

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION**

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

Plaintiffs, *

v. *

UNITED STATES OF AMERICA; UNITED *
STATES FOOD AND DRUG *
ADMINISTRATION; MARGARET *
HAMBURG, Commissioner of the United States *
Food and Drug Administration; and KATHLEEN *
SEBELIUS, Secretary of the United States *
Department of Health and Human Services, *

Defendants. *

CIVIL ACTION
NO. 1:09CV-117-M

(Electronically Filed)

**MEMORANDUM OF AMICI CURIAE
CAMPAIGN FOR TOBACCO-FREE KIDS, AMERICAN CANCER
SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK,
AMERICAN HEART ASSOCIATION, AMERICAN LEGACY FOUNDATION,
AMERICAN LUNG ASSOCIATION, AMERICAN MEDICAL ASSOCIATION,
AMERICAN PUBLIC HEALTH ASSOCIATION, KENTUCKY MEDICAL
ASSOCIATION, ONCOLOGY NURSING SOCIETY,
AND PUBLIC CITIZEN IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Congress enacted the Family Smoking Prevention and Tobacco Control Act (FSPTCA), Pub. L. No. 111-31 (2009), to address tobacco products' enormously harmful impact on public health and to curtail the practices of the tobacco industry that Congress found contribute directly to that harm. For more than 30 years, tobacco use has been the leading preventable cause of death, disease, and disability in the United States. Tobacco products cause nearly one of every three deaths from cancer and one of every five deaths from heart disease. Congress also found explicitly that the tobacco industry has repeatedly circumvented efforts to rein in the conduct that encourages tobacco use, thereby causing tobacco-related death and disease, and that additional steps were essential.

In this case, the plaintiff tobacco companies challenge eleven provisions of the FSPTCA, primarily on the theory that the provisions violate the First Amendment. The Supreme Court's commercial speech jurisprudence, which balances the free speech rights of commercial actors and the government's responsibility to protect the public, provides the framework for assessing this challenge. The challenged provisions are readily sustained under that framework because they ensure that tobacco purchases are made with a full understanding of the enormous health risks posed by tobacco use and are tailored to curtail the marketing practices used by the tobacco industry to mislead consumers and attract underage customers.

INTEREST OF AMICI

Amici curiae are eleven non-profit public health organizations and consumer advocacy groups that for decades have worked to educate the public about and protect the public from the devastating health and economic consequences of tobacco use. Amici are particularly well qualified to assist the Court in understanding the substantial public interest advanced by the

restrictions challenged here and have broad knowledge about the regulatory schemes implemented by the Food and Drug Administration (FDA). A fuller description of each organization is included in the unopposed motion for leave to file this memorandum as amici curiae, which is being filed concurrently with this memorandum.

ARGUMENT

I. The Challenged Restrictions Regulate Commercial Speech.

Congress enacted the FSPTCA in response to a scientific and medical consensus that tobacco products cause nicotine addiction among children and adults, that they present unparalleled health hazards, and that more must be done to reduce the number of Americans who die from tobacco use. Pub. L. No. 111-31, § 2. This lawsuit challenges the constitutionality of two categories of provisions in the Act. First, the plaintiff tobacco companies challenge restrictions that regulate tobacco advertisements that Congress and experts found have the greatest impact on youth and that mislead and discourage adults from quitting. These restrictions include provisions that prohibit advertisements (except in adult publications and adult-only venues) from using the imagery and color that have the greatest impact on youth, while permitting the tobacco industry to communicate information to adult consumers using black-and-white text ads, Pub. L. No. 111-31, § 102(a);¹ prohibit the promotion of tobacco products using brand-name merchandise and sponsorship of events, *id.*; require FDA review for claims regarding modified-risk tobacco products, *id.* § 101(b) (amending 21 U.S.C. § 911); and prohibit inaccurate and misleading references to whether the FDA has approved tobacco products as safe,

¹Section 102(a) of the FSPTCA incorporates provisions of a 1996 FDA regulation on tobacco products, which had been struck down as outside the agency's jurisdiction at that time. *See* (continued . . .)

