Nos. 10-5234 & 10-5235

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; R.J. REYNOLDS TOBACCO COMPANY; COMMONWEALTH BRANDS, INC.; AMERICAN SNUFF COMPANY, LLC, FKA CONWOOD COMPANY, LLC,

Plaintiffs-Appellants/Cross-Appellees,

v.

UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, COMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellees/Cross-Appellants.

On Appeal From The United States District Court For The Western District of Kentucky, Case No. 1:09-CV-117-M (Hon. Joseph H. McKinley, District Judge)

BRIEF FOR DEFENDANTS-APPELLEES/CROSS-APPELLANTS

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

This case presents First Amendment challenges to certain provisions of the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 776 (2009). The district court rejected most of plaintiffs' challenges but invalidated two provisions of the statute. Both sides have appealed. Given the importance of the issues, the federal government respectfully requests oral argument.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331. Final judgment was entered on January 14, 2010. Plaintiffs and the government filed timely notices of appeal on March 5 and March 8, 2010, respectively. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

Plaintiffs challenge provisions of the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "Act") on First Amendment grounds. Plaintiffs appeal rulings that upheld provisions that (1) revise the format of the health warnings required on tobacco product packaging and advertising; (2) require pre-market review by the Food and Drug Administration ("FDA") of any tobacco product that is marketed as one that presents reduced health risks; (3) restrict the sponsorship of events in the name of a tobacco brand and the distribution of branded merchandise; and (4) restrict the distribution of free samples of tobacco products and gifts that reward the purchase of tobacco products.

The government appeals rulings that invalidated provisions of the Act that (1) restrict the use of color and imagery in tobacco product advertising; and (2) preclude claims that a tobacco product is safe or less harmful due to FDA regulation or compliance with FDA standards.

STATEMENT OF THE CASE

The Tobacco Control Act addresses tobacco industry marketing practices that have been the subject of decades of scrutiny by Congress, the Executive Branch, and the courts. The results — reflected in extensive congressional findings and a massive public record — leave no doubt as to certain crucial points. Tobacco products are lethal and addictive. The overwhelming majority of tobacco users become addicted by age 18, at a time when they are particularly unlikely to appreciate the addictive power of nicotine. Tobacco companies have long been aware that they must reach potential new customers while they are underage and the companies have targeted their marketing accordingly.

In a comprehensive 1996 rulemaking, FDA addressed advertising techniques and marketing practices used by the tobacco industry to recruit underage users. In *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000), the Supreme Court found that FDA had "amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." The Court held, however, that FDA generally lacked authority to regulate tobacco products.

Congress enacted the Tobacco Control Act to provide FDA with that statutory authority, and it directed FDA to regulate the manufacture, marketing, and sales of

tobacco products. The Act addresses the promotion and marketing of tobacco products in three principal ways:

Warnings and Health Claims. To ensure that consumers understand the health consequences of tobacco use, the Act requires that tobacco product packaging and advertising bear new, more prominent health warnings of the kind already adopted by other nations including Canada. To ensure that consumers are not misled by unsubstantiated claims that a particular product poses a reduced health risk, the Act requires pre-market FDA review of tobacco products that purport to present such a reduced risk. A related provision precludes claims that compliance with FDA standards means that a tobacco product is safe or less harmful.

Promotional Practices That Target Minors. Congress directed FDA to reissue provisions of its 1996 rule that target advertising practices used by the tobacco industry to recruit children and adolescents. These provisions of the rule restrict the use of color and imagery in tobacco advertising, the sponsorship of events in the name of a tobacco brand, and the distribution of promotional items bearing a tobacco brand name or logo.

Incentive Schemes. The Act restricts the distribution of free samples of tobacco products and gifts that reward tobacco product purchases.

Plaintiffs are manufacturers and distributors of cigarettes and smokeless tobacco. They brought this facial challenge to the Act, contending that each of these provisions violates their First Amendment rights. The district court granted summary judgment to the government on all but two provisions of the Act; it granted summary judgment to plaintiffs with respect to the provision that restricts the use of color and imagery in tobacco advertising, and the provision that precludes claims that compliance with FDA standards means that a tobacco product is safe or less harmful. Both sides have appealed.[1]

STATEMENT OF FACTS[2]

A. Factual Background

Congress crafted the provisions of the Tobacco Control Act on the basis of evidence gathered over decades by all three branches of government regarding the health risks posed by tobacco products and the industry's marketing of those

[1] Plaintiffs' opening brief does not challenge rulings that dismissed their takings claims for lack of jurisdiction, R.100 at 43-46; dismissed their challenge to an outdoor-advertising ban as unripe, *id*. at 35-37; and rejected challenges to a combination-marketing provision, *id*. at 42-43, and a provision governing further restrictions, *id*. at 20-21. Accordingly, those issues are not before this Court.

[2] With leave of this Court, the government filed on disk exhibits that were too large to file through ECF. The index is reproduced in the addendum to this brief.

products. Four crucial features of tobacco use and marketing emerged from these intensive investigations.

First, when used as intended by the manufacturers, tobacco products are deadly. Congress found that "[a] consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects," and that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults." Legislative Findings 1 & 2.[3] "Each year, 440,000 people die of diseases caused by smoking or other form of tobacco use — that is about 20 percent of all deaths in our nation." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009).[4] In a comprehensive 2007 report cited by Congress, the Institute of Medicine ("IOM") observed that "cigarettes are inherently dangerous products that would not be allowed to enter the marketplace if their effects were known and if they were being introduced for the first time."

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[3] The Legislative Findings are codified at 21 U.S.C. § 387, Note and reproduced in Plaintiffs' Addendum at 25A-30A.

[4] All citations to the Congressional Record are to the daily editions, and can be found at http://www.gpoaccess.gov/crecord/09crpgs.html.

Institute of Medicine, "Ending the Tobacco Problem: A Blueprint for the Nation," at 152 (2007) ("2007 IOM Report") (discussed in H.R. Rep. No. 111-58(I) (2009)).

Second, the impact of tobacco products on public health is inextricably linked to the fact that tobacco products are addictive. Tobacco products "are highly addictive because they contain nicotine, one of the most addictive substances used by humans." 2007 IOM Report, at 5. Surveying data for 2004, the Institute of Medicine noted that although 40% of smokers attempted to quit in that year, only between 3% and 5% succeeded. *Id*. at 82.

The tobacco industry has long appreciated the importance of nicotine addiction to their sales. A 1972 internal Reynolds memo, quoted by Congressman Ganske in 2000, acknowledged that "[i]n a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiologic effects." 146 Cong. Rec. H1849 (April 5, 2000). The same memo concluded that "a tobacco product is, in essence, a vehicle for the delivery of nicotine," and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." *Ibid*.

Tobacco companies "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain

addiction." Legislative Finding 49. Although the companies "engineered their products around creating and sustaining this addiction," they "denied and distorted the truth as to the addictive nature of their products for several decades" and "concealed much of their nicotine-related research." *United States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095, 1107, 1124 (D.C. Cir. 2009), *cert. denied*, __ S. Ct. __ (June 28, 2010); Legislative Finding 49.

Third, the tobacco industry has long depended on recruiting underage users who become addicted by age 18. Congress found that despite laws prohibiting the sale of tobacco products to minors, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Legislative Finding 31. The President's Cancer Panel reported in 2007 that "[o]ver 80 percent of adult smokers became addicted to tobacco at or before the age of 18 years." President's Cancer Panel, "Promoting Healthy Lifestyles," at 64 (2007) ("2007 President's Cancer Panel Report"). It stressed that "[e]very day, approximately 4,000 children under age 18 experiment with cigarettes for the first time; another 1,500 become regular smokers. Of those who become regular smokers, *about half* eventually will die from a disease caused by tobacco use." *Ibid*. (emphasis added).

The adolescents who form the industry's pool of new customers systematically "underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose." *Ibid*. One survey showed that "nearly 60 percent of adolescents believed that they could smoke for a few years and then quit." 2007 IOM Report at 91. In another study, only 3% of twelfth-grade smokers estimated that they would be smoking in five years; in reality, 63% of them were still smoking seven to nine years later. *Ibid*.

Tobacco companies have long known that they must reach potential customers while they are underage and the companies have targeted their marketing accordingly. Congress found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Legislative Finding 15.

Fourth, the tobacco industry has for decades misled consumers about the health risks and addictiveness of its products. Beginning with the 1964 landmark report "Smoking and Health," the Surgeon General issued a series of reports addressing the health consequences of smoking and nicotine addiction. In response, tobacco manufacturers undertook a multi-pronged campaign to deny these health hazards and undermine the credibility of the studies, even though they knew the reports were

accurate. The tobacco companies' "efforts to deny and distort the scientific evidence of smoking's harms are demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *United States v. Philip Morris USA, Inc., et al*., 449 F. Supp. 2d 1, 855 (D.D.C. 2006), *aff'd*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, __ S. Ct. __ (June 28, 2010).

At the same time, faced with growing public concern about the health consequences of tobacco use, tobacco companies sought to develop "health reassurance" products that consumers would believe pose lower health risks, provide an alternative to quitting, or represent a step in decreasing the smoker's level of dependence. *Philip Morris*, 566 F.3d at 1107. The manufacturers knew, however, that these ostensibly "reduced risk" products actually provided no health benefit. The D.C. Circuit concluded that tobacco manufacturers "marketed and promoted their low tar brands to smokers — who were concerned about the health hazards of smoking or considering quitting — as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Ibid*. The

manufacturers "were aware that lower tar cigarettes ... do not actually deliver the low levels of tar and nicotine advertised." *Ibid.*

B. Regulatory Background

In 1996, FDA issued regulations that aimed to cut adolescent use of tobacco products in half within seven years. 61 Fed. Reg. 44396, 44539 (1996). The Supreme Court concluded, however, that FDA generally lacked authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to regulate cigarettes and smokeless tobacco. *Brown & Williamson*, 529 U.S. at 126.

That ruling left no doubt as to the seriousness of the public health crisis addressed by the regulations. The Court emphasized that "[i]n its rulemaking proceeding, the FDA quite exhaustively documented that 'tobacco products are unsafe,' 'dangerous,' and 'cause great pain and suffering from illness.'" *Id*. at 134 (quoting 61 Fed. Reg. 44412). FDA "found that the consumption of tobacco products presents 'extraordinary health risks,' and that 'tobacco use is the single leading cause of preventable death in the United States.'" *Ibid*. (quoting 61 Fed. Reg. 44398). FDA determined that "'[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths,' and that '[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents,

alcohol, homicides, illegal drugs, suicides, and fires, combined.'" *Id*. at 134-35 (quoting 61 Fed. Reg. 44421). FDA "characterized smoking as 'a pediatric disease,'" *id*. at 135 (quoting 61 Fed. Reg. 44421), "because 'one out of every three young people who become regular smokers ... will die prematurely as a result.'" *Ibid*. (quoting 61 Fed. Reg. 44399).

This evidence of the severe health risks posed by use of tobacco products was key to the Supreme Court's reasoning. The Court concluded that, given the inherently dangerous qualities of cigarettes and smokeless tobacco, FDA regulation of these tobacco products as drugs under the FDCA would require the agency to ban them. *Id*. at 136. Because other federal statutes regulating cigarettes and smokeless tobacco showed that Congress had not meant for these products to be banned, the Court concluded that Congress could not have intended that they be regulated as drugs. *Id*. at 137-39.

Brown & Williamson unequivocally recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." 529 U.S. at 161. At the same time, the decision left a regulatory void that remained unfilled until Congress enacted the Tobacco Control Act in 2009.

C. The Tobacco Control Act

As discussed in our Argument, the Tobacco Control Act addresses the promotion and marketing of tobacco products in three principal ways.

