld. Finally, the restriction must not be more restrictive than necessary to achieve the governmental interest.²³ This step examines the “fit” between the interest and the means chosen to achieve it.²³ The government must show, not merely that its regulation directly advances an important objective, but also that the means used are not more extensive than necessary to achieve that goal.^{(n.4) 23}

Although some Supreme Court justices have advocated eliminating any variation in the level of protection afforded truthful commercial speech and fully protected or “core speech,”^{(n.5) 7,24} the Court has reaffirmed the *Central Hudson* test. What has changed, however, is the rigor with which some justices have applied the test, particularly the test’s third and fourth prongs.^{(n.6) 25,26} In earlier cases the Court had accepted a variety of restrictions to directly advance the state’s interest in a manner that was not unduly restrictive.^{(n.7) 27} In recent years the Court, although often divided, has imposed a much higher burden of proof on

the government to link the ends sought with the means used.^{(n.8) 24,28}

In *Lorillard v. Reilly*,⁷ for example, the Supreme Court struck down a Massachusetts regulation that prohibited the advertising of cigarettes, cigars, and smokeless tobacco products within 1,000 feet of any school or playground. Six members of the Court were satisfied that the state's interest was directly advanced by the restrictions on outdoor cigar and smokeless tobacco advertising,^{(n.9) 7} thus meeting the third standard in *Central Hudson*. However, five members of the Court held that the 1,000-foot rule was more extensive than necessary to serve the state's interests, thus failing to satisfy the fourth step of *Central Hudson*. Specifically, they found that the attorney general did not "carefully calculate the costs and benefits associated with the burden on speech imposed by the regulations"^{7(p.561)} (internal punctuation omitted). For example, they stated that the attorney general did not consider the impact of the restriction in metropolitan areas, which would be greater than in rural areas: "The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring."^{7(p.563)} Although, in the Court's opinion, "[a] careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests," the state "cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products."^{7(p.565)} The state's interest in protecting children was insufficient, in the Court's opinion, to completely override the legitimate interests of tobacco retailers to convey to adults truthful information about their products and the choice of adults to receive such information.

In *Thompson v. Western States Medical Center*,²⁹ a six-member majority of the Court struck down a provision of the Food

and Drug Administration Modernization Act (FDAMA) of 1997²⁹ that would have prohibited pharmacists from advertising compounded drugs.^{(n.10) 29,30} The FDA argued that the restriction on advertising was necessary to balance the interest in providing compounded drugs to those patients who require them with the need to preserve the integrity of the new drug approval process by ensuring that compounding remains on a small scale. Although the Court agreed that the government's objective was substantial and that the means chosen might directly achieve the objective, it concluded that the FDA had not shown its methods were no more extensive than necessary. The Court noted that several alternatives to restricting speech could have been used to draw a line between compounding and large-scale manufacturing, such as by limiting the number of compounded drugs sold by a particular pharmacist or pharmacy or by prohibiting the use of commercial-scale equipment to compound drugs. According to the Court,

The Government simply has not provided sufficient justification here. If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.^{29(p.373)}

Compelled Commercial Speech

Just as the First Amendment protects the right to speak, it protects the right to refrain from speaking. The Supreme Court has articulated two complementary rationales for affording First Amendment protection against compelled speech. First, to compel a person to enunciate a view in which he or she does not believe violates freedom of conscience or belief.³¹ This reasoning was used to invalidate state laws making flag salute and the pledge of allegiance compulsory³²

or requiring automobile owners to display license plates carrying the state motto “Live Free or Die.”³³ Second, government-compelled speech may deter the speaker from expressing his or her own views.³¹ The Court struck down state laws prohibiting anonymous handbills³⁴ and campaign literature³⁵ because these laws discouraged a person’s underlying right to publish and disseminate his or her work.

The Supreme Court’s compelled-speech jurisprudence is concerned principally with political and social discourse as opposed to product health and safety.^(n.11)³⁶ However, in *United States v. United Foods, Inc.*,³⁷ the Court makes clear that its compelled speech doctrine applies to commercial speech.^(n.12) In that case, the Court held that a federal statute requiring mushroom producers and importers to pay for generic advertising promoting the mushroom industry is coerced speech: “First Amendment values are at serious risk if the government can compel ... [citizens to subsidize speech] on the side that it favors.”^(n.13)^{37(p.411)}

Lower courts have also grappled with the circumstances under which the government may compel disclosures in the commercial context. In *International Dairy Foods Association v. Amestoy*,³⁸ dairy manufacturers challenged a Vermont law that required labeling of products from cows treated with recombinant bovine somatotropin (rBST, a synthetic growth hormone that increases milk production). The federal court of appeals analyzed the regulation under *Central Hudson*, concluding that the asserted government interest (“consumer curiosity”) was insufficiently strong to justify the regulation.

In other circumstances, lower courts have viewed compelled disclosure as preferable to an outright ban on speech. In *Pearson v. Shalala*, the D.C. Circuit Court struck down an FDA regulation requiring

prior approval of “health claims” for dietary supplements (i.e., claims on labels linking the use of the supplement to prevention of a particular disease or condition).^(n.14)³⁹ The FDA required that such claims be supported by “significant scientific agreement,” a standard defined and enforced by the agency.^(n.15)³⁹ The court held that the significant scientific agreement standard was unconstitutional because it precluded manufacturers from making claims having less scientific support in conjunction with a disclaimer, stating,

It is clear ... that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a “far less restrictive” means.^{39(p.658)}

Misleading Speech

The first prong of the *Central Hudson* test makes clear that First Amendment protection will be afforded only to truthful commercial speech about a lawful activity. Commercial speech that is misleading, deceptive, or untruthful or that concerns illegal activity is outside the protection of the First Amendment. As the Supreme Court explained in *Rubin v. Coors Brewing Co.*,

Not only does regulation of inaccurate commercial speech exclude little truthful speech from the market, but false or misleading speech in the commercial realm also lacks the value that sometimes inheres in false or misleading political speech. Transaction-driven speech usually does not touch on a subject of public debate, and thus misleading statements in that context are unlikely to engender the beneficial public discourse that flows from political controversy. Moreover, the consequences of false commercial speech can be particularly severe: Investors may lose their savings, and consumers

may purchase products that are more dangerous than they believe or that do not work as advertised. Finally, because commercial speech often occurs in the place of sale, consumers may respond to the falsehood before there is time for more speech and considered reflection to minimize the risks of being misled.^{28(p.496)}

However, the Supreme Court has provided little guidance to aid in a determination of what is misleading commercial speech. For the most part, cases decided by the Court have involved challenges to government restrictions of speech acknowledged by both sides to be truthful. In a few instances, mostly involving professional advertising, the Court has addressed contentions by the government that certain types of advertising will mislead consumers.^{(n.16) 40–42} These opinions have not, however, dealt in depth with what factors should be used to assess whether a particular communication is deceptive or misleading.³¹ The Court has indicated that even when speech is potentially misleading, the remedy is additional disclosure, such as mandated warning labels, and not a categorical ban.^(n.17)

Impact of the Supreme Court on Tobacco Advertising Restrictions

The Supreme Court's jurisprudence has created a difficult dilemma for public health authorities. Narrowly tailored restrictions on tobacco advertising, while more defensible under the fourth ("reasonable fit") prong of *Central Hudson*, are at the same time less likely to generate the type of concrete evidence of effectiveness necessary for the third prong's "direct advancement" requirement. More sweeping restrictions, on the other hand, while more likely to advance the government's objective of deterring tobacco use (see chapter 7), are less likely to satisfy the narrowly tailored requirement. Thus, the Court's rulings create a conundrum

for public health authorities seeking to craft tobacco advertising restrictions that are both demonstrably effective and likely to be deemed constitutional by the current Supreme Court.⁴³