id. § 103(b) (amending 21 U.S.C. § 331(tt)). Second, the tobacco companies challenge several provisions mandating new health warnings in advertisements and on product packaging. These provisions require warnings on the top 50 percent of cigarette packaging and images depicting the health consequences of smoking consistent with the growing body of scientific evidence on warning labels. Pub. L. No. 111-31, § 201(a) (amending Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 4(a)).²

Both types of restrictions target mass-market advertisements and product packaging, the self-evident purpose of which is to sell tobacco products. These forms of expression “do[] no more than propose a commercial transaction,” *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976) (internal quotation omitted), and thus fall easily within the definition of commercial speech. *See* Mem. Op. & Order of Nov. 5, 2009, at 11-12 (analyzing restriction on making unapproved modified-risk claims directed to consumers under commercial speech doctrine). Moreover, as discussed below, less traditional forms of marketing covered by the Act, such as branded merchandise and event sponsorship, impact youth percep-

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

² The tobacco companies also challenge restrictions on distributing free samples and promotional gifts. Pub. L. No. 111-31, § 102(a). These restrictions, however, regulate conduct, not speech. Because there is no constitutional right to give or receive free tobacco samples and gifts, there is no constitutional barrier to outlawing these practices. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570 (2001) (noting that tobacco companies had abandoned challenge to sampling provisions).

The companies also challenge the FSPTCA insofar as it authorizes the FDA to reissue its 1996 prohibition on outdoor tobacco-product advertising within 1,000 feet of a public playground, public park, or school. Pub. L. No. 111-31, § 102(a). Congress has instructed the FDA, in reissuing the 1996 rule, to “include such modifications” to the 1996 restriction as the FDA “determines are appropriate in light of governing First Amendment case law.” *Id.* Because the FDA has not yet announced how or whether it will issue the outdoor advertising provision, the
(continued . . .)

tion and use of tobacco products. For example, placing a Marlboro logo on a T-shirt converts the T-shirt into a walking billboard advertising those cigarettes. *See also Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994) (holding letterhead and business cards to be commercial speech); *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 112 (6th Cir. 1995) ("Speech need not closely resemble a typical advertisement to be commercial."). Like a traditional billboard, such devices constitute commercial speech because they are "related solely to the economic interests of the speaker and its audience." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980).

II. The Advertising Restrictions Easily Satisfy The *Central Hudson* Test.

Restrictions on commercial speech are evaluated under the test first set forth in *Central Hudson*. Under that test, commercial speech that concerns an unlawful activity or is false or misleading receives no First Amendment protection. *Id.* at 566. Although several provisions of the FSPTCA are designed to prevent misleading commercial speech, commercial speech that is truthful and non-misleading may also be restricted to the extent that the restriction satisfies a three-part test: "First, the government must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be 'narrowly drawn.'" *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 624 (1995) (citation omitted).

Central Hudson reflects a high degree of sensitivity to First Amendment values, but at the same time recognizes that government often has a legitimate need to regulate commercial transactions. Thus, although courts require the government to substantiate the need for and

challenge to this provision is unripe.

relationship of its chosen restrictions to the governmental interest, they also give substantial deference to the judgment of the legislature or regulating agency, “leav[ing] it to governmental decisionmakers to judge what manner of regulation may best be employed.” *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

Never before has a set of marketing restrictions been based on as many studies, as much scientific evidence, or such an extensive record of industry conduct to circumvent efforts to protect the public health. Accordingly, the provisions satisfy *Central Hudson* and do not run afoul of the First Amendment.

A. The Government Has A Strong Interest In Protecting The Public From Tobacco’s Detrimental Health Effects.

The first prong of *Central Hudson* requires the government to identify “a substantial interest in support of its regulation.” *Went For It*, 515 U.S. at 624. Here, in enacting the marketing restrictions at issue, Congress was responding to the severe health threat posed by tobacco use. *See generally* Pub. L. No. 111-31, § 2 (findings). Congress had before it overwhelming evidence that tobacco use has created a public health crisis that both severely affects public health and has enormous economic costs in terms of health care expenditures and lost productivity, that virtually all new tobacco users begin as children, and that millions of adults have been misled by the actions of the tobacco industry, with tragic consequences. Thus, as the Supreme Court stated in considering another case about regulation of tobacco products, “[t]his case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use.” *Brown & Williamson*, 529 U.S. at 125. There can be no question that the government’s interest in the “health, safety and welfare of its citizens” is substantial. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995); *see*

also Lorillard, 533 U.S. at 555 (“[N]one of the [tobacco company] petitioners contests the importance of the State’s interest in preventing the use of tobacco products by minors.”).