First, Congress enacted measures to ensure that consumers are given accurate information about the health risks posed by tobacco products. Congress required that existing warnings be replaced with new warnings of a type already adopted by Canada and other nations. In addition, to address the tobacco industry's history of making misleading health claims, Congress required pre-market FDA review of products marketed as posing reduced risks, and barred claims that a product is safe or less harmful by virtue of FDA regulation.

Second, Congress directed FDA to reissue provisions of the 1996 rule that target advertising practices used by the tobacco industry to recruit children and adolescents. One of these provisions restricts the use of color and imagery in advertisements. A second provision bars the sponsorship of events in the name of a tobacco brand, and a third bars the distribution of merchandise bearing a tobacco brand name or logo.

Third, Congress restricted incentives to use or purchase tobacco — the distribution of free samples of tobacco products, and gifts that reward the purchase of tobacco products.

D. District Court Proceedings

Plaintiffs sought a preliminary injunction to block enforcement of the provision requiring pre-market FDA review of products marketed as presenting reduced risks. The district court denied the motion in an opinion issued after briefing and an evidentiary hearing. R.65.

On consideration of the parties' cross-motions for summary judgment and supporting materials, the court upheld the warning requirements and the pre-market review requirement. R.100 at 21-33. It invalidated the provision barring claims that a tobacco product is safe or less harmful by virtue of FDA regulation, because the court believed that the provision applies to non-commercial speakers. *Id*. at 34-35.

The court upheld two of the provisions that target advertising practices particularly attractive to youth — the restriction on brand name sponsorship of events, and the restriction on distribution of branded merchandise. *Id*. at 15-20. It concluded, however, that the restriction on use of color and imagery in tobacco advertising sweeps too broadly, believing that Congress could have exempted color and imagery with no special appeal to youth. *Id*. at 15.

Finally, the court sustained the restrictions on free samples and gifts that reward the purchase of tobacco, explaining that the provisions regulate conduct rather than speech. *Id*. at 41-42.

SUMMARY OF ARGUMENT

The Tobacco Control Act confronts what the Supreme Court correctly described as the single most significant threat to public health in the United States. The Act grants FDA broad authority to regulate tobacco products and, in the provisions at issue here, imposes requirements and restrictions on the marketing of cigarettes and smokeless tobacco. The challenged provisions have overwhelming support in a massive public record, and plaintiffs' First Amendment challenges should be rejected.

A. The district court correctly sustained the provisions of the Act that ensure that consumers will receive accurate information about the health risks of tobacco use, as discussed in Argument Point II. It is settled that Congress may require health warnings on cigarettes and smokeless tobacco, and the content of the revised warnings is accurate and unchallenged. The revised format accords with the specifications of a World Health Organization treaty signed by the United States and 167 other nations, and whose effectiveness has been documented in extensive independent research. It is plainly permissible for Congress to update the format of the health warnings to ensure their effectiveness.

The provision of the Act that requires pre-market FDA review of ostensible reduced-risk tobacco products ensures that consumers are not misled by

unsubstantiated claims that a particular product presents reduced risks. It responds to the industry's history of misleading the public about the purported health benefits of "light" and "low tar" cigarettes. The pre-market FDA review requirement mirrors the requirement that has long been in place for drugs, and is an equally permissible exercise of Congress's power.

A related provision of the Act precludes claims that would mislead consumers into believing that compliance with FDA standards means that a tobacco product is safe or less harmful. The district court invalidated this provision because it believed, mistakenly, that the provision extends to persons other than commercial actors and was therefore subject to strict scrutiny. Correctly construed, this provision clearly satisfies the test for commercial speech.

B. Congress properly directed FDA to reissue provisions of the 1996 rule that target advertising and marketing techniques that have been particularly successful in attracting underage users, as discussed in Argument Point III. Congress recognized that the overwhelming majority of current tobacco users became addicted by the age of 18. The tobacco industry has long recruited this underage population, who are most susceptible to its noninformational advertising techniques and most likely to overestimate their resistance to nicotine addiction. In targeting techniques used to attract children and adolescents, Congress placed no restriction on the communication

of accurate information through text in tobacco advertisements. Instead, it precluded the use of color and imagery, while excepting advertisements in magazines directed to adult audiences. These provisions are narrowly tailored to address the substantial government interest in curbing underage tobacco use.

The district court did not question the importance or utility of these restrictions, but believed that they could have been crafted even more narrowly. The well-documented history of the tobacco industry's violation and circumvention of previous restrictions on its advertising demonstrates, however, that there is no basis to set aside the line drawn by Congress. Likewise, the district court correctly recognized that there is no basis to invalidate restrictions on other marketing techniques used to attract adolescents — the sponsorship of events in the name of a tobacco brand, and the distribution of branded merchandise.

C. Congress also acted well within constitutional limits when it curtailed commercial practices that stimulate underage demand, as discussed in Argument Point IV. The district court correctly held that the statutory restrictions on the distribution of free samples of tobacco products and gifts that reward tobacco purchases are regulation of commercial conduct with no significant expressive element. These conduct restrictions do not implicate, much less violate, the First Amendment.

ARGUMENT

I. Standard Of Review

The summary judgment order is subject to *de novo* review. Two overarching principles govern this Court's review of plaintiffs' claims.

First, this lawsuit presents a facial challenge to an Act of Congress. Facial challenges are "disfavored" and cannot succeed unless "the law is unconstitutional in all of its applications" or has no "plainly legitimate sweep." *Wash. State Grange v. Wash. State Repub. Party*, 552 U.S. 442, 449-450 (2008).

Second, in reviewing Congress's determinations, the Court is not to "reweigh the evidence de novo, or to replace Congress' factual predictions with [its] own." *Turner Broadcasting System, Inc. v. FCC*, 520 U.S. 180, 211 (1997). The Supreme Court has emphasized that "[t]he Constitution gives to Congress the role of weighing conflicting evidence in the legislative process." *Id.* at 199. Thus, "[e]ven in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Id*. at 196. The "relevant inquiry ... is not whether Congress, as an objective matter, was correct" in its determinations as to the problems

to be addressed or the tailoring of the remedies. *Id*. at 211. "Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress." *Ibid*. As long as that standard is satisfied, "summary judgment for [the government] is appropriate regardless of whether the evidence is in conflict." *Ibid*.

The discussion below addresses the challenged provisions in an integrated fashion and does not break out for separate treatment the two provisions that are the subject of the government's appeal. Those two provisions are discussed below at Points II(C) and III(B).

II. The Revised Warning Format And The Regulation Of Tobacco Products Marketed As Presenting Reduced Risks Ensure That A Decision To Use Tobacco Is Based On Information That Is Accurate And Not Misleading.

A. Congress Mandated A New Warning Format Of The Type Already Required By Canada And Other Nations Based On Abundant Evidence That This Format Conveys Accurate Information Far More Effectively Than Preexisting Warning Requirements.

1. Congress was amply justified in concluding that the new warning format is more effective than the prior format.

Warnings and other disclosure requirements "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech" and may be required "in order to dissipate the possibility of consumer confusion or deception." *Zauderer v.*

Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985); *see also Milavetz v. United States*, 130 S. Ct. 1324, 1339-40 (2010).

Congress's authority to require that tobacco product packaging and advertising bear health warnings is uncontested. Such warnings have been required for cigarettes since 1965 and for smokeless tobacco since 1986. *See* Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92, 79 Stat. 282 (1965); Comprehensive Smoking Education Act of 1984, Pub. L. 98-474, 98 Stat. 2200 (1984); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30 (1986).

The Tobacco Control Act updates the content and the format of these health warnings. Plaintiffs do not challenge the accuracy of the new content. The district court observed that the content of the warnings — such as "Cigarettes are addictive" — "is objective and has not been controversial for many decades." R.100 at 27-28.[5]

Plaintiffs' challenge is directed instead to the *format* of the warnings. Before 2009, the United States was "one of the few countries in the developed world that [had] not updated its warnings in the past 20 years." 2007 IOM Report, at C-2.

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[5] In contrast, the ordinance challenged in the case on which plaintiffs rely (Pl. Br. 20-21) required video game retailers to display a "subjective and highly controversial message." *Entertainment Software Association v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (distinguishing cigarette warnings).

Under prior law, cigarette warnings appeared on the side of a package and constituted less than 5% of an advertisement. R.70-2 at 29 (Krugman). Under the new statute, warnings must comprise the top 50% of the front and rear panels of cigarette packs, 30% of the two principal display panels on smokeless tobacco packaging, and 20% of cigarette and smokeless tobacco advertising. 15 U.S.C. §§ 1333, 4402. Congress directed the Secretary of Health and Human Services to promulgate regulations requiring that graphic warnings accompany the text on cigarette packages. *Id.* § 1333. The new cigarette warnings will take effect 15 months after issuance of the graphics regulations, which have not yet been issued. *Ibid*. The new smokeless tobacco warnings are already in effect, as this recent comparison illustrates:

http://well.blogs.nytimes.com/2010/05/03/new-bold-warnings-on-tobacco-ads/

The new warnings format is in accordance with the "international consensus reflected in the World Health Organization's Framework Convention on Tobacco Control." R.100 at 26. The United States is a signatory to this treaty, which, with 168 signatories, is "one of the most widely embraced treaties in UN history." http://www.who.int/fctc/en/.

Although plaintiffs assert that Congress's revisions to the format of the warnings were "unjustified," Pl. Br. 21, the evidence before Congress clearly substantiates its judgment that the prior warnings were an ineffective means of communicating information. In 1994, "the Surgeon General reported that the few empirical studies dealing 'with the visibility of the cigarette warnings in advertising ... consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers.'" R.100 at 25 (quoting 1994 Surgeon General's Report, at 168). In 2007, "the Institute of Medicine likewise declared that the 'basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way.'" *Ibid*. (quoting 2007 IOM Report, at 291). "In testimony to Congress, the Chair of the IOM's Committee on Reducing Tobacco Use described the warning on cigarette packs as 'invisible.'" *Ibid*. (quoting H.R. 1108, Family Smoking Prevention and Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th

Cong. 42 (2007) (testimony of Richard Bonnie)). The IOM Report "cited several studies showing that 'the U.S. text warnings on the side of packages demonstrate low levels of salience among smokers.'" *Ibid*. (quoting 2007 IOM Report, at C-3).

The IOM Report stressed that "graphical warnings 'may be particularly important for communicating' with consumers with low levels of education, given evidence that such smokers 'are less likely to recall health information in text-based messages than people with more education.'" *Id*. at 25-26 (quoting 2007 IOM Report, at 295, C-3). "[O]ne study showed that the current warnings 'require a college reading level' and thus 'may be inappropriate for youth and Americans with poor reading abilities.'" *Ibid*. (quoting 2007 IOM Report, at C-3).

Contrary to plaintiffs' assertion, the "government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance." R.100 at 24-25. Indeed, plaintiffs' expert acknowledged that "size, color, visual images, novelty and distinctiveness from its surroundings" are the "most common" techniques used to gain attention. R.71-5 ¶17 (Faber).

Congress "informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada." R.100 at 27 (citing 2007 IOM Report, at 291-92). Although plaintiffs discount the Canadian experience (Pl. Br. 22), "[s]tudies

of Canadian smokers have shown that more than half 'reported that the pictorial warnings have made them more likely to think about the health risks of smoking' and that 'approximately 95 percent of youth smokers and 75 percent of adult smokers report that pictorial warnings have been effective in providing them with important health information.'" R.100 at 27 (quoting 2007 IOM Report, at 294). "One study comparing Canadian and U.S. warnings found that while '83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,' only '7 percent of U.S. students' did the same." *Ibid*. (quoting 2007 IOM Report, at C-3 to C-4). "Indeed, there is no more efficient method of reaching smokers than through the use of graphic and highly visible warning labels." Peters, E., *et al.*, "The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers," Nicotine & Tobacco Research, vol. 9, no. 4, pp. 473-481, at 479 (Apr. 2007).