Although some advocates believe that focused and tailored advertising bans clearly aimed at preventing youth tobacco use could still be implemented consistent with Supreme Court jurisprudence,⁴⁴ achieving this would be an uphill battle, at the very least. The only area in which bans have been held constitutional has been in electronic media; this historical anomaly is viewed by some observers as both constitutionally suspect and unlikely to be repeated.^(n.18)

One avenue that remains largely unexplored could theoretically enable public health advocates to effect consumer protection consistent with First Amendment constraints. The Court has consistently stated that speech must be truthful and nonmisleading to receive First Amendment protection, but, as stated above, the Court has not examined manufacturers' obligations under this requirement. As might be inferred from the "Misleading Speech" section above, many cigarette advertisements could be considered deceptive or misleading because of implied health claims. In addition, it is arguable that tobacco advertisements, to the extent that they fail to disclose the serious health hazards associated with use of the products, are deceptive and misleading and therefore not entitled to First Amendment protection.⁴³

In the *Lorillard* case discussed earlier, the Supreme Court had, but failed to use, an opportunity to further consider what constitutes deceptive speech. In a partial dissent, Justice David Souter noted that the attorney general for Massachusetts "remains free to proffer evidence that the advertising is in fact misleading."^{77(p.590)} Thus, the door was left open for a future case to argue that images associating tobacco

products with a vibrant, athletic lifestyle, while failing to disclose the full scope of their health effects and addictiveness, are deceptive and misleading.³¹ On the basis of such an argument, courts could impose on manufacturers the obligation to add language sufficiently balanced and informative such that the advertisements are not misleading.

As already noted, the courts have consistently shown a preference for more speech rather than less and have viewed compelled disclosure as preferable to speech restrictions. Thus, for example, a court would be more likely to deem constitutional the government-mandated requirements for health warnings on tobacco packages and advertisements (including photos or other images illustrating the health effects of tobacco use), the inclusion of package inserts detailing the dangers of tobacco use and available treatments and resources for quitting, and industry funding of “corrective” advertising compared with laws that ban or significantly restrict tobacco product advertising.⁴³

Morrison⁴⁵ argues that one of the premises behind the Supreme Court’s protection of commercial speech is that it conveys useful information, and therefore the Court might be persuaded by evidence of tobacco advertising’s lack of utility. Morrison suggests that criteria could be established to assess the content of cigarette advertising, including the percentage of an advertisement devoted to “useful” information (e.g., information on price or tar and nicotine content). However, this author acknowledges that such a study might not necessarily change votes in the Court. In light of the challenging prospects for favorable judicial review of statutory restrictions on tobacco advertisements, some have advocated for increased funds for counteradvertising and for changing the preemption provisions of the FCLAA, as discussed in the next section.

Preemption of Warnings under the FCLAA

The 1964 Surgeon General’s report on smoking and health⁴⁶ spurred government interest in regulating tobacco advertising. The FTC sought to require disclosure on cigarette packages and in advertising that smoking is dangerous to health.⁴⁷ Many states and cities also began to consider new tobacco regulations. Public health advocates sought the broadest possible regulation at all levels of government. The tobacco industry, however, became increasingly interested in federal preemptive regulation as a means of avoiding more far-reaching restrictions by states and municipalities.⁴³

The FCLAA,⁴⁸ originally enacted in 1965, requires the inclusion of health warnings specified by the government on cigarette packaging for cigarettes sold or distributed in the United States and in print advertising.^(n.19) As amended in 1969,⁴⁹ the FCLAA also contains a provision stating,

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.⁵⁰

State is defined in the FCLAA as including “any . . . political subdivision of any State.” This type of language, which prevents states and localities from acting, is known as *preemption*. The federal government’s power to preempt, and thereby nullify, state and local laws is grounded in the Supremacy Clause of Article VI of the U.S. Constitution, which proclaims that the laws of the United States “shall be the supreme law of the land . . . anything in the Constitution or Laws of any State to the contrary notwithstanding.”⁵¹ Thus, in general, state law that conflicts with federal law is considered to be without legal effect.^(n.20)

The legislative history of the FCLAA indicates that Congress used preemption to protect “commerce and the national economy” from being “impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.”^{52,53} The FCLAA, though widely viewed as a public health regulatory initiative, also served certain tobacco industry goals: forestalling FTC regulation, preempting state and local requirements, and softening the warnings that had been proposed by public health advocates.^{43,47}

The consequences of federal preemption for efforts to restrict cigarette advertising and promotion can be seen in the *Lorillard* decision. In addition to its ruling based on First Amendment jurisprudence, the Supreme Court ruled five to four that the FCLAA preempted Massachusetts from regulating outdoor and retail point-of-sale cigarette advertising.⁷ Justice Sandra Day O’Connor, writing for the Court, rejected the Massachusetts attorney general’s argument that the advertising restrictions were not “based on smoking and health” because they did not address the content of the advertising but instead sought to reduce youth exposure to such advertising. According to Justice O’Connor, this was an unduly narrow reading of the statute:

The context in which Congress crafted the current pre-emption provision leads us to conclude that Congress prohibited state cigarette advertising regulations motivated by concerns about smoking and health. At bottom, the concern about youth exposure to cigarette advertising is intertwined with the concern about cigarette smoking and health.^{7(p.548)}

Similarly, Justice O’Connor rejected the argument that the restrictions addressed only the location of the advertising and not its content, stating that the FCLAA preempted all requirements and prohibitions based on smoking and health.⁷ She added, however, that the Court’s ruling would not

prohibit general billboard zoning regulations or laws that prohibited certain conduct, such as underage possession of cigarettes or unlawful sales of cigarettes to minors.⁷

However, the Supreme Court has also held that the preemptive effect of the FCLAA is limited in that it does not completely preclude lawsuits by those who claim they were injured by tobacco products. In *Cipollone v. Liggett Group, Inc.*,⁵⁴ the executor of the estate of a lifetime smoker who died of lung cancer sued several tobacco companies, alleging that they did not provide adequate warnings about the health risks of smoking, expressly warranted that their products were not dangerous to the health of consumers, tried to neutralize the effects of statutory warnings, ignored medical evidence about the dangers of smoking, and conspired to prevent such medical evidence from reaching the general public.^{54,55} The trial court awarded the decedent’s husband \$400,000, but the appellate court reversed this on the basis that the plaintiff’s claims were preempted under the FCLAA. The Supreme Court, however, found that although the FCLAA expressly preempted tort claims based on inadequate health warnings in tobacco advertising or promotion after 1969, it did not preempt claims against cigarette manufacturers for breach of express warranty, misrepresentation, or conspiracy.^(n.21) Thus, the Court distinguished between tort claims that implicitly challenged the uniform labeling scheme of the FCLAA and those that did not directly relate to that scheme.