Tobacco products are unique among consumer goods: They kill up to one-half of the people who use them as they are *intended* to be used. World Health Organization, *Report on the Global Tobacco Epidemic* 8 (2008) (WHO 2008 Report), *available at* www.who.int/tobacco/mpower/en/; President’s Cancer Panel, *Annual Report* 61 (2006-2007) (President’s Cancer Panel Report), *available at* Defendants’ Public Record Materials, Tab 43 (Defs. Material). Tobacco is responsible for more than 400,000 premature deaths each year. As Congress found, report after report shows that tobacco-industry marketing contributes directly to youth tobacco use. And industry marketing encourages many adults to switch to certain tobacco products rather than to quit, based on a false belief, fostered by the tobacco industry, that those products are safer. CDC, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004*, 57 MMWR 1226-28 (Nov. 14, 2008) (CDC, *Smoking-Attributable Mortality*), *available at* www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm; National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*, Smoking and Tobacco Control Monograph No. 19, at 4 (June 2008) (NCI Monograph 19), *available at* Defs. Material, Tab 20; Pub. L. No. 111-31, § 2(13). All told, more than 12 million people in the United States have died from smoking cigarettes since the first Surgeon General’s report on the hazards of smoking was issued in 1964. President’s Cancer Panel Report 61. Despite decades of effort by the government and the public health community, tobacco use remains high: In 2008, more than one in five adults in the United States were smokers, and in 2007, one in five high school students was a smoker. CDC, *Cigarette Smoking Among Adults and Trends in Smoking Cessation*,

58 MMWR 1227-32 (Nov. 13, 2009), *available at* www.cdc.gov/mmwr/preview/mmwrhtml/mm5844a2.htm; CDC, *Cigarette Use Among High School Students—United States, 1991-2007*, 57 MMWR 689-91, Table 1 (June 27, 2008), *available at* www.cdc.gov/mmwr/preview/mmwrhtml/mm5725a3.htm; Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 51-52 (2007) (IOM Report), *available at* Defs. Material, Tab 16. The statistics on smokeless tobacco use are similarly alarming: Among high school boys, nearly one in seven currently uses smokeless tobacco. NCI Monograph 19, at 234.

Cigarette smoke can accurately be described as poison. It contains 69 known carcinogens, multiple poisonous gases, and thousands of chemicals. President's Cancer Panel Report 62. A recent figure estimates that 158,000 people die each year from lung and bronchial cancer caused by smoking. CDC, *Smoking-Attributable Mortality*. Smoking causes cardiovascular disease (including heart attacks), coronary heart disease, emphysema, aortic aneurysms, bladder cancer, esophageal cancer, kidney cancer, laryngeal cancer, oral cancer, pancreatic cancer, acute myeloid leukemia, stomach cancer, uterine cancer, cervical cancer, and liver cancer. *United States v. Philip Morris*, 449 F. Supp. 2d 1, 147-48 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009); *see* Pub. L. No. 111-31, § 2(2). And exposure to secondhand smoke can cause heart disease and lung cancer, as well as other health problems. CDC Fact Sheet, *Secondhand Smoke Causes Heart Disease* (updated May 29, 2009) (reporting that between 22,700 and 69,000 people die each year as a result of heart disease caused by secondhand smoke); CDC Fact Sheet, *Secondhand Smoke Causes Lung Cancer* (updated May 29, 2009); CDC Fact Sheet, *Secondhand Smoke Causes Sudden Infant Death Syndrome* (updated May 29, 2009), *all available at* Defs. Material, Tab 42. Among youth—even before smoking has become a lifelong habit—smoking

causes immediate health effects such as respiratory symptoms, reduced physical fitness, and stunted lung growth and function. President's Cancer Panel Report 64. For any given individual, long-term smoking reduces average life expectancy by 14 years. NCI Monograph 19, at 4. Thus, here, Congress was concerned with the more than 8 million Americans who live with smoking-related chronic illnesses, as well as the shocking death toll. Pub. L. No. 111-31, § 2(13).