Research examining the impact of the Canadian graphic warning labels on smoking behavior shows that smokers who had read, thought about, and discussed the new labels were more likely to have quit, tried to quit, or reduced their smoking. 2007 IOM Report, at 295. One-fifth of Canadian smokers said that they smoked less because of the labels, and one-third said they were more likely to quit because of the

warnings. *Ibid*. Former smokers identified the pictorial warnings as important factors in quitting and in subsequently remaining nonsmokers. *Ibid*.

These results were corroborated by the International Tobacco Control ("ITC") Project, which conducted a cohort survey of a representative sample of more than 8,000 adult smokers from Canada, Australia, the United States, and the United Kingdom, involving five waves of data collected over five years. *Ibid*.; *see also* Borland, R., *et al*., "Impact of graphic and text warnings on cigarette packs: findings from four countries over five years," 18 Tobacco Control 358 (June 2009). "Overall, the study found that warnings that are graphic, larger, and more comprehensive in content were associated with greater health knowledge." 2007 IOM Report, at 294. For example, 85% of Canadian respondents cited packages as a source of health information; in contrast, only 47% of U.S. smokers cited packages as such a source. *Ibid*. Specific health warnings were associated with knowledge about specific diseases. *Ibid*. More recent ITC Project work, which took into account the graphic warnings introduced in Australia in 2006, "strengthened the existing evidence that reactions to warnings predict subsequent quitting." Borland, *supra*, at 359; *see also id*. at 359-60 (reporting that "after the new (and changed to graphic) Australian warnings were implemented, all four measures of self-reported impact increased significantly among Australian smokers").

Plaintiffs nonetheless insist that "the new warnings will not reduce tobacco use." Pl. Br. 22. For support, they rely on the declaration of their expert, Dr. Viscusi, who admitted at trial in *United States v. Philip Morris* that his research was commissioned by tobacco industry law firms for use in litigation. R.98-1 at A16. Dr. Viscusi's declaration ignores the extensive body of independent research just discussed, which directly contradicts his assessment. As plaintiffs note (Pl. Br. 22), Dr. Viscusi's chart gives the impression that smoking rates increased in Canada after new warnings were introduced. Dr. Viscusi created that impression, however, by switching, midstream, from one data source to another. *See* R.71-3 at 45 n.41 (noting change in data sources). When a consistent source is used, it shows that smoking prevalence among Canadians aged 15 or older dropped from 24% in 2000 (before the warnings were introduced) to 22% in 2001 and 21% in 2002. *See* Canadian Tobacco Use Monitoring Survey.[6] Youth smoking rates show greater declines, from 14% in 2000/2001 to 10% in 2003 to 8% in 2005. *See* Shields, M., Statistics Canada, "Smoking — prevalence, bans and exposure to second-hand smoke," at 1 (Aug. 2007).[7]

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[6] http://hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/_ctums-esutc_prevalence/prevalence-eng.php

[7] http://www.statcan.gc.ca/pub/82-003-x/2006007/article/smoking-fumer/10198-eng.pdf

2. Congress was amply justified in concluding that consumers underestimate the risks presented by tobacco use.

Plaintiffs assert that tobacco users and potential users already know and indeed "overestimate" the risks presented by tobacco use. Pl. Br. 21-22. Thus, they contend that the warnings "address an information deficit" that is "non-existent." *Id*. at 23 (citing *Ibanez v. Florida Department of Business & Professional Reg*., 512 U.S. 136, 146 (1994)). Plaintiffs once more premise their contention on the Viscusi declaration.

Myriad independent studies contradict Dr. Viscusi's position. The 2007 IOM Report explained that "adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior." 2007 IOM Report, at 93. Although adolescents overestimate certain risks, such as the statistical risk of lung cancer, they underestimate the degree to which smoking can shorten life and the likelihood that they will suffer tobacco-related disease. *Id*. at 89-90. Both adolescent and adult smokers were more than twice as likely as nonsmokers to doubt that tobacco use, even for a period of 30 to 40 years, would cause death. *Id*. at 90. Adolescents fail to recognize that smoking causes more deaths than gunshots, car accidents, alcohol, and the use of other drugs. *Ibid*. And they "typically

underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose." 2007 President's Cancer Panel Report, at 64; *see also* 2007 IOM Report, at 89, 91.

Dr. Viscusi disregarded this body of investigation, and his limited discussion of scientific studies was inaccurate. For example, Dr. Viscusi invoked the research of Drs. Weinstein and Slovic to support his claim that "young people overestimate the dangers of smoking to an even greater degree [than adult smokers]." R.71-3 ¶41. Drs. Weinstein and Slovic were experts for the government in *United States v. Philip Morris* and their findings were described by the district court in that case. What these experts actually found is that "most people have only a superficial awareness that smoking is dangerous," 449 F. Supp. 2d at 578 (citing Slovic); "individuals have little knowledge of the reality of the pain, suffering, and despair of those with lung cancer, emphysema, congestive heart failure, and other smoking related diseases," *ibid*. (citing Weinstein & Slovic); "[m]ore than 70% of adults and 80% of adolescents overestimated the likelihood that lung cancer is curable," *ibid*. (citing Weinstein & Slovic); "adolescents not only underestimate the harm that results from smoking cigarettes, but are overly optimistic about their ability to quit smoking," *ibid*. (citing Weinstein); and "[m]ost smokers only begin to think of risk after they have started to smoke regularly and have already become addicted," *id*. at 576 (citing Slovic).

Summarizing, the *Philip Morris* court explained that "the research and expert testimony demonstrate that most youth, at a time when they are deciding whether to start smoking, have a very inadequate understanding of the medical consequences, physical pain, and emotional suffering which results from smoking and the unlikelihood of their being able to quit smoking at some future time." *Id*. at 579-80.

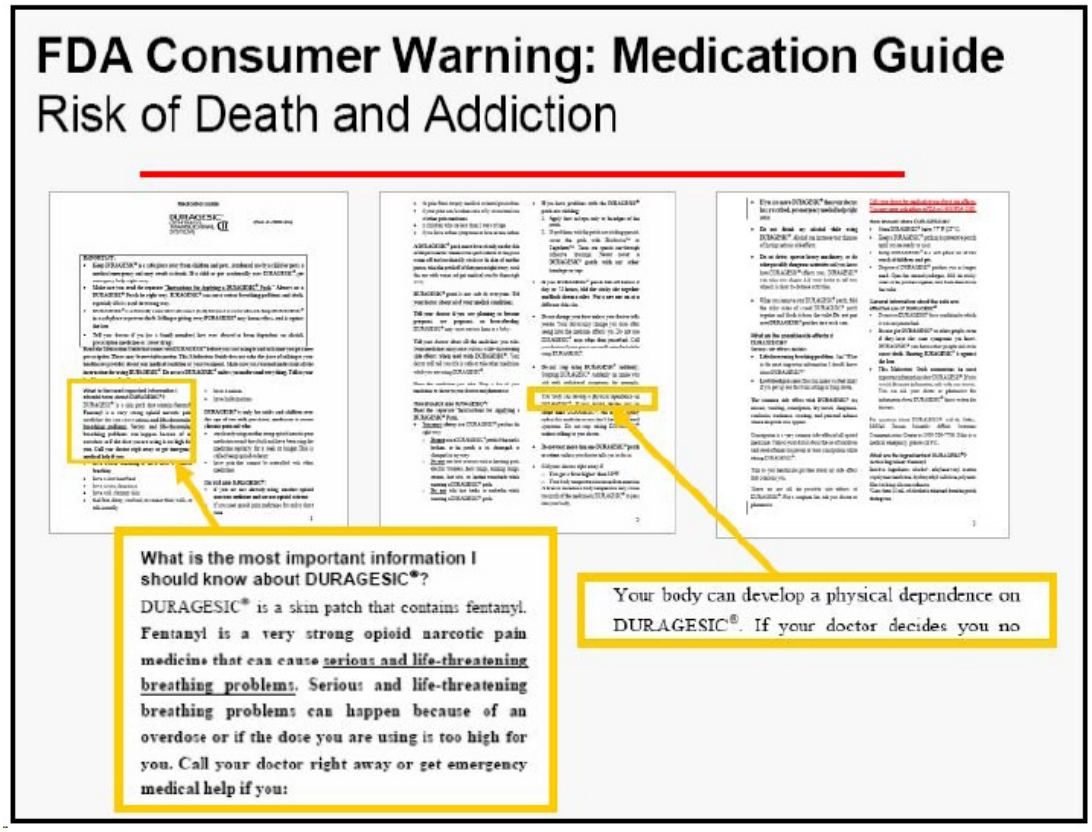
3. The Canadian-style format is not "unduly burdensome."

Plaintiffs contend that warnings of the kind required in Canada are "unduly burdensome" and leave inadequate room for their commercial speech. Pl. Br. 24. But as the district court explained, "half of cigarette packs, 70% of smokeless tobacco packages, and 80% of advertisements remain available for their speech." R.100 at 27. The Canadian Supreme Court unanimously rejected a challenge analogous to the one asserted here, finding that "[t]he benefits flowing from the larger warnings are clear" while "[t]he detriments to the manufacturers' expressive interest in creative packaging are small." *J.T.I. MacDonald Corp. v. Canada*, 2007 SCC 30, ¶139 (2007) (lawsuit by tobacco companies including Imperial, parent of Commonwealth Brands).

Nor is it novel for federal law to require extensive disclosures in drug labeling and advertising. Dr. Viscusi admitted that prescription drug companies must "include all of a drug's risk information" as well as other information about the drug in print advertisements. R.71-3 ¶80. Although these disclosures are collectively described as

the "Brief Summary," the information required is so extensive that it "would take many minutes to read or scroll down a TV screen," *ibid*., and "is usually presented on its own page of a print ad." FDA, Drug Advertising: Glossary of Terms.[8]

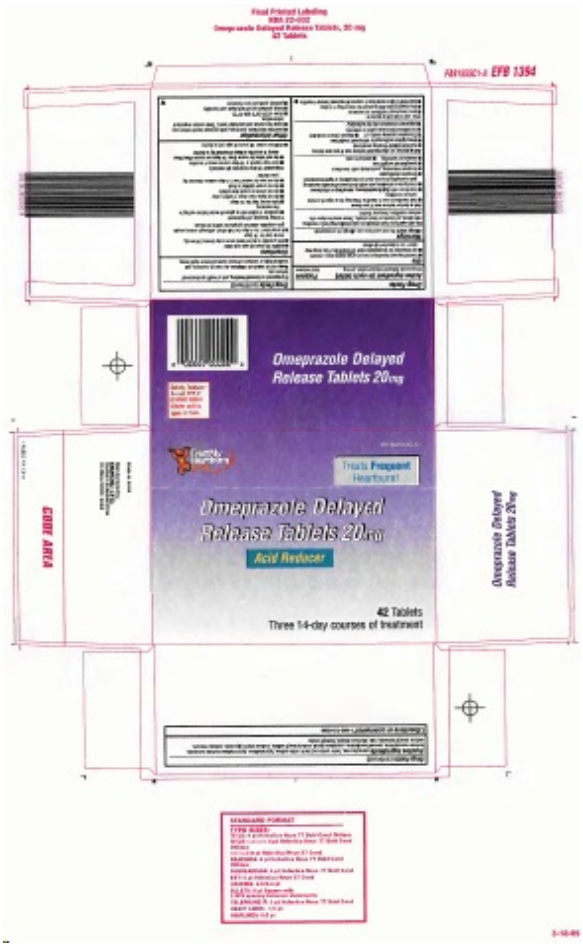
The labeling of prescription drugs likewise must include detailed information on warnings, precautions, contraindications, and adverse reactions, as Dr. Viscusi's example illustrates:



R.71-3 ¶79.