The Comprehensive Smokeless Tobacco Health Education Act⁵⁶ requires placement of government-specified health warnings on smokeless tobacco packages and in advertisements and banned smokeless tobacco advertising on television and radio. Like the FCLAA, the Smokeless Tobacco Act preempts state and local requirements for health warnings on packaging and in advertising (except for outdoor billboard

advertisements). However, it does not preempt state and local restrictions on smokeless tobacco advertising and promotion analogous to the FCLAA's preemption of restrictions on cigarette advertising and promotion that are "based on smoking and health." Furthermore, no federal legislation preempts state or local restrictions on the advertising and promotion of other tobacco products, namely, cigars, pipe tobacco, and roll-your-own cigarette tobacco.⁵⁷

The FDA's Unsuccessful Efforts to Regulate Tobacco Products

The Federal Food, Drug, and Cosmetic Act authorizes the Secretary of Health and Human Services to regulate drugs and medical devices. The statute defines a drug as an "article" that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"⁵⁸ or that is "intended to affect the structure or any function of the body."⁵⁹ A medical device is similarly defined, except that it "does not achieve its primary intended purposes through chemical action within or on the body of man [and] ... is not dependent upon being metabolized for the achievement of its primary intended purposes."⁶⁰ Before marketing a drug or device, a manufacturer must submit sufficient data for the agency to ascertain that there is reasonable assurance that the product is safe and effective.⁶¹

For most of its history, the FDA did not assert its jurisdiction over tobacco products. In the late 1970s, the agency declined petitions to consider cigarettes containing nicotine as a drug or medical device,⁶² relying on its "consistent position that cigarettes will not be deemed a drug unless health claims are made by the vendors."^{62(p.237)} An appellate court subsequently upheld the FDA's position as a reasonable interpretation of the agency's statutory authority—indeed, one that was fully consistent with "administrative and judicial emphasis upon manufacturer and

vendor intent as the cornerstone" of the Federal Food, Drug, and Cosmetic Act.^{62(p.243)}

During the tenure of Commissioner David Kessler (1990–97), the FDA reconceived its jurisdiction over tobacco. According to Kessler, this change was prompted by the agency's discovery of new information in internal documents from tobacco manufacturers evidencing their awareness of the addictive properties of nicotine and that tobacco products were essentially a vehicle for its delivery. Moreover, the agency learned of methods used by manufacturers to increase the nicotine content of tobacco products and to enhance the drug's impact.^{63–65}

In 1995, the FDA proposed a rule outlining a regulatory approach that would include restrictions on the sale, distribution, and advertisement of tobacco products.⁶⁶ Consistent with Kessler's view that tobacco use was principally a pediatric disease in that most smokers begin smoking before they are 18 years old, the proposed rule restricted its scope to reducing youth and adolescent access to tobacco products and exposure to tobacco advertising and promotion. Restricting the focus to youth also appears to have been an attempt to enhance the political attractiveness of the FDA's approach.⁶⁵ However, Kessler, in testimony before Congress, acknowledged "the possibility that regulation of the nicotine in cigarettes as drugs would result in the removal of nicotine-containing cigarettes from the market, limiting the amount of nicotine in cigarettes to levels that are not addictive, or otherwise restricting access to them, unless the industry could show that nicotine-containing products are safe and effective."^{63(p.157)}

The FDA received more than 700,000 comments on the proposed rule, more than "at any other time in its history on any other subject."^{67(p.44418)} In 1996, the FDA issued a final rule, "Regulations Restricting

the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,”⁶⁸ which classified nicotine as a drug and cigarettes and smokeless tobacco as “drug delivery devices.” The agency found that tobacco products “affect the structure or any function of the body” within the meaning of the statute because nicotine has “significant pharmacologic effects,” including “psychoactive, or mood-altering, effects on the brain,” that cause addiction.^{68(p.44631)} Further, the agency concluded that these effects were “intended,” as required by the statute, because (1) they “are so widely known and foreseeable that these effects may be deemed to have been intended by the manufacturers,”^{68(p.44687)} (2) the products are designed by manufacturers to achieve these effects,^{68(p.44849)} and (3) the products are used by consumers primarily to achieve these effects.^{68(p.44807)} The agency coupled its jurisdictional assertion with evidence of the profound public health detriment caused by these products—namely, more than 400,000 deaths per year as a result of illnesses caused by smoking.^{68(p.44398)}

The FDA construed tobacco products as “combination products” in that they combine a drug (nicotine) with a device (the cigarette or smokeless tobacco) to deliver it. Relying on its discretion to regulate combination products as drugs or devices, the FDA chose to regulate tobacco under the “restricted devices” provisions of the Federal Food, Drug, and Cosmetic Act.⁶⁹ These provisions give the agency significant latitude to restrict the sale, distribution, and use of a device based on the “potentiality for harmful effect or the collateral measures necessary to its use.”⁶⁹

On the basis of this classification, the FDA promulgated rules regarding the promotion, labeling, sale, and distribution of tobacco products. These rules prevented the sale of cigarettes and smokeless tobacco to persons younger than 18 years of age, required retailers to verify through photographic

identification the age of all purchasers younger than 27 years of age, prohibited the sale of cigarettes in quantities of less than 20, prohibited the distribution of free samples, and prohibited sales through self-service displays and vending machines except in adult-only locations.^{68(pp.44616–17)} The promotion regulations required that any print advertising appear in a black-and-white, text-only format, unless the publication in which it appears was read almost exclusively by adults; prohibited outdoor advertising within 1,000 feet of any public playground or school; prohibited the distribution of any promotional items, such as T-shirts or hats, bearing a tobacco-product brand name; and prohibited sponsorship of any athletic, musical, artistic, or other social or cultural event using a tobacco-product brand name (allowing only corporate-name sponsorship provided that the corporate name was not similar or identical to the name of a tobacco product).^{68(pp.44617–18)} The labeling regulation required that the statement “A Nicotine-Delivery Device for Persons 18 or Older” appear on all tobacco product packages.^{68(p.44617)}

Tobacco manufacturers, retailers, and advertisers challenged the final rule in federal district court, arguing that (1) the FDA lacked jurisdiction to regulate tobacco products and (2) the advertising restrictions violated the First Amendment. The district court upheld the FDA’s jurisdiction to regulate tobacco products and found its access and labeling regulations lawful but held that its advertising and promotion restrictions exceeded its authority.⁷⁰ On appeal, the Fourth Circuit Court reversed, holding that the FDA lacked jurisdiction to regulate tobacco products and that the court did not address the advertising and promotion restrictions or the First Amendment challenge.⁷¹ The FDA appealed the ruling on its jurisdiction to the U.S. Supreme Court.

In a five to four vote, the Supreme Court ruled that the FDA’s governing statute did

not confer jurisdiction to regulate tobacco because such an interpretation would be inconsistent with congressional intent.⁷¹ The Court reasoned that if the FDA were to correctly apply its statutory authority to regulate medical devices to tobacco products, the FDA would be obligated to find them unsafe and remove them from the market. However, such action would be inconsistent with several statutes (including the FCLAA) that show Congress's intent to maintain, and even promote, tobacco products in the marketplace while at the same time informing consumers of the associated adverse health consequences.^{71(p.143)} The majority opinion written by Justice O'Connor stated, "Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA."^{71(p.144)} The Court was not persuaded by the FDA's justification that its regulatory framework, under which tobacco products were restricted but not banned, was preferable to a ban, which would create a "black market."^{71(p.140)} The Court held that in considering product safety, the agency could not take account of factors external to the product's intended use such as the potential for a black market.^{71(p.141)}

The Court's decision left no room for FDA regulation of tobacco products as currently marketed absent Congress's amending the Food, Drug, and Cosmetic Act to explicitly confer such authority. The Court's decision may also discourage other agencies from asserting jurisdiction over tobacco or interpreting existing jurisdiction expansively. The Court construed Congress as having made a policy decision to maintain and even promote a market for tobacco products and to narrowly circumscribe agency authority to warn of the dangers of tobacco use.

However, legislation to give the FDA authority to regulate tobacco products

was passed by the U.S. Senate on July 15, 2004 (by a vote of 78–15), but companion legislation in the U.S. House of Representatives was not adopted.^{72,73} Similar legislation (S. 625 and H.R. 1108) was approved by the Senate Committee on Health, Education, Labor, and Pensions on August 1, 2007 (by a vote of 13–8) and the House Committee on Energy and Commerce on April 2, 2008 (by a vote of 38–12).

The Court's ruling does not preclude FDA action against tobacco products making explicit claims about health benefits. For example, the FDA might assert jurisdiction to regulate tobacco products that manufacturers claim to be less harmful to health than are other brands. The agency could argue that such products are drugs because manufacturers' claims show their intent to mitigate disease.