Likewise, the severe negative health consequences of smokeless tobacco have long been known. *See generally* Surgeon General's Report, 1986, *available at* Defs. Material, Tab 13. Smokeless tobacco contains 28 carcinogens and can cause pancreatic cancer, oral cancer, and other mouth diseases. IOM Report 30; CDC Fact Sheet, *Smokeless Tobacco* (updated Sept. 16, 2009), *available at* Defs. Material, Tab 42. Smokeless tobacco also threatens both male and female reproductive health and can cause low birth weight and premature birth. CDC Fact Sheet, *Smokeless Tobacco*. Like the nicotine in cigarettes, the nicotine in smokeless tobacco is highly addictive. *Id.*

Youth were an important concern to Congress when it enacted the FSPTCA, and rightly so. Congress found that “virtually all” new tobacco users are minors. Pub. L. No. 111-31, § 2(4). Every day, almost 3,900 children under the age of 18 try smoking for the first time and almost 1,000 become daily smokers. Substance Abuse and Mental Health Servs. Admin., *Results from the 2008 National Survey on Drug Abuse and Health* (2009), *available at* <http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm>; *see also* President's Cancer Panel Report 64 (2005 figures). Although there has been some success in reducing high-school tobacco use over the last decade, that success has stalled in recent years and has been partially counteracted by the uptick in young adults who start using tobacco. IOM Report 57. Moreover, minors' use of smokeless

tobacco, in addition to posing a health risk in its own right, increases the likelihood that those minors will become cigarette smokers as adults. CDC Fact Sheet, *Smokeless Tobacco*; Haddock, *Evidence that smokeless tobacco use is a gateway for smoking initiation in young males*, 32 Preventative Med. 262, 267 (2001), *available at* Defs. Material, Tab 68.

Although the tobacco industry for decades denied that it targeted youth in its advertising, Judge Kessler found those assertions to be false. *Philip Morris*, 449 F. Supp. 2d at 676; *see also* Pub. L. No. 111-31, § 2(5) (“Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons.”). The tobacco industry’s own documents show that the industry devoted “decades of research and development of strategic plans designed to capture the youth market.” NCI Monograph 19, at 157. Using focus groups and surveys of teenagers, the industry developed brand names, logos, slogans, and vividly colored visuals to appeal especially to youth. *Id.* at 63-64, 157. Applying such marketing devices, tobacco companies attempted to “convey rugged independence, rebelliousness, love of life, adventurousness, confidence, self-assurance, and belonging to the ‘in’ crowd.” *Philip Morris*, 449 F. Supp. 2d at 676. They also targeted youth by sponsoring sporting events and concerts. Pub. L. No. 111-31, § 2(19).

Unfortunately, youth have proved especially vulnerable to the industry’s targeted marketing campaigns. As Congress found, “[t]obacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.” Pub. L. No. 111-31, § 2(5). Young people are more influenced by tobacco marketing and are more likely than adults to smoke a recognized brand-name cigarette. NCI Monograph 19, at 158; Pub. L. No. 111-31, § 2(23). The Joe Camel ad campaign, perhaps the most famous example of the targeted cam-

paigns, demonstrates the susceptibility of the youth market. After R.J. Reynolds (RJR) introduced the character in 1988, the company's share of the youth market increased 60 percent within a few years. 61 Fed. Reg. 44619, 45426 n.1213 (1996) (FDA tobacco regulation). During that same period, adult use of Camel cigarettes showed no significant increase. *Id.*

