UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Nos. 10-5234/5235

DISCOUNT TOBACCO CITY & LOTTERY, INC., et al.,
Appellants/Cross-appellees,

v.

UNITED STATES, et al.,
Appellees/Cross-appellants.

Appeal from the United States District Court
for the Western District of Kentucky

BRIEF OF AMICI CURIAE CAMPAIGN FOR TOBACCO-FREE KIDS, AMERICAN ACADEMY OF PEDIATRICS, 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 APPELLEES/CROSS-APPELLANTS UNITED STATES, ET AL.

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DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Amici Curiae Campaign for Tobacco-Free Kids, American Academy of Pediatrics, 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, are all non-profit organizations that have no parents, subsidiaries, or affiliates that have issued shares or debt securities to the public.

/s/
Allison M. Zieve

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INTEREST OF AMICI

Amici curiae are twelve non-profit public health organizations, consumer advocacy groups, and physicians associations 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 history of tobacco regulation and tobacco industry promotional techniques. A fuller description of each organization is included in an addendum to this brief. All parties have consented to the filing of this brief.

BACKGROUND

The legal questions in this case cannot be considered apart from the public health imperative that lies at the heart of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Act was enacted to stem the constant tide of severe and often deadly preventable health problems caused by tobacco use in this country and to curtail the abusive marketing practices that perpetuate these problems. FSPTCA, Pub. L. No. 111-31, § 2 (Findings). The statistics are grim: More than 400,000 people in this country die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease. 61 Fed. Reg. 44396, 44398 (1996); CDC,

Smoking and Tobacco Use: Fast Facts (May 2009)[1] (smoking is responsible for 443,000 deaths per year). An overwhelming majority of adult smokers started smoking before age 18. And nearly one-half of the children who become regular smokers will die prematurely from a tobacco-related disease. President's Cancer Panel, *Annual Report* 64 (2006-2007) (President's Cancer Panel Report).[2]

Despite laws in all 50 states banning the sale of tobacco products to anyone under age 18, one in five high school students smokes cigarettes. CDC, *Cigarette Use Among High School Students–United States, 1991-2009* (July 2010).[3] Every day, almost 3,900 children under the age of 18 try smoking for the first time; and every day, 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);[4] *see also* 61 Fed. Reg. at 44568 (more than one million minors try their first cigarette each year); President's Cancer Panel Report 64 (2005 figures). After the industry began targeting youth in advertising for smokeless tobacco products, minors' use of smokeless tobacco products greatly increased. 60 Fed. Reg. 41314, 41318 (1995); *see*

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[1]www.cdc.gov/tobacco/data_statistics/fact_ sheets/fast_ facts/index.htm.

[2]*Available at* http://deainfo.nci.nih.gov/advisory/pcp/pcp07rpt/pcp07rpt.pdf.

[3]www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm.

[4]http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm.

id. at 41331. Today, 15 percent of male high school students use smokeless tobacco. CDC, *Youth Risk Behavior Surveillance–United States, 2009*, at 69 (June 4, 2010).[5]

Although for many years the tobacco industry feigned ignorance of the addictive nature of its products, the Food and Drug Administration (FDA) tobacco rulemaking in 1995 and 1996, and the extensive findings of Judge Kessler in *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010), presented overwhelming evidence that the industry's public statements were lies. As Judge Kessler concluded,

> [O]ver the course of more than 50 years, [the tobacco industry] lied, misrepresented, and deceived the American public, including smokers and the young people they avidly sought as "replacement smokers," about the devastating health effects of smoking and environmental tobacco smoke, they suppressed research, they destroyed documents, they manipulated the use of nicotine so as to increase and perpetuate addiction, they distorted the truth about low tar and light cigarettes so as to discourage smokers from quitting, and they abused the legal system in order to achieve their goal—to make money with little, if any, regard for individual illness and suffering, soaring health costs, or the integrity of the legal system.

Id. at 852.

The tobacco industry not only lied about the risks of smoking generally, but for decades implemented a scheme to convince smokers that so-called "light," "low-tar,"

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[5]www.cdc.gov/mmwr/pdf/ss/ss5905.pdf.

or "low-nicotine" cigarettes were less harmful than regular cigarettes—claims that the industry knew to be false. *Id*. at 445, 468, 531. The companies promoted their low-tar brands to smokers who were concerned about cigarettes' health hazards or considering quitting, to encourage them not to quit. *Id.* at 508; *see Philip Morris*, 566 F.3d at 1107. The scheme was highly successful: Sales of purportedly "low-tar" and "low-nicotine" brands increased from two percent of total cigarette sales in 1967 to almost 92.7 percent in 2006. *Philip Morris*, 449 F. Supp. 2d at 508; FTC, *Cigarette Report for 2006*, at 7 (2009);[6] *see also Philip Morris*, 449 F. Supp. 2d at 507-08 (companies "continu[ing] to make[] false and misleading statements regarding low-tar cigarettes in order to reassure smokers and dissuade them from quitting").