The Court's ruling also does not preclude state action to restrict minors' access to tobacco products along the lines proposed by the FDA. For example, all 50 states and the District of Columbia (D.C.) prohibit the sale of tobacco products to minors, which in most cases is defined as 18 years of age. Further, 45 states and D.C. restrict the distribution of free samples of tobacco products, and 10 states restrict direct consumer access to tobacco products by, for example, prohibiting self-service displays or requiring direct contact between retailers and customers.⁷⁴

The FTC's Limited Efforts to Regulate Tobacco Advertising

The FTC is an independent federal agency established by Congress in 1914.⁷⁵ The Federal Trade Commission Act (FTC Act) declares unlawful "unfair or deceptive acts or practices in or affecting commerce"⁷⁶ and directs the FTC to prevent such activities. ^(n.22) False or misleading advertising is considered an unfair trade

practice and therefore unlawful. Thus, the agency has clear authority to take action against false advertising that misleads the public, including advertising for tobacco products.

However, having statutory authority does not necessarily imply that it is broadly exercised. As summarized below, the FTC's role has been largely limited to enforcing legislated tobacco labeling requirements and reporting to Congress concerning the effectiveness, or lack thereof, of these laws.

The FTC can take action against false or misleading advertising through its adjudicatory (quasi-judicial) authority, in which case judgments apply only to the parties to the case. Alternatively, the agency can use general rule-making procedures to promulgate industrywide guidelines as trade regulation rules.⁴⁷(pp.510-11) Between 1938 and 1968, the FTC invoked its adjudicatory authority 25 times in regard to health claims made in cigarette advertising.⁷⁷ However, because adjudicatory judgments applied only to the parties to the case, "the Commission found itself putting out brush fires of deception while the inferno raged on."⁷⁷(p.70)

Following the issuance of the 1964 Surgeon General's report on smoking and health,⁴⁶ the FTC determined that cigarette advertising that failed to disclose the health risks of smoking was "unfair and deceptive."⁷⁸ It proposed a trade regulation rule that would have made it a violation of the FTC Act "to fail to disclose, clearly, and prominently, in all advertising and on every pack, box, carton or other container [of cigarettes] ... that cigarette smoking is dangerous to health and may cause death from cancer and other diseases."⁷⁸(p.8325) This regulatory effort was, however, rendered moot before it was implemented by the passage of the FCLAA in 1965.

The FCLAA articulated two policy goals: (1) informing the public about the

dangers of smoking and (2) protecting commerce and the national economy by preventing "diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health."^{48,79} In contrast to the FTC trade regulation rule, the FCLAA required the warning "Caution: Cigarette Smoking May Be Hazardous to Your Health" to be placed on cigarette packages but not in advertising. The language of the warning was much milder than the FTC would have required and its dissemination more limited. Some did not view the FCLAA as a public health victory but saw it instead as an "unashamed act to protect private industry from government regulation"^{(n.23) 43}(p.2991)

The FCLAA in 1965 and the Comprehensive Smokeless Tobacco Health Education Act in 1986 directed the FTC to report to Congress concerning sales and advertising for cigarettes and smokeless tobacco, respectively. The FTC issued its first report to Congress in 1967, in which it recommended that the warning label be changed to "Warning: Cigarette Smoking Is Dangerous to Health and May Cause Death from Cancer and Other Diseases."⁸⁰(p.30) In 1969, Congress enacted the Public Health Cigarette Smoking Act,⁴⁹ which amended the FCLAA. This act prohibited cigarette advertising on television and radio and required that each cigarette package contain the label "Warning: The Surgeon General Has Determined That Smoking Is Dangerous to Your Health." In 1981, the FTC issued a staff report that concluded that the current health-warning labels had little effect on public knowledge and attitudes about smoking.⁸¹ In response, Congress enacted the Comprehensive Smoking Education Act of 1984,⁸² which required four specific health warnings on all cigarette packages and advertising: "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 Risks to Your Health"; "Surgeon General's Warning: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight"; and "Surgeon General's Warning: Cigarette Smoke Contains Carbon Monoxide." (The warnings mandated for cigarette advertisements on outdoor billboards are slightly shorter versions of the same messages.)⁸³

Responding to evidence that smokeless tobacco use causes oral cancer, nicotine addiction, and other health problems, in 1986 Congress passed the Comprehensive Smokeless Tobacco Health Education Act.⁵⁶ This law required rotating warning labels on smokeless tobacco packaging and advertisements, in a circle-and-arrow format:⁴⁷ "Warning: This product may cause mouth cancer"; "Warning: This product may cause gum disease and tooth loss"; and "Warning: This product is not a safe alternative to cigarettes."^{84,85} As with the labeling of other tobacco products, the FTC was charged with enforcing this requirement.

In 1999, the FTC issued a report to Congress in which it recommended warning labels for cigar packaging and advertising.⁸⁶ The Commission noted that cigar sales had increased 43% in one year, from \$613 million in 1996 to \$876 million in 1997, and stated, "The dramatic increase in cigar use in America has occurred in tandem with the increase in promotional activities surrounding cigar smoking."⁸⁶ The FTC recommended that three warnings for cigars be required on a rotating basis: "Warning: Regular cigar smoking can cause cancers of the mouth and throat, even if you do not inhale"; "Warning: Inhaling cigar smoke can cause lung cancer. The more deeply you inhale, the greater your risk"; and "Warning: Cigars are not a safe alternative to cigarettes."⁸⁶ The report also recommended that Congress enact legislation prohibiting

the advertisement of cigars on television, radio, and any other electronic media regulated by the Federal Communications Commission. Although Congress did not enact legislation as recommended by the FTC, some of these recommendations were achieved through consent agreements entered into with cigar manufacturers.

The FCLAA explicitly exempted from preemption the FTC's ability to take action against unfair or deceptive acts or practices in the advertising of cigarettes.⁸⁷ The agency has used this authority to initiate proceedings in response to promotional efforts it considered unfair or deceptive. Some of the FTC's earlier actions (between 1938 and 1968) were mentioned above and reviewed by Fritschler.⁷⁷ More recently (in May 1997), the FTC took on a long-time cigarette icon—Joe Camel. The agency filed a complaint against R.J. Reynolds Tobacco Company charging that the company's use of the cartoon character was an unfair trade practice in that it was a deliberate attempt to target smokers younger than 18 years of age and calling on the company to "cease and desist from advertising to children through the Joe Camel character or others like it."⁸⁸⁻⁹⁰ In filing this complaint, which was decided in a three to two vote by the FTC commissioners, the agency reversed a 1994 decision not to take action against the advertising campaign.^{91,92} R.J. Reynolds subsequently filed a challenge to the FTC complaint but then decided to remove Joe Camel from its domestic advertising. The FTC initially continued to pursue the complaint and to seek a court order barring the company from using Joe Camel or his fellow cartoon camels again in advertisements and requiring the company to pay for an antismoking campaign targeted to teenagers.⁹³ The FTC dropped the complaint in 1999, relying instead on the Master Settlement Agreement (see chapter 3), a multibillion-dollar settlement between the tobacco industry and 46 states that achieved the goals the FTC was seeking.⁹⁴

In 2000, the FTC entered into a consent agreement with seven cigar manufacturers representing 95% of the cigars sold in the United States. The agreement settled a complaint filed by the FTC against the manufacturers in which it charged that failure to disclose health risks of cigars is a deceptive and unfair business practice. Under the consent agreement, the manufacturers agreed to place one of five warnings on cigar packages and in advertising. These warnings are as follows: “Surgeon General Warning: Cigar Smoking Can Cause Cancers Of The Mouth And Throat, Even If You Do Not Inhale”; “Surgeon General Warning: Cigar Smoking Can Cause Lung Cancer And Heart Disease”; “Surgeon General Warning: Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight”; “Surgeon General Warning: Cigars Are Not A Safe Alternative to Cigarettes”; and “Surgeon General Warning: Tobacco Smoke Increases The Risk Of Lung Cancer And Heart Disease, Even In Nonsmokers.”