Reducing youth tobacco use is crucial because, in large part due to nicotine addiction, young smokers do not "mature out" of using tobacco. IOM Report 58, 79. As a result of nicotine's strongly addictive nature, quitting is very difficult and can be accompanied by acute withdrawal symptoms. *Id.* at 80. Although about 40 percent of smokers try to quit every year, the successful quit rate is only 2 to 5 percent. *Id.* at 82. Because of the negative health impacts and the difficulty of quitting, a full ninety percent of smokers regret having ever started to smoke. IOM Report 88. These facts make the tobacco industry's deception about the health effects of its products even more harmful. And yet, as Judge Kessler found in 2006, "[w]hile nicotine shares certain key attributes of heroin, cocaine, and other drugs," many tobacco companies, including plaintiffs RJR and Lorillard, lied to the public for years, continuing "to assert that smoking is no more addictive than coffee, chocolate, and exercise." *Philip Morris*, 449 F. Supp. 2d at 209 (finding that tobacco companies "continue to publicly deny and distort the truth as to the addictiveness of cigarette smoking and nicotine's role in the addiction").

In addition to its interest in protecting the public's health, Congress has a strong interest in reducing the taxpayer burden of providing health care to future generations of smokers and the other economic and social costs of tobacco use. Smoking costs \$193 billion per year in health care spending and loss of productivity due to premature death resulting from smoking-related disease. CDC, *Smoking-Attributable Mortality*. Smoking-related health care expenditures cost an

estimated \$30 billion annually in the Medicaid program and \$27 billion in the Medicare program. CDC, *Sustaining State Programs for Tobacco Control: Data Highlights 2006*, at 17, www.cdc.gov/tobacco/data_statistics/state_data/data_highlights/2006/index.htm (Medicaid estimate); Zhang, *Cost of Smoking to the Medicare Program, 1993*, 20 Health Care Financing Rev. 1-19 (1999), available at www.tcsg.org/tobacco/99SummerHCFR.pdf (Medicare estimate).

Other societal costs, not accounted for in these estimates, are harder to quantify. For instance, these estimates do not count the value of losing a loved one, losing the family provider when a smoker dies leaving a dependent spouse or minor children, or the suffering that smokers endure as they die from painful and intractable smoking-induced illnesses.

Under established commercial speech jurisprudence, any one of these interests would qualify as “substantial” under *Central Hudson*. Taken together, the government’s interests in protecting the health and welfare of its population, conserving scarce health care resources, and ensuring the productivity of members of society are not only substantial but compelling, occupying the highest rung on any hierarchy of governmental interests.

B. The Challenged Restrictions Are Narrowly Tailored And Directly Advance The Government’s Interest.

The final steps of *Central Hudson* require the government to “demonstrate that the challenged regulation advances the Government’s interest in a direct and material way” and that there is a reasonable “‘fit’ between the legislature’s ends and the means chosen to accomplish those ends.” *Went For It*, 515 U.S. at 624. The means chosen to promote the government’s interest need not be “the single best disposition,” *Fox*, 492 U.S. at 480; they must be reasonably in proportion to the interest served. *See Went For It*, 515 U.S. at 633. The FSPTCA satisfies these *Central Hudson* prongs as well.

The “evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption.” NCI Monograph 19, at 211. Children in particular are heavily influenced by tobacco advertising, and “limiting youth exposure to advertising will decrease underage use of smokeless tobacco” and cigarettes. *Lorillard*, 533 U.S. at 561. Based on a thorough examination of volumes of evidence showing the relationship between tobacco advertising and the particular forms of marketing addressed in the Act, Congress reasonably concluded that the challenged FSPTCA provisions were crucial to protect public health. Congress relied here on substantial and persuasive evidence that past efforts and current regulation of tobacco are not working and that the additional marketing restrictions will be more effective in decreasing tobacco consumption. As Defendants’ November 13 submission of Public Record Material shows, this evidence includes, among other things, numerous National Cancer Institute monographs, the President’s Cancer Panel’s 2007 report, Institutes of Medicine reports, numerous consumer surveys, scientific studies, and the extensive factual findings contained in the 1600-page decision of the U.S. District Court in *United States v. Philip Morris*, 449 F. Supp. 2d 1. *See* Notice of Filing of Materials by United States, Nov. 13, 2009.