[8] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm

Even for less dangerous over-the-counter ("OTC") drugs, FDA regulations impose detailed labeling requirements. 21 C.F.R. § 201.66. The wrapper or outside container for a retail OTC package must contain a "Drug Facts" panel with information on the active ingredient, drug purpose, indications, directions, warnings, inactive ingredients, and other information. *Id*. § 201.66(c). For many products, the required disclosures comprise more than 50% of the packaging, as shown below:



R.80-3 at B4 (OTC heartburn medication).

At bottom, plaintiffs urge the Court to substitute the tobacco industry's judgment for the determinations that were made by Congress on the basis of substantial evidence. That would be impermissible even if the Court were reviewing agency regulations. *See Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (noting deference owed to FDA determination of information required on drug labeling). The Supreme Court has made clear that the reasonableness of a congressional determination is measured "by a standard more deferential than we accord to judgments of an administrative agency," lest a court "infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Turner*, 520 U.S. at 195, 196.

B. Congress Required Pre-Market Review Of Tobacco Products That Are Claimed To Present A Reduced Risk To Preclude The Type Of Unsubstantiated Health Claims That Have Characterized The Marketing Of Tobacco Products.

1. Manufacturers have long marketed purportedly "reduced risk" tobacco products that have not in fact reduced risk.

The Act requires pre-market FDA review of tobacco products that purportedly present reduced health risks. 21 U.S.C. § 387k. The provision's purpose is "to prevent misleading claims about so-called modified risk tobacco products: it authorizes the FDA to review the scientific evidence that the product will, in fact,

'reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.'" R.65 at 15 (quoting 21 U.S.C. § 387k(b)(1)).

Congress's decision to require pre-market review was informed by the tobacco industry's long history of marketing of "low tar" cigarettes with misleading health claims. *See* Legislative Findings 38 & 39. For decades, tobacco companies "marketed and promoted their low tar brands to smokers — who were concerned about the health hazards of smoking or considering quitting — as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Philip Morris,* 566 F.3d at 1107. The companies also failed to disclose to the Federal Trade Commission their research "showing that [machine] test results do not reflect the amount of tar and nicotine that consumers of 'light' cigarettes actually inhale." *Altria Group, Inc. v. Goode*, 129 S. Ct. 538, 550 n.14 (2008).

"By engaging in this deception," the companies "dramatically increased their sales of low tar/light cigarettes, assuaged the fears of smokers about the health risks of smoking, and sustained corporate revenues in the face of mounting evidence about the health dangers of smoking." *Philip Morris*, 449 F. Supp. 2d at 561. The market share for "low tar" brands increased from 2% of cigarette sales in 1967, *id*. at 508, to 92.7% in 2006. Federal Trade Commission, Cigarette Report for 2006, at 7 (2009).

In 2001, the National Cancer Institute ("NCI") issued a comprehensive report on "low tar" cigarettes. NCI, "Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine" (2001). In a passage later quoted by Senator DeWine, NCI explained that "[t]he use of these 'decreased risk' cigarettes has not significantly decreased the disease risk. In fact, the use of these cigarettes may be partly responsible for the increase in lung cancer for long-term smokers who have switched to the low-tar/low-nicotine brands." 150 Cong. Rec. S5962 (May 20, 2004).

The Surgeon General testified to Congress in 2003 that the promised health benefits of "low-tar" brands were illusory. Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S5999 (June 3, 2009). "We now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual increase in death and disease among smokers." *Id*. at S6000. The Surgeon General admonished Congress to heed that experience in considering the marketing of smokeless tobacco products, stressing that smokeless tobacco is a known human carcinogen. *Ibid*.

2. The pre-market FDA review requirement for tobacco products that purportedly present a reduced risk parallels the preexisting requirement for drugs and presents no First Amendment problem.

The statutory provision requiring pre-market review of purported reduced-risk tobacco products parallels preexisting FDCA provisions applicable to drugs and, like the drug provisions, it presents no First Amendment problem. The FDCA requires pre-market FDA review of "new drugs," and defines "drugs" to include articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). "Intended use" is an objective standard that turns on the nature of the claims made about the product. *Whitaker v. Thompson*, 353 F.3d 947, 948 (D.C. Cir. 2004). "Regardless of the actual physical effects of a product, it will be deemed a drug ... where the labeling and promotional claims show intended uses that bring it within the drug definition." *United States v. Article ... Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (citing cases); *see also Kordel v. United States*, 335 U.S. 345 (1948) ("health food products" were drugs because they were claimed to ameliorate various ills).

This Court's decision in *United States v. 250 Jars ... "Cal's Tupelo Blossom U.S. Fancy Pure Honey*," 344 F.2d 288 (6th Cir. 1965), illustrates that principle. This Court held that jars of honey were properly seized as unapproved drugs because

they were displayed for retail sale along with booklets and leaflets claiming that honey cures disease.

Under the drug scheme, "claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose — and, therefore, as evidence whether the product is or is not a drug." *Whitaker*, 353 F.3d at 953. This evidentiary use of speech is permissible under the First Amendment. *Whitaker*, 353 F.3d at 953; *United States v. Article of Drug Designated B-Complex Cholinos Capsules*, 362 F.2d 923, 927 (3d Cir. 1966). Indeed, Reynolds itself urged the Supreme Court that "[c]laims in the market — oral or written; on labels, in advertising, or in salespersons' presentations — provide an objective, easily identifiable and administrable basis for determining FDA jurisdiction." 1999 WL 712566, at *15 (brief filed in *Brown & Williamson*).

The pre-market review requirement for tobacco products that purportedly reduce health risks works the same way as the new drug approval provisions. The Tobacco Control Act requires pre-market FDA review of a "'modified risk tobacco product,'" R.65 at 2 (quoting 21 U.S.C. § 387k(a)), and defines such a product in terms of its intended use, as a product "'sold or distributed for use to reduce harm or risk of tobacco-related disease.'" *Ibid*. (quoting 21 U.S.C. § 387k(b)(1)). This

intended use of a tobacco product is determined from claims made on labeling and advertising, as well as other claims the manufacturer directs to consumers that would reasonably be expected to cause consumers to believe the product presents reduced risk. *Id*. at 2-3 (quoting 21 U.S.C. § 387k(b)(2)(A)).

Plaintiffs get matters backwards when they urge that the purpose of pre-market review is to block "truthful[]" information. Pl. Br. 28. The D.C. Circuit rejected precisely such a contention in *Whitaker*, where the manufacturer claimed that the pre-market approval requirement barred a "true and non-misleading statement about its [product's] salutary effects." 353 F.3d at 952. The purpose of pre-market review is to evaluate the manufacturer's evidence that the product will, in fact, achieve its claimed purpose. R.65 at 15 (citing 21 U.S.C. § 387k(b)(1)). Plainly, Congress can require that tobacco companies — like pharmaceutical companies — make this evidentiary showing. Senator Merkley observed that it was "frankly unbelievable that while we heavily regulate the production and sale of aspirin, a product that is not addicting and not destructive, tobacco, which is addictive and is destructive, goes without regulation." 155 Cong. Rec. S5999 (June 3, 2009).

Contrary to plaintiffs' contention (Pl. Br. 36, 46-47), it is permissible for FDA to consider population-wide effects in determining whether an ostensible reduced-risk product actually will reduce risk. R.65 at 21-22 (discussing statutory criteria that

FDA must consider in evaluating an application to market a reduced-risk tobacco product). There is no constitutional right to market a product that, on balance, would be detrimental to the public health, and the FDCA "generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'" *Brown & Williamson*, 529 U.S. at 134 (citation omitted).

The need for pre-market FDA review of the scientific evidence supporting claims of reduced risk is illustrated by plaintiffs' assertion that smokeless tobacco products present reduced health risks relative to cigarettes. Pl. Br. 10-11. To support their claim of reduced risk, plaintiffs cite the testimony of a Reynolds executive who admitted at the preliminary-injunction hearing that Reynolds has not publicly disclosed the results of its own smokeless tobacco research. 10/8/09 Tr. 64 (Swaugert); *compare Altria*, 129 S. Ct. at 550 n.14 (tobacco companies failed to disclose their research "showing that [machine] test results do not reflect the amount of tar and nicotine that consumers of 'light' cigarettes actually inhale"). Plaintiffs also cite the declaration of their expert, Dr. Rodu, who admitted that his research is financed by tobacco companies including Reynolds.[9]

[9] R.72-1 ¶17 (Rodu); http://www.smokersonly.org ("Financial Support")

The purpose of pre-market FDA review is to determine whether such reduced-risk claims are truthful and not misleading. Although Dr. Rodu asserts that smokeless tobacco products will help smokers "quit using cigarettes altogether," R.72-1 ¶6, that claim has not been the subject of any rigorous independent review. Moreover, the marketing of smokeless tobacco products in ways that increase and reinforce cigarette addiction is emerging as a significant threat to public health. *See*, *e.g.*, Tomar, S., *et al*., "Patterns of dual use of cigarettes and smokeless tobacco among US males," 19 Tobacco Control 104, 108 (Dec. 2009). "The major US cigarette companies now control nearly the entire US smokeless tobacco market and aggressively promote dual product use, which may portend a lessening in the decline in smoking, increased dual use, perpetuation of dependence and continued high levels of tobacco related death and disease." *Ibid*. One study indicated that Marlboro "snus," a smokeless tobacco product marketed in the United States, delivers less nicotine than "snus" sold in Sweden and thus "will leave the smoker craving for a cigarette." Foulds, J. & Furberg, H., "Is low-nicotine Marlboro snus really snus?," 5 Harm Reduction Journal 5:9, at 3 (Feb. 2008). Many smokeless tobacco products are explicitly "marketed to smokers as a way to sustain their addictions in places where smoking is no longer allowed." 155 Cong. Rec. S6149 (June 4, 2009) (Sen. Durbin). Reynolds' website "boasts that 'snus can be enjoyed almost anywhere, regardless of growing smoking

bans and restrictions,'" *ibid*., and the motto of its retail store ads is "Pleasure For Wherever." R.98-1 at A1.

These concerns are underscored by evidence that "youth are encouraged to experiment with low-nicotine starter products and subsequently graduate to higher-level nicotine brands or switch to cigarettes as their tolerance for nicotine increases." 155 Cong. Rec. S6000 (June 3, 2009) (quoting 2003 Statement of Surgeon General Carmona); *see also* 149 Cong. Rec. E1148 (June 5, 2003) (letter from Rep. Waxman). As Dr. Rodu observes, "[m]odern smokeless tobacco products can be used invisibly anytime and anywhere, much like a breath mint."[10] Because they require no spitting, they escape detection in the school environment. Senator Merkley noted that the original container for Camel "snus" was round, "but teachers in school noticed these containers in their students' pockets." 155 Cong. Rec. S5999 (June 3, 2009). Reynolds redesigned the packages to resemble cell phones "so that teachers can't recognize that these are smokeless tobacco products in their students' pockets." *Ibid*. In stores, Camel "snus" is "advertised next to displays of candy and Peppermint Patties." *Ibid*. Senator Merkley explained that a "teenager who tries one of these products — whose brain is still being wired and, therefore, is much more susceptible to the influence of nicotine — is much more likely to become addicted

[10] http://www.smokersonly.org

and become a lifelong customer or reliable customer. That is why the tobacco companies are marketing tobacco candy to our children." *Ibid*.