This FTC consent agreement superseded a 1988 settlement under California’s Proposition 65, which had required that cigars sold in the state of California include on their packaging (but not in advertisements) a warning label stating the following: “WARNING: This product contains chemicals known to the State of California to cause cancer, birth defects, and other reproductive harm.” Cigar manufacturers had printed the California warning on the packages of manufactured cigars sold nationally.^{47,95} The FTC consent agreement preempted a California law that was set to take effect on September 1, 2000, which would have required new rotating warnings on cigar packages sold in the state.⁹⁶

The FTC’s methodology for measuring the tar and nicotine levels of cigarettes has come under scrutiny in recent years. Beginning in the 1960s, various branches of the government sought to encourage tobacco companies to produce low-tar cigarettes and

to encourage smokers to reduce their risk by switching to low-tar brands.⁹⁷ In 1967, pursuant to its authority to prohibit unfair or deceptive advertising claims, the FTC authorized establishment of a laboratory to analyze mainstream cigarette smoke (i.e., the smoke that is drawn through the cigarette rod during puffing).⁹⁸ The purpose of the program was to provide smokers seeking to switch to lower-tar cigarettes with a single, standardized measurement with which to choose among existing brands. The FTC protocol used a machine to simulate smoking in a standardized way and measure tar and nicotine yields in mainstream smoke for each cigarette brand. In 1970, the FTC began to develop a trade regulation rule that would have required disclosure of tar and nicotine ratings in all cigarette advertising. In response, five major cigarette manufacturers and three small companies agreed voluntarily to disclose the FTC ratings in certain types of advertising. The FTC added carbon monoxide to the protocol in 1980, but its disclosure in advertising is not required. Industry disclosure of tar and nicotine yields on some cigarette packages occurs voluntarily, but rarely for brands with 8 mg or more of tar.^{47(p.489)} In 1987 the FTC closed its laboratory and began to collect data on tar, nicotine, and carbon monoxide yields, through a compulsory process, from cigarette companies, which conduct the testing through the Tobacco Industry Testing Laboratory, using the FTC method.⁹⁹

On the basis of the FTC protocol, manufacturers have for decades advertised certain brands as “light” or “low tar.” In the 1990s, scientists began to question the FTC methodology, alleging that the protocol did not effectively predict the amount of tar and nicotine a smoker would receive during actual smoking.¹⁰⁰ One report concluded that

measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information

on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different brands of cigarettes.¹⁰¹

The Centers for Disease Control and Prevention believes that existing evidence (1) does not support recommending that smokers switch to low-yield cigarette brands and (2) does not support the conclusion that changes in cigarette design have appreciably reduced the incidence of diseases caused by smoking.¹⁰²

In 1997, the FTC issued a notice in the *Federal Register* seeking comments on proposed changes to the FTC methodology. No final rule implementing these changes has been issued. In 2000, the FTC issued an alert in which it warned consumers that cigarette tar and nicotine ratings cannot predict the amount of tar and nicotine a smoker will receive from a particular cigarette. The alert states, "Smoking 'low tar' or 'light' cigarettes does not eliminate the health risks of smoking."¹⁰³

In 1994, the FTC announced a settlement with the American Tobacco Company, prohibiting the company from disseminating ads for Carlton or any other cigarettes that make certain misrepresentations about the relative amount of tar and nicotine consumers will receive by smoking certain cigarette brands.¹⁰⁴ However, the agency has not undertaken any industrywide enforcement efforts against cigarette manufacturers advertising "low-tar," "light," or other low-yield cigarettes for making false or misleading claims. Legislation mentioned above (S. 625 and H.R. 1108 in the 110th Congress) that would give the FDA authority to regulate tobacco products would ban the use of terms such as "light," "mild," or "low" in advertising and on package labels.

Class action lawsuits have been filed in several states alleging that cigarette companies engaged in fraudulent claims by marketing "low-tar" and "light" cigarettes despite knowledge that such cigarettes were no less dangerous, and perhaps were more dangerous, than other cigarettes.^{105,106} One class action failed because of a longstanding FTC agreement with tobacco companies that they would voluntarily measure tar and nicotine levels. In a four to two decision reached in 2005, the Illinois Supreme Court overturned a lower court ruling in favor of a class of consumers who argued they were defrauded by Philip Morris's marketing of "light" and "lowered tar and nicotine" cigarettes.¹⁰⁷ The Supreme Court relied on section 10(b)(1) of the Illinois Consumer Fraud and Deceptive Practices Act, which exempts conduct "specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." In determining that the claims at issue were "specifically authorized" by the FTC, the Illinois court relied heavily on a 1970 agreement between the FTC and U.S. cigarette companies, directing them to voluntarily measure their brands' tar and nicotine yields. In 2006, the U.S. Supreme Court denied a petition for a *writ of certiorari*, allowing the state high court's decision to stand.¹⁰⁷

Preemption arguments did not, however, prevail in a challenge by R.J. Reynolds to a California law prohibiting the distribution of free cigarettes. The justices said that California, one of 16 states regulating free tobacco promotions, had the right to ban free cigarette sampling because tobacco is a health hazard and because Congress has not spoken against state laws regulating the time, place, and manner in which cigarettes are sold or distributed. Nevertheless, California's highest court overturned the \$14.8 million fine the state imposed on R.J. Reynolds Tobacco Co. for illegally doling out free cigarettes at a beer fest, a biker rally,

and other public events, and sent the case back to a lower court to consider whether the fine was excessive and whether the tobacco maker had acted in bad faith.¹⁰⁸

With low-yield claims under attack, some manufacturers have begun to market cigarettes with explicit claims of lowered risk. In 1996, for example, R.J. Reynolds began to test-market Eclipse, which used a design that was purported to present less risk of cancer and produce less inflammation in the respiratory system. Slade and colleagues concluded that there was not satisfactory evidence that this cigarette is less harmful than are conventional cigarettes.^{109,110} As noted above, another new R.J. Reynolds brand, Advance, is marketed with the slogan “Great Taste. Less Toxins.”¹¹¹ The FTC has yet to consider whether such claims are false or misleading.

The FTC has a long history of oversight of tobacco advertising and its statutory authority would appear quite broad in its direction to prohibit any “false or misleading” advertising claims. Nevertheless, some view the agency’s activities in this area as fairly limited,¹¹² particularly when compared with its more aggressive stance with respect to advertising for other products (e.g., those promising weight loss).^{113,114} For example, one might argue that advertisements depicting healthy, vibrant smokers are inherently false and misleading because they imply that smoking is a healthful activity. However, the FTC has largely refrained from undertaking enforcement action against tobacco advertisements on these or similar grounds.

Comparison of the United States with Other Countries’ Experience

In 2000, the U.S. Surgeon General issued a report on reducing tobacco use in the United States. The report concludes that tobacco products are far less regulated

in the United States than in many other developed countries.¹¹⁵ In particular, the report finds that warning labels on cigarette packages in the United States are weaker and less conspicuous than those of some other countries.¹¹⁵ In addition, the report states that current regulation of advertising and promotion of tobacco products in the United States is considerably less restrictive than in several other countries.¹¹⁵

The sections below review the oversight of tobacco advertising and promotions in Canada and the European Union as examples of marketing controls outside the United States and describe the WHO FCTC. Further, the American Cancer Society has published a comprehensive review of information on tobacco production, trade, consumption, disease burden, and legislation (including marketing controls) for 196 countries and territories.¹¹⁶

Canada

Although the United States and Canada share a continent, they are miles apart in the extent to which they have pursued many tobacco control policy interventions. For more than a decade, for example, the Canadian legislature has sought to protect public health and prevent youth smoking through a variety of substantial restrictions on tobacco advertising and promotion.