As these materials show, unlike commercial speech restrictions held unconstitutional in other cases, Congress did not adopt the FSPTCA restrictions as a “first resort,” without exploring the feasibility of other options. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002). Rather, for decades multiple government jurisdictions have tried less restrictive measures to rein in tobacco use. Congress rightly found that those measures have invariably fallen short because the industry has creatively evaded the restrictions by finding ways to advertise to smokers and, in particular, to minors, through other means. “Tobacco manufacturers are some of the best market-

ers in the world—and increasingly aggressive at circumventing prohibitions on advertising, promotion and sponsorship that are designed to curb tobacco use.” WHO 2008 Report 36. And they 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. Tobacco companies spend billions of dollars each year on advertising—\$12.8 billion in the year 2006, representing \$35 million each day. FTC, Cigarette Report for 2006, at 3 (Aug. 2009), *available at* Defs. Material, Tab 31; FTC, Smokeless Tobacco Report for 2006, at 2 (Aug. 2009), *available at* Defs. Material, Tab 32. Accordingly, Congress found that “past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents” and that, as a result, “comprehensive restrictions on the sale, promotion, and distribution of such products are needed.” Pub. L. No. 111-31, § 2(6).

The ban on sponsorship provides a good example. Efforts to limit the impact of brand-named sponsorship on youth and to discourage tobacco use date back almost 40 years to 1971, when the Public Health Cigarette Smoking Act banned broadcast television advertisements for cigarettes. In response, the tobacco companies began sponsoring broadcast sporting events, such as auto racing. Television coverage of event sponsorship gave the tobacco companies the benefits of television advertising without the requirement of any accompanying health warnings to protect the public. NCI Monograph 19, at 82-83. Thus, for example, “[t]he Kool cigarette brand was exposed or mentioned to approximately 136 million television viewers and over five million racing event attendees in 2002.” *Philip Morris*, 449 F. Supp. 2d at 666.

Likewise, tobacco companies have found creative ways to work around restrictions on brand-named sponsorship included in a 1998 settlement agreement with 46 States, known as the

Master Settlement Agreement (MSA). The MSA limited the number of events that tobacco companies could sponsor. Although many tobacco companies signed the MSA (some as original signatories and others later) and thereby agreed to the limit, they continued to look for loopholes. For example, Brown & Williamson documents describe the company's "Kool MIXX Campaign" as "grassroots programs that fuse or mix different elements of hip-hop that will showcase artists' skills and stretch the brand muscles . . . [and] [b]uild awareness, trial and image of Kool among Urban ASU [Adult Smoker Under] 26 year old smokers." *Philip Morris*, 449 F. Supp. 2d at 663.

In the MSA, the companies also agreed to a ban on billboard advertising of cigarettes. After the ban went into effect, cigarette companies began diverting their advertising budget from billboards to exterior store advertising. The advertisements, which plaster areas such as doors, windows, and gas station walls, have many of the same effects as billboards. NCI Monograph 19, at 83-84. Despite the various marketing restrictions agreed to in the MSA, a Massachusetts Department of Health study released in 2000, "found that cigarette advertising in magazines with high youth readership actually increased by 33 percent after the November 1998 Master Settlement Agreement, in which the tobacco companies agreed not to market to kids." Campaign for Tobacco-Free Kids, *Tobacco Company Marketing to Kids 2* (Sept. 22, 2009), available at www.tobaccofreekids.org/research/factsheets/pdf/0008.pdf. "An American Legacy Foundation study found that magazine ads for eight of the top ten cigarette brands reached 70 percent or more of kids five or more times in 1999." *Id.* (footnote omitted). Despite broad-based efforts to reduce and restrict marketing of cigarettes to youth, in the last decade, tobacco companies have continued their emphasis on marketing methods that reach young people. These methods include giving away branded products that appeal to youth, such as t-shirts and sunglasses that are

packaged with cigarettes. American Lung Association, *Big Tobacco on Campus: Ending the Addiction* 7-8 (2008) (ALA Report); President's Cancer Panel Report 85. For example, in 2007, RJR initiated its "Camel No. 9" campaign, which featured shiny bright pink and teal artwork in vintage-style fashion advertisements and included style and beauty tips published in magazines with millions of youth readers. *Current State Efforts to Enforce the Master Settlement Agreement's Cigarette Marketing Restrictions*, NAAGazette, Feb. 15, 2008. RJR also sponsored events, ostensibly restricted to adults, at which goody bags were handed out, filled with candy-flavored lip gloss, cell-phone jewelry, other trinkets, and coupons for a clothing store popular with youth. *Id.*; see also ALA Report 7-8 (event sponsorship at bars popular with young adults); President's Cancer Panel Report 85. And as Congress found, the tobacco industry uses promotions at sporting events to make smoking appear to be "an integral part of sports and the healthy lifestyle associated with rigorous sporting activity." Pub. L. No. 111-31, § 2(19).