3. The pre-market review requirement is readily sustained under *Central Hudson*.

As discussed above, the statutory provision that requires pre-market FDA review of tobacco products that purport to present reduced health risks parallels the longstanding FDCA regime applicable to drugs and devices, and its use of promotional claims to determine a product's intended use is consistent with the First Amendment. *Whitaker*, 353 F.3d at 953; R.100 at 29-30. The provision is also easily sustained under the framework established in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), for review of restrictions on commercial speech. *See* R.65 at 11-25.

"The First Amendment's concern for commercial speech is based on the informational function of advertising." *Central Hudson*, 447 U.S. at 563. Consequently, there is no protection for "commercial messages that do not accurately inform the public about lawful activity" or relate to illegal activity. *Id*. at 563-64. If the communication is neither misleading nor related to unlawful activity, the government may impose restrictions that directly advance a substantial government interest and are no more extensive than is necessary to serve that interest. *Id*. at 566.

That standard does not require the legislature to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Ibid*.; *accord Pagan v. Fruchey*, 492 F.3d 766, 771 (6th Cir. 2007) (*en banc*).

Plaintiffs argue (Pl. Br. 28-32) that "strict scrutiny" applies to the subpart of the statutory definition that includes as evidence of a tobacco product's intended use statements that a manufacturer "direct[s] to consumers through the media or otherwise ... respecting the product" that would be reasonably expected to cause consumers to believe that the product presents a reduced risk. 21 U.S.C. § 387k(b)(2)(A)(iii). Plaintiffs contend that a manufacturer's claims about its product are not commercial speech if they are directed to consumers through media such as press releases, booklets, or television appearances. Pl. Br. 29.

This contention has "no basis in either fact or law." R.65 at 12. "Speech need not closely resemble a typical advertisement to be commercial." *Ibid*. (quoting *Semco, Inc. v. Amcast, Inc*., 52 F.3d 108, 112 (6th Cir. 1995)). And tobacco companies relied for decades on false claims directed at consumers through press releases, booklets, and television programs. *Philip Morris*, 566 F.3d at 1116, 1121,

1128 (providing examples). These claims were commercial speech because they were made for the "purpose of obtaining cigarette proceeds." *Id*. at 1116.

The fact that statements may "discuss cigarettes generically without specific brand names, or link cigarettes to an issue of public debate, does not change the commercial nature of the speech." *Id*. at 1144 (citing *Bolger v. Youngs Drug Products Corp*., 463 U.S. 60, 66 n.13, 67-68 (1983)); *see also* R.65 at 19. Nor does it matter if the manufacturer is addressing an issue of public health. In *Bolger*, for example, the Supreme Court held that pamphlets highlighting the importance of condom use — including one titled "Plain Talk about Venereal Disease" — were commercial speech because they were disseminated by a condom manufacturer whose name was mentioned only on the bottom of the last page of the pamphlets. 463 U.S. at 62 n.4.

Plaintiffs are wrong to characterize the pre-market review requirement as "viewpoint discrimination." Pl. Br. 32. The Act does not "proscrib[e] a viewpoint"; it requires that manufacturers "go through a process of having their regulated product approved for sale as 'modified risk' before making untested claims about the relative health benefits of that product." R.100 at 32. The government "has a substantial interest in protecting consumers from misleading tobacco industry claims about allegedly reduced risk products." R.65 at 13; Legislative Findings 36-37, 40. And

Congress determined that pre-market FDA review is the "*only way* to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products." R.65 at 18 (quoting Legislative Finding 43).

Plaintiffs provide no basis for a court to reject Congress's determination. Plaintiffs argue that the government should ensure the accuracy of a manufacturer's reduced-risk claims through after-the-fact fraud enforcement rather than pre-market FDA review. Pl. Br. 40. But even if the industry had no history of making false health claims, after-the-fact enforcement comes too late for the addicted consumer. Given the tobacco industry's history of "making false or misleading statements to promote the sale of cigarettes," *Philip Morris*, 566 F.3d at 1120, Congress was not required to rely on measures "tried and found wanting." R.65 at 18.

Plaintiffs assert that the government's interest would be served by requiring "disclaimers" on tobacco products that are promoted as reduced risk. Pl. Br. 39. But Congress "expressly rejected the idea that requiring disclaimers for modified risk tobacco products would be effective, citing the Federal Trade Commission's determination that 'consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.'" R.65 at 18-19 (citing Legislative Findings 41 & 42). Although, in *Pearson v. Shalala*, 164 F.3d 650

(D.C. Cir. 1999), the D.C. Circuit concluded that disclaimers would suffice to protect consumers from inaccurate health claims about certain dietary supplements, the court stressed that those supplements did not "in any fashion *threaten* consumer's health and safety," and distinguished drugs because "the potential harm presumably is much greater." *Id*. at 656 & n.6.[11]

4. Plaintiffs' cases are inapposite.

Plaintiffs rely on two lines of cases, both inapposite here. In the first, the Supreme Court invalidated advertising bans that applied to uncontroversial factual information, such as information about a product's price or availability for sale. *See* R.65 at 17 (discussing *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748 (1976) (price of drugs); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (price of alcohol); and *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) (availability of compounded drugs)); *see also BellSouth v. Farris*, 542 F.3d 499, 500, 504-05 (6th Cir. 2008) (provision that barred telecommunications providers from identifying a state tax on their bills).

[11] Plaintiffs incorrectly suggest (Pl. Br. 40) that their position finds support in regulations applicable to prescription drug advertising. The cited regulations apply to drugs that already have FDA approval — not to unapproved drugs.

By contrast, the provision at issue here "targets *misleading* commercial speech by requiring" FDA to assess "whether a tobacco product promoted as reduced risk actually reduces health risks associated with tobacco use." R.65 at 17. "In the context of regulated drugs and other such products ... the determination of whether a particular claim is misleading inherently depends on many things, including scientific evidence about the product, the intended consumers' use of the product, and the ability of would-be consumers to recognize that narrowly true health or risk claims may only be narrowly true." *Id*. at 15. "The Supreme Court's skepticism of statutes founded on the 'paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely' is therefore inapplicable here." *Id*. at 17 (quoting *44 Liquormart*, 517 U.S. at 497).[12]

Plaintiffs' second line of cases concerns the procedural protections required when the government imposes a "prior restraint" on films, books, or other core protected speech. Pl. Br. 45-48. The district court correctly explained that those cases provide no support for plaintiffs' position here. R.65 at 20-25, R.100 at 30-33.

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[12] Plaintiffs assert that a claim that a product is chemical- or additive-free "only appeals to consumers who prefer organic products for environmental or other reasons and is *not* perceived by any consumer to convey a health benefit." Pl. Br. 34. The Canadian Supreme Court, however, found that tobacco companies use "additive free" claims to "convey the impression that the products are wholesome and healthful," despite evidence showing these products "are in fact no safer than other tobacco products." *J.T.I. Macdonald*, 2007 SCC 30, ¶61.

The Supreme Court has indicated that traditional prior restraint doctrine may not apply to commercial speech. R.65 at 20 (citing *Central Hudson*, 447 U.S. at 571 n.13). But even if it applies, it requires only that a restraint be a narrowly tailored means of advancing a substantial governmental interest.

Thus, when the Second Circuit considered the argument that a 540-day period for FDA review of dietary-supplement claims was an unconstitutional prior restraint, the court applied the same test "that the Supreme Court regularly applies to commercial speech," asking "'whether the regulation ... is not more extensive than is necessary to serve [the asserted governmental] interest.'" *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 228 (2d Cir. 1998). The court upheld the 540-day period "given the need to protect consumers before any harm occurs," to "evaluate the evidence in support of labeling claims," and to develop "a record on the matter so that a court can determine whether the regulated speech is, in fact, truthful and non-misleading." *Ibid*.

FDA announced in guidance that it intends to act on application to market a reduced-risk tobacco product within 360 days. *See* R.100 at 30. Although FDA guidance is not binding, *ibid*., the Administrative Procedure Act requires federal agencies to pass upon matters presented to them "within a reasonable time," 5 U.S.C. § 555(b), and authorizes reviewing courts to "compel agency action unlawfully

withheld or unreasonably delayed," *id*. § 706(1). *See* R.100 at 31. Plaintiffs have not even filed an application to market a reduced-risk tobacco product and thus cannot assert agency delay.

The district court correctly rejected plaintiffs' contention that FDA has unfettered discretion to deny such an application, explaining that the criteria for evaluating an application are set out in the statute. R.65 at 21-22. As noted, these criteria require FDA to consider evidence that an ostensible reduced-risk product will reinforce existing addiction or addict new users. *See* pp.36-40, *supra*. Considerations of this sort are a familiar feature of the drug approval scheme, and bear no resemblance to *United Food & Commercial Workers Union v. Southwest Ohio Regional Transit Authority*, 163 F.3d 341, 346 (6th Cir. 1998), where this Court affirmed a preliminary injunction barring a transit authority from rejecting a pro-union advertisement "on the grounds that the ad was too controversial and not aesthetically pleasing." *Id*. at 346; R.100 at 33.

Plaintiffs wrongly assert (Pl. Br. 43) that Congress cannot place the burden on manufacturers to produce evidence to support an application to market a tobacco product as one that presents a reduced health risk. Drug manufacturers must produce evidence to support an application to market a new drug. *See* 21 U.S.C. § 355. Congress certainly can require that tobacco companies — which have long concealed

their unfavorable research from regulators, *see Altria*, 129 S. Ct. at 550 n.14; *Philip Morris*, 566 F.3d at 1124 — make a comparable evidentiary showing.

C. The District Court Erroneously Invalidated 21 U.S.C. § 331(tt) Due To The Court's Mistaken View That The Provision Applies To Non-Commercial Actors.

A related provision of the Act bars "any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that ... (4) the product is safe or less harmful by virtue of — (A) its regulation or inspection by the [FDA]; or (B) its compliance with regulatory requirements set by" the FDA. 21 U.S.C. § 331(tt)(4). The district court invalidated this statutory provision because the court mistakenly interpreted the provision to apply to non-commercial (as well as commercial) actors. R.100 at 34-35.

The government respectfully urges that this ruling be reversed. Even if Section 331(tt)(4) did extend to non-commercial actors, that would not provide basis for invalidating the provision on its face or as applied to commercial actors like plaintiffs. *Wash. State Grange*, 552 U.S. at 449-50 (facial challenge standard).

Moreover, it is clear from the statutory context that Congress did not intend to reach non-commercial actors such as "news organizations" or "politicians." R.100 at 34. The statutory findings cite the concern that "manufacturers" will mislead or

confuse consumers with claims based on FDA regulation, Legislative Finding 46, and the language of Section 331(tt) tracks the language of the modified-risk provision: it applies to statements "directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising." Section 331(tt) is thus properly interpreted to reach the same commercial actors. Indeed, three of the four listed methods of communication — labels, labeling, and advertising — are used by commercial actors only. The inclusion of "media" in this series must be informed by the surrounding terms. *Hall Street Associates, L.L.C. v. Mattel, Inc.*, 552 U.S. 576, 586 (2008) ("when a statute sets out a series of specific items ending with a general term, that general term is confined to covering subjects comparable to the specifics it follows"); *United States v. Stevens*, 130 S. Ct. 1577, 1588 (2010) ("an ambiguous term may be 'given more precise content by the neighboring words with which it is associated'"). And it is a "cardinal principle" of statutory interpretation that a court will construe a statute so as to avoid raising a serious a constitutional issue. *Zadvydas v. Davis*, 533 U.S. 678, 689 (2001).[13]

[13] In a footnote, the district court questioned whether other subparts of Section 331(tt) that plaintiffs do not challenge would suffice to advance the government's interest. R.100 at 35 n.9. Absent subpart 4, however, a manufacturer could circumvent the pre-market review requirement for products claimed to present a reduced health risk by asserting that FDA regulation makes its product safe or less harmful.