Like the First Amendment to the U.S. Constitution, however, section 2(b) of Canada’s Charter of Rights and Freedoms¹¹⁷ protects freedom of expression,^(n,24) and the Canadian Supreme Court, like its U.S. counterpart, has held that such protection includes commercial speech.^{118,119} The Canadian Supreme Court has based this view on the need to protect the receiver and the belief that a free-market economy relies on having fully informed consumers.^(n,25) Unlike the First Amendment, however, section 2(b) may be overridden

by section 1 of the charter, which permits the legislature to place limits on the freedoms protected in the charter if they are “demonstrably justified in a free and democratic society.”^(n.26)

In recent years, the Canadian legislature and courts have struggled with the inherent conflict between the constitutional guarantee of free speech and laws intended to protect the public and foster public health.¹²⁰ This struggle has been particularly apparent in the case of tobacco advertising and promotion. The 1988 Tobacco Products Control Act (TPCA)¹²¹ largely banned tobacco advertising. The TPCA also prohibited retailers from displaying signs with tobacco brand names or trademarks, prohibited manufacturers from applying tobacco trademarks to other products or using tobacco-product brand names in sponsorship (weakened by an ambiguity in the law discussed in the section on “Ineffectiveness of Partial Advertising Bans,” chapter 3), and required the placement of “health indicators” on cigarette packages as imposed by regulation.

After the TPCA was passed, tobacco manufacturers sued the Canadian government, arguing that the statute exceeded the federal government’s legislative authority and violated the constitutional protection of freedom of expression.¹²² The trial court rejected both arguments,¹²³ but the Quebec Court of Appeal¹²⁴ overturned the lower court’s decision. In *RJR MacDonald Inc. v. Canada* (Attorney General),¹²⁵ the Canadian Supreme Court, in a 5–4 ruling, struck down certain provisions of the advertising restrictions and labeling requirements, holding that they violated section 2(b) of the Charter and were not justified under section 1.^{125(pp.10–12)}

First, the court held that the government had not adequately justified a complete advertising ban. In particular, the

government did not distinguish between “lifestyle” advertising (i.e., evocative or emotionally appealing advertising), which, the court found, “is designed to increase consumption,” and “informational” or “brand preference” advertising, which “has not been shown to have this effect.”^{125(p.15)} With respect to the prohibition on the use of logos on articles other than tobacco products, the court held that the government had not adequately demonstrated a link between the objective of decreasing tobacco consumption and the ban on logos.¹²⁵ In regard to the health warning requirement, the government’s failure to permit manufacturers to attribute the health warnings violated section 2(b) of the charter because “freedom of expression necessarily entails the right to say nothing or the right not to say certain things.”^{125(p.9)} While the majority found the warning labels themselves to be a justifiable impairment on expression, the government failed to demonstrate the need for the warnings to be unattributed.¹²⁰

The Canadian Supreme Court left open the possibility that “less intrusive alternative measures would be a reasonable impairment of the right to free expression, given the important objective and the legislative context.”¹²⁵ In 1997, the Canadian legislature enacted the Tobacco Act.¹²⁶ A response to the court’s objections, the Tobacco Act is more nuanced in its approach to advertising restrictions. The act prohibits lifestyle advertising,¹²⁷ defined as “advertising that associates a product with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, excitement, vitality, risk or daring,”¹²⁸ and restricts advertising to media primarily targeted at adults.^{127,128} However, the act permits manufacturers to use informational and brand-preference advertising to promote their products to adult smokers.^{127,128} Also in response to the court’s ruling, the act permits attribution of mandated health warnings.^{126(p.13)}

In 2000, the Canadian government mandated new health warnings to appear on cigarette packages. Under these regulations, manufacturers must dedicate at least 50% of the “principal display surfaces” of each cigarette pack to 1 of 16 warnings that combine a textual warning with a visual image, such as a diseased mouth, a lung tumor, a brain after a stroke, a damaged heart, or a limp cigarette (coupled with a warning that smoking can cause impotence). Warnings inside each package offer tips on quitting.¹²⁹ These warnings began to appear on cigarette packages in 2001.

Several manufacturers challenged the requirements imposed by the Tobacco Act as unconstitutional, but the trial court (the Quebec Superior Court) dismissed the claim.¹³⁰ On August 22, 2005, the Quebec Court of Appeal upheld most of the stipulations of the act. However, because the court allowed event sponsorship using corporate names (as long as they are not also tobacco product brand names), the Canadian government appealed the decision to the Canadian Supreme Court.¹³¹ The tobacco manufacturers cross-appealed in an attempt to defeat some of the provisions held to be constitutional. On June 28, 2007, the Supreme Court issued a unanimous (nine to zero) ruling in favor of the government’s appeal and against the cross-appeal, thereby upholding the order of the trial court and the provisions of the original statute.¹³²

Perhaps because of Canada’s proximity to the United States and because the two countries share many cultural values,¹³³ tobacco control advocates in the United States often look to Canada as a model for the United States to follow. In reality, there appears to be little diffusion of tobacco control policies from Canada to the United States.¹³³ The reasons for this are many and varied and are largely beyond the scope of this chapter. With respect to prohibitions on

advertising, however, it is worth noting that the Canadian Supreme Court and the U.S. Supreme Court, while having on paper similar constitutional parameters to work from, have come to different conclusions about where to place the fulcrum in balancing freedom of expression and public health protection. Although the Canadian Supreme Court struck down certain provisions of the TPCA, it left much room for more nuanced restrictions (and upheld the Tobacco Act), room that likely would not be available if the U.S. Supreme Court were to evaluate similar legislation. This may in part be due to the relative newness of the charter itself, which permits greater flexibility to address emergent health threats. In addition, unlike the U.S. Supreme Court, the Canadian Supreme Court is operating against a backdrop of broad political and social consensus at the provincial and national levels on the public health need to reduce tobacco use. This consensus may have led the Canadian Supreme Court to grant more latitude to the legislature in restricting tobacco advertising and promotion.

European Union

The European Union banned tobacco advertising on television and radio and tobacco company sponsorship of television programs in 1989.¹³⁴ In 1998, the EU enacted a directive banning tobacco advertising and sponsorship in all EU Member States.^{135,136} The directive would have phased out all advertising and sponsorship by 2006. The directive was based on several provisions of the Treaty Establishing the European Community.¹³⁶ In particular, Article 100a(1) permits the adoption of laws that have as their objective the establishment and functioning of the internal market, meaning the “abolition, as between Member States, of obstacles to the free movement of goods, persons, services, and capital”¹³⁶ The council argued that the directive

was necessary to facilitate trade among member states,¹³⁶ since conflicting national advertising laws could impede the free movement of media, such as newspapers and magazines,¹³⁷ and create distortions in competition.¹³⁶

The Federal Republic of Germany, which opposed the directive, and several British tobacco companies thereafter challenged its legality, arguing that the council and the parliament had exceeded their authority. In 2000, the Court of Justice of the European Community overturned the directive.^{138,139} The court held that the ban was too broad to be justified as an internal market measure. In particular, the court said it could not see how a ban on advertising tobacco on posters, parasols, ashtrays, or in theaters could help facilitate trade in those products between EU Member States.¹⁴⁰ However, the court stated that a more limited ban that focused on eliminating foreseeable obstacles to the free movement of goods and services, and for which distortion of competition was appreciable, would be valid under the treaty.¹³⁶