In recent years, the tobacco companies have significantly increased their in-store, or point-of-sale advertising, which was not covered by the MSA but is addressed in the FSPTCA. According to the Federal Trade Commission, in 2006 (the latest year for which data are available), the cigarette companies spent over \$242 million on point-of-sale advertising, a 33.1 percent increase from 2005. FTC, *Cigarette Report for 2006*, at 4. This amount is vastly more than what the tobacco companies spent on newspaper, magazine, and outdoor advertising combined. In addition, cigarette companies spent more than \$430 million in 2006 on payments to retailers to facilitate the placement and display of cigarettes in stores. Point-of-sale tobacco advertising is nearly universal. A study in 2000 found that 80 percent of retail outlets have interior tobacco advertising, 60 percent have exterior advertising, and over 70 percent have

functional items (such as shopping carts, clocks, or change mats) that advertise tobacco products. Wakefield, *Tobacco Industry Marketing at Point of Purchase After the 1998 MSA Billboard Advertising Ban*, 92 Am. J. Pub. Health 937, 939 (Table 2) (June 2000), available at <http://ajph.aphapublications.org/cgi/reprint/92/6/937?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=wakefield&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>. Research indicates point-of-purchase tobacco advertising impacts not only what brands of cigarettes kids buy but also the number of kids who buy cigarettes. A study published in the May 2007 issue of *Archives of Pediatrics and Adolescent Medicine* found that retail cigarette advertising increased the likelihood that youth would initiate smoking. See Slater, *The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake*, 161 Archives of Pediatrics and Adolescent Med. 440-45 (May 2007); see also Pub. L. No.111-31, § 2(24) (“Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.”).

Tobacco companies have used other unconventional marketing strategies as well. For instance, they have applied their brand names to unrelated products in what is called “brand stretching” and have tried to associate certain colors with certain brands to evade restrictions. NCI Monograph 19, at 85. As the National Cancer Institute reported, “tobacco marketers can overcome laws that restrict only traditional forms of tobacco advertising,” and “when one media form is prohibited, the tobacco industry finds media ‘substitutes.’” *Id.* at 84, 85.

Congress adopted FSPTCA to respond to the pattern of evasion and specific techniques by which tobacco companies evade advertising restrictions, thereby encouraging tobacco use by youth. In light of this history, Congress’s conclusion that “advertising regulations that are

stringent and comprehensive have a greater impact on overall tobacco use and young people's use," Pub. L. No. 111-31, § 2(27), is beyond dispute.

III. The Mandated Health Warnings, Based On Strong Evidence Related To Warning Labels And Evidence That Current Warnings Are Ineffective, Are Reasonable.

Although plaintiffs challenge the FSPTCA provisions mandating health warnings and images in advertisements and on product packaging, "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed." *Zauderer v. Office of Disciplinary Counsel of S. Ct. of Ohio*, 471 U.S. 626, 651 n.4 (1985). Disclosure requirements have no potential to "offend the core First Amendment values of promoting efficient exchange of information." *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-14 (2d Cir. 2001). On the contrary, such "disclosure furthers, rather than hinders the First Amendment goal of the discovery of truth." *Id.* at 114. Thus, in the context of commercial speech, the First Amendment does not prohibit the government from requiring speakers to make truthful statements of fact. *See Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005) (describing compelled-speech challenge to commercial disclosure requirement as "completely without merit"); *cf. Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 796 n.9 (1988) ("Purely commercial speech is more susceptible to compelled disclosure requirements.").