III. The Act Properly Restricts Advertising And Marketing Techniques That Are Particularly Attractive To Minors.

Congress directed FDA to reissue three provisions of its 1996 rule that target advertising and marketing techniques used by the tobacco industry to recruit new underage customers. These provisions are narrowly tailored to advance the government's compelling interest in curbing underage tobacco use.

A. The Government Has A Compelling Interest In Curbing Underage Tobacco Use.

"Virtually all new users of tobacco products are under the minimum legal age to purchase such products." Legislative Finding 4. Moreover, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Legislative Finding 31. "[D]ecades of experience in tracking tobacco use show that if people do not begin to use tobacco as youngsters, they are highly unlikely to initiate use as adults." Institute of Medicine, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," at 5 (1994) ("1994 IOM Report").

Plaintiffs cannot obscure this central fact by declaring that "[a]dults consume more than 98% of all tobacco products sold in this country." Pl. Br. 1. The critical point is that the vast majority of these adults began using tobacco while still in their

teens. The President's Cancer Panel emphasized that "80 percent of adult smokers became addicted to tobacco at or before the age of 18 years." 2007 President's Cancer Panel Report, at 64; *see also Philip Morris*, 449 F. Supp. at 562 ("over 80% of smokers start smoking before they turn eighteen"); *J.T.I. MacDonald*, 2007 SCC 30, ¶14 (Canadian Supreme Court) ("Most smokers begin as teenagers, between the ages of 13 and 16.").

Plaintiffs wrongly suggest that underage tobacco use is a vanishing phenomenon. Pl. Br. 14 (citing the 2007 IOM Report). Although the 2007 IOM Report predicted that *overall* smoking prevalence will decline in the future, the projected decline does not represent a drop in youth smoking but rather is a consequence of demographics, because the current smoking population is weighted toward "middle-aged and older smokers." 2007 IOM Report, at 6-7. And while youth smoking has declined over time, the rate of decline has slowed in recent years. *See* Centers for Disease Control, "Cigarette Use Among High School Students" (July 9, 2010).[14] As of 2009, 19.5% of students in grades 9-12 reported current cigarette use. *Ibid*. In other words, nearly one out of five high school students smoke.

Recent data show that initiation rates for smokeless tobacco rose between 2002 and 2007 for males aged 12 to 17. National Survey on Drug Use and Health,

[14] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm

"Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007," at 3 (2009). As of 2009, an estimated 15% of high school males were using smokeless tobacco. *See* Centers for Disease Control Fact Sheet, Youth Risk Behavior Surveillance, at 69 (Table 32) (June 4, 2010).[15] Moreover, as discussed above, the major U.S. cigarette companies now control nearly the entire U.S. smokeless tobacco market and aggressively promote the dual use of cigarettes and smokeless tobacco. *See* pp.38-40, *supra*.

Plaintiffs cannot dispute that "the endemic level of youth smoking remains disturbingly high." 2007 IOM Report, at 54. "*Every day*, approximately 4,000 children under age 18 experiment with cigarettes for the first time; another 1,500 become regular smokers. Of those who become regular smokers, *about half eventually will die from a disease caused by tobacco use*." 2007 President's Cancer Panel Report, at 64 (emphasis added).

[15] http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf

B. Congress's Directive To FDA To Promulgate Particular Restrictions On Color And Imagery In Tobacco Advertising Is Narrowly Tailored To Advance The Government's Interest.

1. Congress properly responded to the tobacco industry's practice of targeting advertising to minors.

"The tobacco industry has a long and disturbing history of marketing its products to appeal to young people." 155 Cong. Rec. S5988 (June 3, 2009) (Sen. Lincoln). "In 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use." Legislative Finding 16. "Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Legislative Finding 15.

"Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market." Legislative Finding 24. For example, an internal Philip Morris memorandum quoted in part by Senator Durbin explained that it was "important" for tobacco manufacturers "to know as much as possible about teenage smoking patterns and attitudes. Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens." 155 Cong. Rec. S6007 (June 3, 2009); 144 Cong. Rec.

S5148 (May 19, 1998). Internal documents of plaintiff Reynolds reflect "a company policy that in order to grow and ensure a profitable future, the company must develop new brands that would appeal to and capture a share of the youth market. These young people were described as 'presmokers' and 'learners' in RJR marketing language and were identified as being 14 to 18 year olds." 61 Fed. Reg. 44480.

Tobacco industry documents reviewed in *United States v. Philip Morris* confirmed that "the major United States cigarette companies continue to target and market to youth." Legislative Finding 47 (citing the district court decision). Tobacco companies have "spent enormous resources tracking the behaviors and preferences of youth under twenty-one, and especially those under eighteen." *Philip Morris*, 449 F. Supp. 2d at 580; *see also id*. at 607-16 (internal Reynolds documents); *id*. at 594-598 (internal Lorillard documents). Reynolds tracked the attitudes, preferences, and smoking habits of fourteen to seventeen year olds because, as an internal marketing report explained, the "young adult market, the 14-24 age group" would constitute "a key share of the total cigarette volume — for at least the next twenty-five years." *Id*. at 610; *see also id*. at 612-13 (describing a series of reports entitled "Teenage Smokers (14-17) and New Adult Smokers and Quitters," which analyzed survey data relating to "the smoking behavior of fourteen to seventeen year old smokers").

2. The industry attracts minors with peripheral cues and irrational associations.

The industry's campaign to attract minors is not waged with tools of rational persuasion that invoke the "merits" of taking up tobacco use. Instead, the industry relies on peripheral cues and irrational associations to distract would-be users from the fact that tobacco products are lethal and addictive. The aim, Reynolds acknowledged internally, is to convince a person "with *wholly irrational reasons* that he should try smoking." 61 Fed. Reg. 44480 (quoting Teague, C., Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein (1972)) (emphasis added). Thus, the goal of the advertising is to persuade a person to "start to smoke for purely psychological reasons," such as "to emulate a valued image," "to conform," "to experiment," "to defy," or "to be daring." *Ibid*. (quoting the Teague memo).

This technique is particularly effective with the underage population, which is especially unlikely to appreciate the tenacity of nicotine addiction and, thus, the long-term consequences of tobacco use. *See* pp.26-28, *supra*. "Children are more influenced by tobacco marketing than adults," Legislative Finding 15, because they are "'more susceptible to influence from peripheral cues such as color and imagery' because they have less 'motivation and ability to "elaborate" upon the arguments (pay

attention to and think about the factual information).'" R.100 at 9 (quoting 61 Fed. Reg. 44468). Moreover, "'smoking experimentation commonly occurs at transition points in adolescence when there is a threat to a teen's emerging self-concept.'" *Ibid*. (quoting 1994 IOM Report, at 119). "Teenagers are typically less secure in their identities" and "more subject to social pressure and more attuned to advertising than most groups in the population." 1994 IOM Report, at 119. "[T]eens who admire the attributes depicted by smokers in ads are also more likely to intend to smoke in the future," and "[i]n order to acquire selected attributes of model smokers, adolescents may be motivated to use tobacco, even when they view smoking as negative." *Ibid*.

Accordingly, "'[f]rom the standpoint of the initiation of smoking by youth, the most important feature of tobacco advertising is its noninformational characteristics.'" R.100 at 10 (quoting 2007 IOM Report, at 322). "The images used in tobacco marketing associate smoking with lifestyles and experiences that appeal to young people, and these positive associations tend to displace or override risk information in adolescent decision making." 2007 IOM Report, at 322. "The most compelling data are those that link positive feelings toward smoking with exposure to tobacco advertising and to ownership of commodities with tobacco company logos and paraphernalia." *Ibid*. Color is used to convey a mood — such as red for passion and power, green for harmony and health — and to circumvent other advertising

restrictions. 2008 NCI Report, at 64-65; 2007 IOM Report, at 297. Senator Lincoln observed that the tobacco industry "reaches our kids by saturating convenience stores, drugstores, and gas stations with tobacco advertisements, often placing ads and products near the candy and gum displays, or using other visual tricks such as bright colors and also through sponsorship of sports and entertainment events which are obviously what kids are interested in." 155 Cong. Rec. S5988 (June 3, 2009).

Although the tobacco industry spent more than *$13 billion* in 2005 to promote its products, *see* Legislative Finding 16, plaintiffs assert that tobacco advertising has no material effect on underage use, Pl. Br. 52-54, and insist that the industry's sole objective is "competing for existing adult tobacco consumers." *Id*. at 3. In other words, they claim that the industry has no interest in attracting new customers.

The "long-standing industry position ... that advertising does not create new demand but rather affects the market share among existing smokers" has been thoroughly discredited. 2007 IOM Report, at 321. "Smokers are ... known to be extremely brand loyal, so the brand choice of consumers during the early stages of their smoking 'careers' becomes crucial." 2008 NCI Report, at 57. Reynolds admitted internally that "[t]he brand loyalty of 18-year-old smokers far outweighs any tendency to switch with age." 61 Fed. Reg. 44481 (quoting Diane Burrows, R.J.

Reynolds Tobacco Company, Younger Adult Smokers: Strategies and Opportunities (1984)).

"'Overwhelming'" evidence reviewed in *United States v. Philip Morris* showed that the tobacco industry has "'exploit[ed] adolescents' vulnerability to imagery' through advertisements placed in magazines, on billboards, at retail points of sale, and 'in other venues that historically and currently reach millions of teens.'" R.100 at 9-10 (quoting 449 F. Supp. 2d at 571). After examining industry documents over the course of a nine-month trial, the court found that "'[t]he *central purpose* of the tobacco companies' image advertising is motivating adolescents to smoke.'" *Id*. at 10 (quoting 449 F. Supp. at 572) (emphasis added).

The impact that tobacco advertising has on underage tobacco use is equally well documented. 2007 IOM Report, at 321. Even without the benefit of recent research, the Supreme Court found that advertising restrictions would directly advance the goal of reducing underage tobacco use. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556-61 (2001). Since then, scientific evidence documenting the relationship between advertising exposure and underage tobacco use has accumulated. 2007 IOM Report, at 321. A 2006 report compiled and analyzed 51 studies in peer-reviewed journals that "assessed a link between ... tobacco use outcomes ... and tobacco marketing ... and media." Wellman, *et al*., "The Extent to

Which Tobacco Marketing and Tobacco Use in Films Contribute to Children's Use of Tobacco," 160 *Archives of Pediatrics & Adolescent Medicine* 1285, 1286 (2006) (discussed in H.R. Rep. No. 111-58(I), at 33 (2009)). The Wellman report found that "the odds of becoming a tobacco user are *more than doubled* by exposure to marketing and media. This relationship is robust, with similar effects observed across time in different countries, in cross-sectional and prospective designs using a variety of measures of exposure, and whether the outcome is initiation or tobacco use status." *Id.* at 1291 (emphasis added).

The National Cancer Institute likewise reported that exposure to advertising causes adolescents to begin smoking or move to smoking on a regular basis, and that "'even brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking as well as their intentions to smoke.'" H.R. Rep. No. 111-58(I) (quoting 2008 NCI Report, at 211); *see also* H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th Cong. 42 (2007) (2007 study found that "the more cigarette marketing teens are exposed to in retail stores, the more likely they are to smoke").

Adolescents' choice of brands reflects the extent of brand promotion: more than 80% of youth smoke the three most heavily advertised cigarette brands.

Legislative Finding 23; 61 Fed. Reg. 44482. One study found that high-school students' "cigarette brand preferences correlated with the brands most heavily advertised in the convenience stores within a one-mile radius of their schools." 2008 NCI Report, at 132.

In short, "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Legislative Finding 15.

3. The restrictions on color and imagery are crafted to reach noninformational advertising techniques that have been used to attract children and adolescents to tobacco use.