ARGUMENT

Government restrictions on commercial speech are analyzed under the test set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Under *Central Hudson*, commercial speech that concerns an unlawful activity or is false or misleading receives no First Amendment protection. *Id*. at 566. Commercial speech that is not false or misleading may be restricted to the extent that the restrictions are narrowly tailored to advance a substantial government interest. *Id*.

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[6]www.ftc.gov/os/2009/08/090812cigarettereport.pdf.

This brief divides the provisions at issue into three categories. The first category of restrictions regulates tobacco advertisements that Congress and experts found have the greatest impact on youth and that mislead and discourage adults from quitting. These restrictions 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, FSPTCA § 102(a); prohibit promotion of tobacco products using brand-name merchandise, *id*.; and prohibit sponsorship of events. *Id*. The second category mandates 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. *Id.* § 201(a) (amending 15 U.S.C. § 4(a)). The third category includes provisions requiring a tobacco company to obtain an FDA order before promoting products as reduced risk tobacco products, *id*. § 911 (codified at 21 U.S.C. § 387k), and prohibiting misleading references to whether the FDA has approved tobacco products as safe, *id*. § 103(b) (amending 21 U.S.C. § 331(tt)). All three categories 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.

I. The Challenged Promotional And Labeling Restrictions Easily Pass First Amendment Scrutiny.

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

As the district court held (R.100 at 20, 27-28), Congress has a substantial interest in deterring youth tobacco use and protecting the health of adult smokers. Here, in enacting the marketing restrictions at issue, Congress was responding to the severe health threat posed by tobacco use. *See generally* FSPTCA § 2. Congress had before it overwhelming evidence that tobacco use has created a 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." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). Without question, 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 Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) ("[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);[7] President's Cancer Panel Report 61. And as Congress found, report after report shows that tobacco-industry marketing contributes directly to youth tobacco use. FSPTCA § 2(13); *see* CDC, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses–United States, 2000-2004*, at 1226-28 (Nov. 14, 2008);[8] Nat'l Cancer Inst., *The Role of the Media in Promoting and Reducing Tobacco Use*, Smoking and Tobacco Control Monograph No. 19, at 4 (June 2008)[9] (NCI Monograph 19). More than 12 million people in the United States have died

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[7]www.who.int/tobacco/mpower/en/.

[8]www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.

[9]*Available at* www.cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete_accessible.pdf.

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.

Cigarette smoke can accurately be described as poison. It contains 4,700 chemicals, 250 of which cause cancer or are otherwise toxic. *Id*. at 61. 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. *Philip Morris*, 449 F. Supp. 2d at 147-48; *see* FSPTCA § 2(2). And exposure to secondhand smoke can cause heart disease and lung cancer, as well as other health problems. CDC, *Health Effects of Secondhand Smoke* (updated Jan. 12, 2010)[10] (reporting that, each year, secondhand smoke causes approximately 46,000 people to die prematurely as a result of disease, causes 3,400 nonsmokers to die of lung cancer, and increases the risk of sudden infant death). Among youth—even before smoking has become a lifelong habit—smoking causes immediate health effects such as respiratory symptoms, reduced physical fitness, and

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[10]www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/ health _effects/index.htm#heart.

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.

Likewise, the severe negative health consequences of smokeless tobacco have long been known. *See generally* Surgeon General's Report, *The Health Consequences of Using Smokeless Tobacco* ((1986).[11] Smokeless tobacco contains 28 carcinogens and can cause pancreatic cancer, oral cancer, and other mouth diseases. Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 30 (2007) (IOM Report);[12] CDC, *Smokeless Tobacco Facts* (updated Sept. 16, 2009).[13] Smokeless tobacco also threatens both male and female reproductive health and can cause low birth weight and premature birth. *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. FSPTCA § 2(4); *see supra* p. 2 (citing government statistics on minors' cigarette use). Although there has been some success in reducing high-school tobacco use over the

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[11] *Available at* http://profiles.nlm.nih.gov/NN/B/B/F/C/_/nnbbfc.pdf.