In 2002, the EU voted to outlaw tobacco advertising in newspapers and magazines, on the Internet, and at international sports events.¹⁴¹ The directive, issued in 2003, also includes a prohibition on tobacco company sponsorship of major international sporting events, such as Formula One racing.¹⁴² However, the ban does not include posters, billboards, cinema advertising, and indirect advertising (see chapter 4) such as cigarette logos on clothing. It also does not affect magazines published outside the EU but distributed within it. Most of the provisions were scheduled to take effect in 2005; the Formula One racing sponsorship ban took effect in 2006.¹⁴¹

All Member States should have transposed the directive into national law by July 2005. However, some countries—notably

Germany, the Czech Republic, Hungary, and Spain—failed to do so, leading to legal action by the European Commission.¹⁴³ In December 2006, the EU's highest court upheld the directive and rejected Germany's challenge that it was illegal.¹⁴⁴ Germany, Europe's biggest tobacco market, had argued that tobacco advertising in local newspapers should not be subject to blocwide legislation because it does not affect trade among nations in the 25-member EU. However, the European Court of Justice in Luxembourg held that prohibitions met the conditions to be adopted for the purpose of the establishment and functioning of the internal market.¹⁴⁵

World Health Organization

On May 21, 2003, the World Health Assembly, the governing body of WHO, unanimously adopted resolution WHA 56.1, which included adoption of the FCTC.¹⁴⁶ This represents the first-ever global health treaty negotiated by WHO.¹⁴⁷ The FCTC entered into force on February 27, 2005, 90 days after ratification of the treaty by 40 countries.¹⁴⁸ By April 2008, 154 countries—not including the United States—had become parties to the treaty.¹⁴⁹

Included in the FCTC are provisions aimed at reducing both the supply of and demand for tobacco.¹⁵⁰ Among the provisions intended to reduce demand is a comprehensive ban on tobacco advertising, promotion, and sponsorship (Article 13). However, the treaty also recognizes that compliance with such bans may not be feasible by some signatories because of constitutional constraints that exist within those countries. Thus, ratification does not necessarily require that a country impose a comprehensive ban. Rather, Article 13 of the treaty provides that “each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all

tobacco advertising, promotion and sponsorship.”^{151(p.10)} It states that a country that is not in a “position to undertake a comprehensive ban due to its constitution or constitutional principles” should apply “restrictions” to these activities consistent with its legal environment.^{151(p.10)}

The treaty provides minimum standards that parties must adopt, but again, in accordance with their constitutional principles. These minimum standards include (1) prohibition of advertising, promotion, or sponsorship for a tobacco product that is “false, misleading, or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions”,^{151(p.9)} (2) the inclusion of health warnings in all advertising and “as appropriate” in

promotion and sponsorship; (3) restriction of tobacco advertising, promotion, and sponsorship on radio, television, print media, and “as appropriate” other media, such as the Internet, within a period of five years; and (4) restriction of tobacco sponsorship of international events, activities, and/or participants. Further, in Article 11, the FCTC requires that each party to the treaty “adopt and implement, in accordance with its national law, effective measures to ensure that: (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive, or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular

Framework Convention on Tobacco Control Article 13: Tobacco advertising, promotion and sponsorship^a

1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.
2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:
 - (a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
 - (b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

tobacco product is less harmful than any other tobacco products.”^{151(p.9)}

Article 13 includes several references to the need to eliminate cross-border advertising, specifically expressed to apply to “radio, television, print media and, as appropriate, other media, such as the internet.”^{151(p.11)}

Article 13.7 states that, “Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising, promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law.”^{151(p.11)} These articles are directly intended to address tobacco advertising

and promotion that may cross national borders through international print media (especially magazines), direct broadcast satellite linked to domestic receiving dishes, paid product placement in movies, and the World Wide Web and other Internet-based communication channels. To control cross-border advertising under the FCTC, Kenyon and Liberman have recommended a multilayered approach including formal law and regulation, monitoring and enforcement practices, education, and international cooperation.¹⁵²

The United States signed the treaty in May 2004 but has not ratified it.¹⁴⁹ Article II, section 2, of the U.S. Constitution states that the president “shall have power, by and with the advice and consent of the Senate, to make treaties, provided two-thirds of the

(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;

(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;

(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and

(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.
6. Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising.
7. Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising, promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law. This paragraph does not endorse or approve of any particular penalty.
8. Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship.

^aWorld Health Organization. 2003. World Health Assembly Resolution 56.1. Geneva: World Health Organization. http://www.who.int/tobacco/framework/final_text/en.

Senators present concur.”¹⁵³ By April 2008, the president had not yet submitted the FCTC to the Senate for ratification. It is unclear to what extent ratification would require the United States to impose new restrictions on tobacco advertising, promotion, and sponsorship beyond those already in effect.¹⁵⁴

Summary

The history of efforts to restrict tobacco advertising and promotion in the United States has been closely intertwined with legal and constitutional factors such as constraints established by prior legislation, the proper roles of regulatory agencies, and constitutional protections derived from free speech rights encompassed in the First Amendment. Such issues have taken on increasing prominence, at both domestic and global levels, with the increasing use of policy interventions toward such promotion as a strategy to reduce the disease burden related to tobacco use.

Numerous legislative and regulatory efforts have been launched to date to curb tobacco promotion, including a comprehensive ban on such promotion within the WHO FCTC. Implementation of such broad restrictions, however, has generally been limited by constitutional protections for commercial speech (for example, in the United States and Canada) or legal challenges (such as the EU’s eventual modification of its sweeping 1998 ban of tobacco advertising and sponsorship). At the same time, policies on tobacco advertising and promotional activities have generally evolved to become progressively more restrictive over time. Moves toward broader prohibitions in this area are likely to continue and will probably stimulate further legal and policy debate and analysis.

Conclusions

1. The First Amendment to the U.S. Constitution, as the Supreme Court has interpreted it in recent years, grants broad protection for commercial speech, including speech about tobacco products. The Court has precluded regulation of tobacco products by the U.S. Food and Drug Administration (FDA) on the basis of the Court’s analysis of existing authorities under the FDA’s governing statute and the complex balance that Congress has struck between protecting and promoting trade in tobacco products and informing consumers of their dangers.
2. The Federal Trade Commission has authority to prevent “unfair or deceptive acts or practices in or affecting commerce.” However, the agency’s efforts to prevent tobacco advertisements that are false or misleading have been limited.
3. Canada and the European Union have imposed limitations on tobacco advertising and promotion, but these policies were weakened as a result of legal challenges. Nevertheless, Canadian and European restrictions on tobacco marketing are stronger than those currently in place in the United States.
4. The Framework Convention on Tobacco Control (FCTC), the first treaty ever negotiated by the World Health Organization, calls on each party to the treaty to “undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship ... in accordance with its constitution or constitutional principles.” As of April 2008, 154 countries were parties to the FCTC. The United States signed the treaty in May 2004 but has yet to ratify it.