Accordingly, the FDA can mandate warnings on drug labels, including prominent "black box" warnings that emphasize particular hazards. 21 C.F.R. § 201.57.³ Likewise, the Federal

³That regulation states: "The box must contain, in uppercase letters, a heading inside the box that includes the word 'WARNING' and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the 'Contraindications' or 'Warnings and Precautions' section, accompanied by the identifying number for the section or subsection containing the detailed information."

Trade Commission mandates disclosures by automobile dealers of warranty information in “Buyers’ Guides” on used cars, 16 C.F.R. § 455.2 (specifying format and content of form required to be displayed on window of used car offered for sale to consumers), disclosures in connection with promotion of franchising opportunities, *id.* § 316.1, and disclosures of relationships between an endorser and a seller of a product. *Id.* § 255.5. “There are literally thousands of similar regulations on the books—such as product labeling laws, environmental spill reporting, accident reports by common carriers, [and] SEC reporting as to corporate losses.” *Rowe*, 429 F.3d at 316 (noting that applying strict scrutiny to mandatory disclosures would threaten “literally thousands of similar regulations on the books”). Indeed, cigarette packaging has been subject to compelled health warnings for more than four decades. *See* 15 U.S.C. § 1333. Although the tobacco companies do not challenge them here, their argument would call even these warnings into question.

Here, the requirement that a warning and color image depicting the health consequences of smoking be placed on cigarette packages was crafted in light of abundant evidence that such warnings are far more likely to come to the attention of and have an impact on smokers, especially children. Health warnings on packages are read by precisely the audience that is targeted, at the time that the audience is about to make the decision to purchase or to smoke. The warnings are thus uniquely positioned for effectiveness. Hammond, *Tobacco Packaging and Labeling: A Review of Evidence* 5 (2007), available at www.tobaccolabels.ca/factsheet/article_. “The extent to which smokers read and think about[] and act upon the warnings is highly dependent on their size, position, and design.” *Id.*

A warning label on the front of the package is a necessary step in any effective health campaign. Prior to the FSPTCA, the United States required only a small, text-only warning on the side of the carton. *Id.* at 4. In a 1995 study on how well students could recall the contents of cigarette packaging, only 7 percent of students in the United States mentioned health warnings. At the same time, in Canada, where a text warning appeared on the front of the package, 83 percent of students mentioned the warnings. *Id.* at 5. One Canadian study revealed that smokers thought warnings that covered 80 percent of the package were the most effective. *Id.* at 5.

Experts also agree that health warnings that appear prominently on the front of packaging are more effective—particularly among youth—when those labels involve imagery. The World Health Organization recommends use of images because “pictures with graphic depictions of disease and other negative images [have] greater impact than words alone. . . .” WHO 2008 Report 34; Hammond, at 10. One study showed that 90 percent of youth thought that picture warnings were informative and made smoking seem less attractive. Hammond, at 8. Another study found that children are more likely to read, think about, and talk about picture warnings on cigarette packaging than non-picture warnings. *Id.* at 9.

A growing consensus has emerged that imagery warnings that cover a substantial portion of the front and/or back panels of a cigarette package are the most effective. At least 25 countries now require such graphics on cigarette packaging, including Canada, Brazil, Great Britain, Australia, India, Thailand, Chile, and Switzerland. Canada Cancer Society, *Cigarette Package Health Warnings* 3 (2008), available at http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_en.pdf. Twenty-four countries require at least 50 percent of the front and back panels (combined) of a cigarette container to be used for warnings, and 68 require at least 30 percent of

the combined front and back panel space to be used for warnings. *Id.* at 6-7. The World Health Organization, citing the success of picture warnings in other countries, recommends that warnings, including both pictures and words, “should cover at least half of the packs’ main display areas and feature mandated descriptions of harmful health effects.” WHO 2008 Report 34. This recommendation advocates precisely the type of warning label requirement that Congress enacted in the FSPTCA.

CONCLUSION

For the foregoing reasons and those stated in defendants’ memorandum in support of its motion for summary judgment, defendants’ motion for summary judgment should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

On November 30, 2009, I electronically filed this document through the ECF system, which will send a notice of electronic filing to counsel for all parties in this case.

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