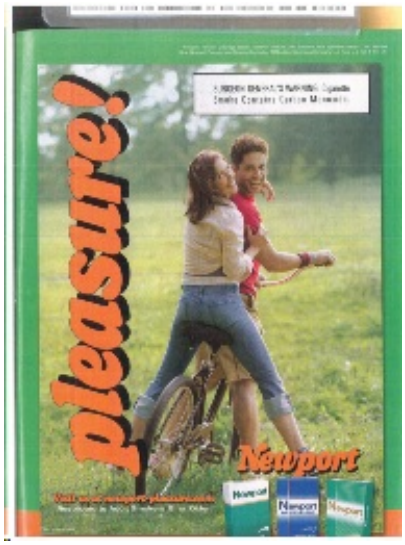
On the basis of this substantial body of evidence, Congress directed FDA to reissue the provision of the 1996 rule that restricts the use of color and imagery in tobacco advertising. *See* 21 C.F.R. § 1140.32(a) (2010) (reissued rule). The restriction does not apply to advertising that appears in an adult publication, defined as a publication read by fewer than 2 million persons under 18 and whose underage readers constitute 15 percent or less of the total readership. It does not affect the packaging of tobacco products.

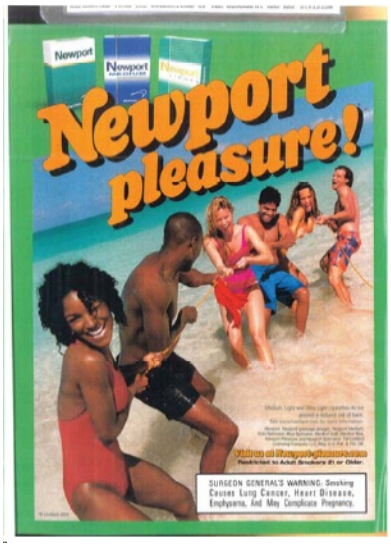
The district court recognized that overwhelming evidence shows that the tobacco industry has "'exploit[ed] adolescents' vulnerability to imagery' through

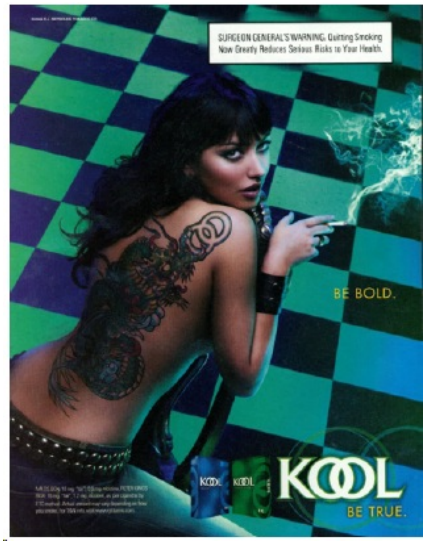
advertisements placed in magazines, on billboards, at retail points of sale, and 'in other venues that historically and currently reach millions of teens.'" R.100 at 9-10 (quoting 449 F. Supp. 2d at 571). The Canadian Supreme Court likewise concluded that "much of the industry's advertising is in fact aimed at youth, and that persuading teenagers to take up smoking was a calculated and deliberate industry advertising strategy." *J.T.I. Macdonald*, 2007 SCC 30, ¶74.

The "Camel Farm" ad campaign run by plaintiff Reynolds is illustrative. (R.80-4, at B-17.) "Under a blue sky in a pastoral Eden, roosters hitch rides on floating tractors, speakers grow out of the ground, and radios fly. This is in a world where the natural laws do not obtain, where cancer and serious health problems can cease to exist. For a product known to cause both, such a world is a potent sales device." *Washington v. R.J. Reynolds Tobacco Co.*, 211 P.3d 448, 453 (Wash. Ct. App. 2009).

This form of advertising "does nothing to 'assur[e] informed and reliable decisionmaking.'" R.100 at 8-9 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977)). Instead, it "purposefully creates meaningless associations between tobacco products and attractive lifestyles," *ibid*., suggesting that tobacco use forms part of a desirable lifestyle that includes activities such as mountain biking, tug-of-war, and sex:







R.70-1 at 10, 13. Plaintiffs' expert admitted as much in recounting the survey data on cigarette ads. He explained: "When asked to indicate what they thought the advertiser was trying to communicate with the image in the ad, respondents generally suggested 'fun' and 'relaxation.' For one of the three cigarette ads examined a number of respondents also mentioned 'sex' (37%)." R.71-5, ¶70 (Faber).

Tobacco imagery thus seeks to distract potential users from the fact that tobacco products are lethal and addictive, and to suggest that tobacco is a harmless indulgence akin to designer clothing and perfume. Indeed, plaintiffs' expert stressed the similarities between imagery in tobacco advertising and imagery used for such innocuous consumer goods and provided this side-by-side comparison (R. 71-5 ¶71 (Faber)):[16]

[16] Additional examples of tobacco imagery are reproduced in Dr. Krugman's affidavit. *See* R.70-1 & R.70-2.

4. The district court erred in concluding that there should be additional exceptions to the restriction on color and imagery.

The restriction that Congress directed FDA to place on the use of color and imagery targets the very practices that have been exploited for years by tobacco manufacturers seeking to attract underage customers. The restriction does not constrain a manufacturer's ability to communicate product information through text. And it does not apply to publications with fewer than 2 million underage readers and whose underage readers comprise 15 percent or less of the total readership. 21 C.F.R. § 1140.32(a). It is conceded that plaintiffs Lorillard, Commonwealth Brands, and American Snuff refrain from placing *any* tobacco advertising — including text advertising — in publications that do not meet these standards.[17] That fact alone is strong evidence of the provision's narrow tailoring.

The district court mistakenly believed that Congress's objective would be served by an even narrower restriction. The court suggested that "Congress could have exempted large categories of innocuous images and colors — e.g., images that teach adult consumers how to use novel tobacco products, images that merely identify products and producers, and colors that communicate information about the nature of

[17] *See* R.71-10 ¶21 (Lorillard); R.71-14 ¶12 (American Snuff); R.71-13 ¶25 (Commonwealth Brands).

a product, at least where such colors and images have no special appeal to youth." R.100 at 15.

Even if such exemptions would not undermine Congress's objective, there would be no basis for invalidating the restriction on color and imagery on its face. Facial challenges are "disfavored" and cannot succeed unless "the law is unconstitutional in all of its applications" or has no "plainly legitimate sweep." *Wash. State Grange*, 552 U.S. at 449-50.

Moreover, it is clear that such exemptions would easily be exploited by the tobacco industry. For instance, the court suggested that "illustrations such as Reynolds' depiction of how its new Camel Crush menthol product works" were not "part of what Congress found to be problematic associative advertising techniques aimed at minors." R.100 at 14. That advertisement, reproduced at right (R.71-8 at 11), offers a brightly colored and stylized depiction of a new cigarette that seeks to convey a sense of excitement about the new product. The ad forms part of an

elaborate marketing campaign in which the product is promoted as an opportunity to "Have a Two-Some." R.71-17, at 4. The ad's informational content is minimal; it is difficult to discern from the advertisement how the product actually works. If such advertisements were permissible, the tobacco industry could easily devise other advertisements that ostensibly illustrate features of new tobacco products while using color and imagery to appeal to youth. Indeed, the development of novel smokeless products attractive to children is emerging as a major threat to public health, given the candy-like appearance of products like Reynolds' Orbs:

(Harvard School of Public Health)

http://consumerist.com/2010/04/tic-tacs-or-tobacco-study-says-camel-orbs-look-too-sweet.html

The experience of the various States with the Master Settlement Agreement ("MSA") confirms the importance of closing all loopholes. Although the MSA bars "any action, directly or indirectly, to target Youth . . . in the advertising, promotion or marketing of Tobacco Products," MSA, § III(a), tobacco companies "dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the [MSA]." Legislative Finding 48. The companies "began to evade and at times even violate the MSA's prohibitions almost immediately after signing the agreement" and "continued to commit violations ... well after the execution of the MSA." *Philip Morris*, 566 F.3d at 1133. Indeed, "Reynolds was *more* likely to advertise in magazines known to have a higher level of exposure to youth than before the MSA was signed," *California ex rel. Lockyer v. R.J. Reynolds Tobacco Company*, 116 Cal. App. 4th 1253, 1259 (Cal. Ct. App. 2004) (emphasis added), and it has repeatedly been found in violation of the MSA's youth marketing provisions. *See*, *e.g.*, *Washington v. R.J. Reynolds Tobacco Company*, 211 P.3d 448 (Wash. Ct. App. 2009) (youth-oriented advertisement in Rolling Stone); *Ohio ex rel. Petro v. R.J. Reynolds Tobacco Company*, 820 N.E.2d 910 (Ohio 2004) (distribution of branded merchandise); *California ex rel. Lockyer v. R.J. Reynolds Tobacco Company*., 107 Cal. App. 4th 516 (Cal. Ct. App. 2003) (outdoor advertising); *Arizona ex rel. Goddard v. R.J. Reynolds Tobacco Company*, 75 P.3d

1075 (Ariz. Ct. App. 2003) (same). State court litigation over the imagery used in Reynolds' "Camel Farm" ad campaign (*see* p.61, *supra*) has taken years and produced mixed results. *See In re Tobacco Cases I*, 2010 WL 2573199, at *4 n.3 (Cal. Ct. App. June 29, 2010) (collecting cases).

Congress was not required to replicate a scheme that is demonstrably subject to evasion. Ample evidence supports Congress's determination that a "less restrictive and comprehensive approaches have not and will not be effective" in reducing underage tobacco use. Legislative Finding 31.

5. Plaintiffs' "myriad" alternatives do not support their claims.

Plaintiffs' "myriad non-speech-restrictive alternatives" (Pl. Br. 56) provide no basis for second-guessing Congress's determination. The district court explained that plaintiffs' proposals are variations on strategies already adopted, and are notable for the extent to which they would impose substantial new costs on state governments and private persons. R.100 at 37-41. Having already externalized billions of dollars in health care costs, plaintiffs now would have society shoulder significant additional burdens to counter the impact that their billions of dollars of advertising has on youth.

"This is not a case where Congress went 'straight to [plaintiffs'] speech.'" R.100 at 41. Indeed, the reissued rule places *no constraint* on a manufacturer's ability to communicate information about its products through text. It targets

"particular advertising and promotion practices that appeal to youth," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 563 (2001), "while preserving the informational function of advertising." Legislative Finding 28.

"Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry." R.100 at 41. "That decision is eminently reasonable ... since every other tool in the government's arsenal is made less effective and more costly by Plaintiffs' use of advertising to stimulate underage demand." *Ibid*.

Congress has barred sales to persons under age 18, required age verification through age 26, prohibited sales through vending machines, provided civil penalties for retailer violations, directed the Secretary to implement a program to ensure compliance, and required FDA to study the implications of raising the minimum age to purchase tobacco products. *Id*. at 39. Congress and many States discourage underage demand with taxes on tobacco products, but the industry undermines these measures with targeted discounts on tobacco products for price-sensitive populations. *Id*. at 39-40 & n.12.

Plaintiffs assert that Congress should have strengthened the Synar amendment by withholding federal block grants for substance-abuse prevention and treatment

from States that fail to prevent nearly all unlawful retail tobacco sales to minors. *Id*. at 38 & n.11. But imposing punitive sanctions on State governments is "hardly less burdensome." *Id*. at 39. It "would also have dubious impact since there is 'little evidence that increased retailer compliance has had a meaningful impact on the availability of tobacco to minors,'" who "tend to 'shift to social sources' of cigarettes, such as older friends and siblings, 'when commercial sources become problematic.'" *Ibid*. (quoting 2007 IOM Report, at 204).