Notes

- n.1 “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.”¹
- n.2 See, for example, *Members of City Council v. Taxpayers for Vincent*.⁵ The Supreme Court has stated that time, place, and manner restrictions do not violate the First Amendment “provided that they are justified without reference to the content of the regulated speech, that they are narrowly tailored to serve a significant governmental interest, and that they leave open ample alternative channels for communication of the information.”¹⁵⁵
- n.3 But see Troy.¹⁵⁶ Troy argues that the Framers of the Constitution believed that the right to advertise was encompassed within the First Amendment’s protection of freedom of the press and that they did not intend to distinguish between commercial and noncommercial speech, but rather between truthful and false speech.
- n.4 In *Bd. of Trustees v. Fox*¹⁵⁷ the Court ruled that the Court of Appeals had erred in requiring the application of a least restrictive means test to a university regulation; the Court instead interpreted the fourth prong of the *Central Hudson* test as a reasonable fit standard. “What our [commercial speech regulation] decisions require is a ‘fit’ between the legislature’s ends and the means chosen to accomplish those ends” (quoting *Posadas v. Tourism Co. of Puerto Rico* [478 U.S. 328, 341 (1986)]²⁷—“a fit that is not necessarily perfect, but reasonable ... that employs not necessarily the least restrictive means but ... a means narrowly tailored to achieve the desired objective.”¹⁵⁷
- n.5 See, for example, *44 Liquormart, Inc. v. Rhode Island*²⁴ in which Justice Clarence Thomas argues that where “legal users of a product or service [are kept] ignorant in order to manipulate their choices in the marketplace, the balancing test adopted in *Central Hudson* ... should not be applied”). See also *Lorillard Tobacco Co. v. Reilly*⁷ (533 U.S. at 572) in which Justice Thomas states that “I continue to believe that when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech in question may be characterized as ‘commercial.’”
- n.6 See Gilhooley,²⁵ which notes that “while the Justices use the same [*Central Hudson*] test, they differ on its meaning in practice.” See also Vladeck,²⁶ which traces the history of the commercial speech doctrine.
- n.7 See, for example, *Posadas v. Tourism Co. of Puerto Rico*,²⁷ which upholds Puerto Rico law prohibiting casino advertising, finding that the government’s interest in reducing the demand for casino gambling by residents of Puerto Rico was substantial and that the regulations directly advanced the government’s interest, and the restrictions were no more extensive than necessary to serve the government’s interest.
- n.8 See, for example, *Rubin v. Coors Brewing Co.*,²⁸ which finds that federal government prohibition on display of alcohol content on beer labels did not sufficiently advance the government’s interest in protecting the health, safety, and welfare of its citizens). See also *44 Liquormart, Inc. v. Rhode Island*,²⁴ which unanimously overturned a state ban on liquor price advertising, while disagreeing on whether the state’s failure related to the direct advancement or reasonable fit prong of *Central Hudson*.
- n.9 Because the Court concluded that the restrictions on cigarette advertising were preempted by the Federal Cigarette Labeling and Advertising Act, it did not render an opinion regarding whether the cigarette advertising restrictions violated the First Amendment.⁷
- n.10 The appellate court ruled that the prohibition on advertising was not severable from the rest of the compounding provision.³⁰ Because petitioners did not challenge the severability determination, the Court’s ruling had the effect of invalidating the entire pharmacy compounding section of FDAMA.²⁹
- n.11 For example, in *Riley v. Nat’l Fed’n of Blind*,³⁶ the Court declined to use a commercial speech test in striking down a statute mandating professional fundraisers to disclose the percentage of charitable contributions actually turned over to the charity. “Even assuming ... that [the mandated] speech in the abstract is indeed merely ‘commercial,’ we do not believe that the speech retains its commercial

- character when it is inextricably intertwined with otherwise fully protected speech [involved in charitable solicitations].”
- n.12 The Court decided the case on the basis of its compelled speech jurisprudence and did not apply the *Central Hudson* test. Nevertheless, some legal commentators view the *United Foods* case as a victory for constitutional protections of commercial speech. See Hudson.¹⁵⁸
- n.13 Four years earlier, in *Glickman v. Wileman Bros. & Elliott*,¹⁵⁹ the Court had upheld similar federal marketing orders requiring California fruit producers to fund a generic advertising program, characterizing the orders as economic regulation that did not impinge on First Amendment rights.¹⁶⁰ The Court in *United States v. United Foods* distinguished its prior ruling by reasoning that the exaction in *Glickman* was ancillary to a comprehensive regulatory program that included several competition-displacing features. In contrast, the federal statute in *United Foods* had no regulatory objective other than the generic advertising.
- n.14 In *Pearson v. Shalala*,³⁹ the claims at issue in the case were that consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer, that consumption of fiber may reduce the risk of colorectal cancer, that consumption of omega-3 fatty acids may reduce the risk of coronary heart disease, and that 0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than is a lower amount in foods in common form.
- n.15 In *Pearson v. Shalala*,³⁹ the regulation at issue stated that the FDA would authorize a health claim only “when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”¹⁶¹
- n.16 See, for example, *Zauderer v. Office of Disciplinary Counsel of Supreme Court*.⁴⁰ This case upholds disciplinary counsel finding that advertising contingent fee arrangement without disclosing the need to pay legal costs was deceptive and misleading, but rejecting prohibition of advertisements offering to represent previous users of a defective birth control device, where advertisements did not promise successful outcome on cases or suggest that the attorney had special expertise in such lawsuits and illustrations were accurate representation of device). See also *Ibanez v. Florida Dep’t of Bus. & Prof’l Regulation*,⁴¹ which finds that attorney’s use of Certified Public Accountant (CPA) and Certified Financial Planner (CFP) designations were not misleading provided that she held an active CPA license and CFP certification. See also *Peel v. Atty. Registration & Disciplinary Comm’n*,⁴² which holds that attorney’s letterhead stating that he was a “Certified Civil Trial Specialist By the National Board of Trial Advocacy” was not actually or inherently misleading where the information was true and verifiable, and the potential for the information to mislead was insufficient to warrant a categorical ban.
- n.17 For example, in *Thompson v. Western States Med. Ctr.*²⁹ the Court states that “[e]ven if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far-less-restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.”
- n.18 Although the FCLAA also banned cigarette advertising in electronic media subject to the jurisdiction of the Federal Communications Commission, at least one commentator has opined that this provision would likely be considered unconstitutional were it enacted today but that a court would be reluctant to overturn a ban that has become so entrenched. See Hoefges⁵³ (quoting from Redish¹⁶²).
- n.19 Cigarette packages, outdoor billboards, and other forms of advertisements must bear one of the following labels: 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 Risks to Your Health; Surgeon General’s Warning: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight; Surgeon General’s Warning: Cigarette Smoke Contains Carbon Monoxide.¹⁶³
- n.20 Preemption doctrine has its origins in the nineteenth-century Supreme Court case *McCulloch v. Maryland*.¹⁶⁴ In that case, the

- Court held unconstitutional the levying of a tax by the state of Maryland on a federal bank. The Court ruled that “the States have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control the operations of the constitutional laws enacted by Congress.” Since then, “it has been settled that state law that conflicts with federal law is ‘without effect’.” See *Cipollone v. Liggett Group*,⁵⁴ which quotes *Maryland v. Louisiana* (451 U.S. 725, 746 [1981]). See also Garner and Whitney.¹⁶⁵
- n.21 In *Cipollone*, the Court concluded that section 5 of the 1965 act preempted only “state and federal rule making bodies from mandating particular cautionary statements and did not preempt state-law damages actions.”⁵⁴ See also Ausness,⁵⁵ which concluded, however, that the 1969 amendment to the act did have a limited preemptive effect.
- n.22 The 1914 statute prohibits only unfair methods of competition. The Wheeler Lea Amendment of 1938 expanded the agency’s jurisdiction to include unfair and deceptive trade practices and to prohibit false ads of drugs, devices, food, and cosmetics. See Wheeler-Lea Amendment of 1938¹⁶⁶ and *FTC v. Sperry & Hutchinson Co.*¹⁶⁷
- n.23 Bayer and colleagues⁴³ (quoting from Brenner¹⁶⁸).
- n.24 Section 2(b) of the charter states, “Everyone has the following fundamental freedoms: Freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication.”¹¹⁷
- n.25 In *Ford v. Quebec*, the Canadian Supreme Court states, “Over and above its intrinsic value as expression, commercial expression which, as has been pointed out, protects listeners as well as speakers plays a significant role in enabling individuals to make informed economic choices, an important aspect of individual self-fulfillment and personal autonomy. The court accordingly rejects the view that commercial expression serves no individual or societal value in a free and democratic society and for this reason is undeserving of any constitutional protection.”^{118,120}
- n.26 Section 1 of the charter provides the following: “The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.”¹¹⁷

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