Plaintiffs contend that Congress should "penaliz[e] youth use by suspending offenders' drivers' licenses." Pl. Br. 57. In other words, plaintiffs are simultaneously developing candy-flavored smokeless tobacco products that evade detection in the school environment, *see* pp.39-40, *supra*, while advocating punishment of underage users unlucky enough to be caught. Contradictions aside, punishing children is not a "less burdensome" alternative to restricting promotional techniques used by the industry to stimulate underage demand. That is not the kind of "narrow tailoring" prescribed by the Supreme Court.

C. The District Court Correctly Sustained The Restrictions On Brand Name Event Sponsorship And Distribution Of Branded Merchandise.

Congress also required FDA to reissue two other provisions of the 1996 rule aimed at marketing techniques that target underage consumers. The district court correctly upheld both provisions.

1. Sponsorship

Congress directed FDA to reissue the provision of the 1996 rule that bars manufacturers from sponsoring athletic, social, and cultural events "in the brand name" of a tobacco product. *See* 21 C.F.R. § 1140.34(c) (2010) (reissued rule). This restriction does not affect a manufacturer's ability to sponsor events in its corporate name. *Ibid*.

Plaintiffs' expert recognized that brand-name sponsorship is used "to creat[e] an association with an event people care about." R.71-5 ¶43 (Faber). Sponsorship "associates tobacco use with exciting, glamorous, or fun events such as car racing and rodeos, and provides an opportunity for 'embedded advertising' that actively creates a 'friendly familiarity' between tobacco and sports enthusiasts, many of whom are children and adolescents." 61 Fed. Reg. 44527; R.100 at 15. Upholding a similar ban, the Canadian Supreme Court explained that "sponsorship promotion is

essentially lifestyle advertising in disguise." *JTI-Macdonald Corp*., 2007 SCC 30, ¶120.

"'[T]he exposure (which includes television broadcasts) that young people have to sponsored events is substantial.'" R.100 at 16. "Even though cigarette advertising is not permitted on television in the United States, tobacco companies continue to receive millions of dollars' worth of national television exposure for their brands through sponsoring sports events such as auto racing." 2008 NCI Report, at 83. At the time of the 1996 FDA rulemaking, it was estimated that more than 64 million children each year were exposed to tobacco-related advertising on television through auto-racing sponsorship. 61 Fed. Reg. 44528; *see also Philip Morris*, 449 F. Supp. 2d at 664. In 1999, "the tobacco industry received over $120 million of television exposure in the United States" through sponsorship of such events. *Philip Morris*, 449 F. Supp. 2d at 665. In 2002, "the total exposure received by RJR of its cigarette brands at televised racing events" was worth "$1.2 billion." *Id*. at 666. "'Sports sponsorship in communities and on television has permitted Winston, Marlboro, Copenhagen, and Skoal to reach large numbers of youth and young adults ... to associate the brands with the allure of racing and rodeo heroes.'" R.100 at 16 (quoting 2008 NCI Report, at 158).

Although the MSA limits brand-name sponsorship, *see* MSA § III(c), tobacco companies have exploited its exemption for one "brand name sponsorship" each year, MSA § III(c)(2)(A), defined to include "a single or multi-state series or tour," MSA § II(j). Tobacco companies actually "increased their sponsorship budgets [after] signing the MSA." *Philip Morris*, 449 F. Supp. 2d at 664. In 2001, three years after the MSA was signed, tobacco sponsorship included Winston's association with NASCAR; Skoal racing teams at National Hot Rod Association events; the Players, Kool, and Marlboro teams at Championship Auto Racing; and Copenhagen booths at Professional Rodeo Cowboys Association and professional bull-riding events. 2008 NCI Report, at 154-55. Annual viewership of tobacco-sponsored races swelled to 513 million in 2001, leading one study to conclude that "cigarette manufacturers have used auto racing sponsorships to successfully circumvent both the ban on televised cigarette advertising and the intent of the [MSA] not to target youth." Morrison, M.A., *et al*., "Inhaling and Accelerating: Tobacco Motor Sports Sponsorship In Televised Auto Races, 2000-2002," 15 Sports Marketing Quarterly 7, 12 (2006).

The district court correctly rejected plaintiffs' contention that there should be an exception to the sponsorship restriction for "adult-only" events. There is "substantial evidence that minors are regularly exposed to tobacco advertising at ostensible adult-only facilities." R.100 at 12. One survey found that nearly half of

Massachusetts youth aged 12-17 (representing over 214,000 teens) were exposed to tobacco advertising at ostensible adult-only facilities. Bogen, K., *et al.*, "Consequences of marketing exceptions in the Master Settlement Agreement: Exposure of youth to adult-only tobacco promotions," 8 Nicotine & Tobacco Research 467, 469 (2006).

Moreover, even if events are attended primarily by adults, "the exposure (which includes television broadcasts) of young people to sponsored events is substantial." 61 Fed. Reg. 44529. "The events themselves offer marketing opportunities for trackside billboards, sampling, hospitality tents, and promotional giveaways, like hats, sunglasses, and programs." *Philip Morris*, 449 F. Supp. 2d at 665. At retail locations including grocery and convenience stores, Reynolds displayed the Winston Motorsports simulator, the Winston or Camel show car, the "well known Winston Cup or Smokin' Joe driver, surrounded by a small army of fans ... complete with autograph session," extensive signage, and an inflatable Winston or Camel cigarette pack that was "an awe inspiring 15 feet tall." *Id*. at 666.

2. Branded merchandise

Congress also directed FDA to reissue the provision of the 1996 rule barring manufacturers from distributing promotional items bearing the name or logo of a tobacco brand. *See* 21 C.F.R. § 1140.34(a) (reissued rule). Studies show that

obtaining branded merchandise "precedes, and reliably predicts, smoking initiation, even when controlling for other factors that have been shown to influence smoking uptake.'" R.100 at 18 (quoting NCI, "Changing Adolescent Smoking Prevalence," at 206 (2001)); *see also* Biener, L. & Siegel, M., "Tobacco Marketing and Adolescent Smoking: More Support for a Causal Inference," 90 Am. J. Pub. Health 407, 409 (2000) (intensive longitudinal study showing that branded merchandise influences smoking receptivity).

Moreover, these items "create a new advertising medium — the 'walking billboard' — which can come into schools or other locations where advertising is usually prohibited." 61 Fed. Reg. 44521. Because such items "'penetrate the young persons' world, they are very effective in creating the sense that tobacco use is widely accepted, which ... is extremely important to children and adolescents.'" R.100 at 19 (quoting 61 Fed. Reg. 44525). The "'ubiquity of such specialty items ... conveys the impression that tobacco use is the norm,'" *ibid*. (quoting 1994 IOM Report, at 10), "'which in turn fosters experimentation with tobacco and smokeless products by young people.'" *Ibid*. (quoting 61 Fed. Reg. 44525) (citing 1994 IOM Report, at 10).

Despite industry claims to distribute branded merchandise to adults only, a Gallup survey found that roughly half of all adolescent smokers, and roughly one quarter of non-smokers, owned at least one item blazoned with the brand name of a

tobacco product. R.100 at 19 (citing 61 Fed. Reg. 44525-26); *see also* 1994 IOM Report, at 110 (similar finding in study of 8,000 children in New York State). FDA determined that "[t]here is no way to limit the distribution of these items to adults only." 61 Fed. Reg. 44525. And even if branded items were "distributed to adults only, this would not prevent the wearers from becoming walking advertisements that would continue to display the attractive imagery," 61 Fed. Reg. 44526 — divorced from the required health warnings.

Plaintiffs assert that Congress should have exempted "matchbooks and key chains." Pl. Br. 55. But in 2000 alone, Reynolds distributed more than *a billion* branded matchbooks. *Ohio ex rel. Petro v. R.J. Reynolds Tobacco Co.*, 820 N.E.2d 910, 913 (Ohio 2004). Its distributor conceded that "for every person who picks up a matchbook, there are 8 other people who typically see it as well." *Ibid*. The Ohio Supreme Court found "matchbooks to be of the same character as key chains, pens, and clothing — items that, because of their usefulness, become tempting billboards for marketers." *Id*. at 918.

IV. The Act's Provisions That Restrict Free Tobacco Product Samples And Gifts To Reward The Purchase Of Tobacco Products Do Not Violate The First Amendment.

The Act generally bars the distribution of free samples of tobacco products. *See* 21 U.S.C. § 387a-1(a)(2)(G). Free samples are "an inexpensive and easily

accessible source of these products to young people," 61 Fed. Reg. 44460, who have been able to "obtain free samples easily" notwithstanding "industry-developed, voluntary codes that supposedly restrict distribution of free samples to underage persons." *Ibid*.; *see also id*. at 45244-45 & nn.1206-1208;1994 IOM Report, at 216-21.

Congress also directed FDA to reissue the 1996 rule barring gifts that reward the purchase of tobacco products. *See* 21 C.F.R. § 1140.34(b) (reissued rule). Notwithstanding tobacco industry claims that these promotions are meant for adults, "many teens report participating in promotional activities." 60 Fed. Reg. 41314, 41336 (1995). One study "found that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash and Marlboro miles." 61 Fed. Reg. 44527.

The district court correctly reasoned that these provisions do not implicate, much less violate, the First Amendment. R.100 at 41-42. Provisions that regulate conduct without a significant expressive element do not implicate the First Amendment, *see Arcara v. Cloud Books, Inc*., 478 U.S. 697, 706-07 (1986), and any minimal speech interest that plaintiffs might assert is far outweighed by the need to curb underage tobacco use.

The free sample provision regulates the distribution of a product, R.100 at 41-42, and there is no constitutional right to distribute free samples of products that are lethal and addictive. The distribution of drugs is strictly controlled under the Controlled Substances Act, which makes it "unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). But for a statutory exemption, tobacco products would "meet the criteria for classification of a Schedule 1 drug." 2007 IOM Report, at 152.

Nor is there a First Amendment right to reward tobacco purchases with "'prizes, such as MP3 players, digital cameras, and prepaid gifts from the Discover Network.'" R.100 at 42 (quoting R.33 ¶¶95, 158 (Amended Complaint)). Such rewards create "an incentive to purchase the tobacco product by reducing the product's real price; the consumer gets the product and the non-tobacco 'gift.'" 60 Fed. Reg. 41336. The Supreme Court has repeatedly made clear that the government may regulate demand and supply through price regulation, characterizing such measures as "non-speech-related" means. *Thompson*, 535 U.S. at 372; *see also 44 Liquormart*, 517 U.S. at 507 (price regulation "would not involve any restriction on speech").

Plaintiffs note (Pl. Br. 59-60) that the Fifth Circuit in *Bailey v. Morales*, 190 F.3d 320 (5th Cir. 1999), held that chiropractors have a First Amendment right to give "rebates, free samples, and risk-free trials." *Id*. at 325. That ruling cannot be squared with the principles set out by the Supreme Court, and certainly cannot extend to the distribution of products that are lethal and addictive.

CONCLUSION

For the foregoing reasons, plaintiffs' First Amendment challenges to various provisions of the Tobacco Control Act should be rejected and all of the challenged provisions should be upheld.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)(7)(B)

I hereby certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times New Roman font, and number of words is 16,263.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of July, 2010, I caused the foregoing brief to be filed and served through the Court's ECF system. All counsel of record are registered ECF users.

/s/ Alisa B. Klein
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* Because the public-record materials that the government filed in district court were too large to be submitted via ECF and are thus not on the electronic docket, the government filed those exhibits on disk with leave of this Court. *See* 3/22/2010 Order. For the Court's convenience, the index to those materials that was filed in the district court is attached.

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