[12] *Available at* http://books.nap.edu/openbook.php?record_id=11795.

[13] www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm.

last decade, that success has stalled in recent years and has been partially counteracted by the uptick in young adults who start using smokeless tobacco. IOM Report 57. And minors' use of smokeless tobacco increases the likelihood that those minors will become cigarette smokers as adults. CDC, *Smokeless Tobacco Facts*; Haddock, *Evidence that smokeless tobacco use is a gateway for smoking initiation in young males*, 32 Preventative Med. 262, 267 (2001).

Reducing youth tobacco use is crucial because 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 two to five percent. *Id*. at 82. Because of the negative health impacts of tobacco use 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 appellants R.J. Reynolds (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 address the health problems experienced by 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 disease and 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 (updated May 29, 2009)[14] (Medicaid estimate); Zhang, *Cost of Smoking to the Medicare Program, 1993*, 20 Health Care Financing Rev. 1-19 (1999)[15] (Medicare estimate). Other societal costs, not susceptible to being quantified, include 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.

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[14]www.cdc.gov/tobacco/data_statistics/state_data/data_highlights/2006/index.htm.

[15]Â *vailable at* www.tcsg.org/tobacco/99SummerHCFR.pdf.

Under established commercial speech jurisprudence, any one of these interests would qualify as "substantial." 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 remaining 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." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 624 (1995); *Lorillard*, 533 U.S. at 528. The FSPTCA satisfies these steps as well.

1. 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 "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." FSPTCA § 2(6). 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 generally* R.70 (Defendants' Exhs.). As these and other 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).

In particular, despite broad-based efforts to reduce and restrict marketing of cigarettes to youth, tobacco companies have continued their emphasis on marketing methods that reach young people—for example, by giving away branded products that appeal to youth, such as t-shirts and sunglasses that are packaged with cigarettes. FSPTCA § 2(5) ("Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons."); Am. Lung Ass'n, *Big Tobacco on Campus: Ending the Addiction* 7-8 (2008) (ALA Report);[16] President's Cancer Panel Report 85. This type of marketing continued even after the district court

[16]http://slati.lungusa.org/reports/CollegeSmokingTrendReport- Embargoed.pdf.

decision in *Philip Morris*. 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*, NAA Gazette, 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*. One year later, the number of girls with a favorite cigarette ad increased by ten percent, and 22 percent listed Camel as their favorite cigarette ad—twice as many as in four interviews conducted before the start of the RJR campaign. Pierce, et al., *Camel No. 9 Cigarette-Marketing Campaign Targeted Young Teenage Girls*, Pediatrics 619, 623 (Apr. 2010).[17] This finding is especially significant because adolescents who have never smoked but have a favorite cigarette ad have a "50% increase in probability of future experimentation with smoking." *Id*. at 624; *see also* FSPTCA § 2(19) (congressional finding that tobacco industry uses promotions at sporting events to make smoking appear to be

[17] *Abstract available at* http://pediatrics.aappublications.org/cgi/content/abstract/125/4/619.

"an integral part of sports and the healthy lifestyle associated with rigorous sporting activity"); R.100 at 15.

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; *see* R.100 at 17. 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.

The tobacco companies have also found ways to evade the restrictions agreed to in a 1998 settlement agreement with 46 States, known as the Master Settlement Agreement (MSA). For example, although the MSA limited the number of events that tobacco companies could sponsor, and many companies signed the MSA (some as original signatories and others later) and thereby agreed to the limit, they searched for loopholes. Thus, Judge Kessler found that "[t]he advertising campaigns of the

three leading youth brands, Marlboro, Newport, and Kool, for youth have not changed since the MSA." *Id*. at 850.

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);[18] *see also* R.100 at 17. "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." Campaign for Tobacco-Free Kids, *supra*, at 2 (footnote omitted).

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

[18]www.tobaccofreekids.org/research/factsheets/pdf/0008.pdf.

addressed in the FSPTCA. According to the Federal Trade Commission, in 2006 (the latest year for which data are available), the cigarette companies increased spending on point-of-sale advertising by 33.1 percent from 2005 to 2006. FTC, *Cigarette Report for 2006*, at 4. Spending on point-of-sale advertising exceeds the tobacco companies' spending on newspaper, magazine, and outdoor advertising combined. *Id*. 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. 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).[19]

Importantly, research indicates that point-of-purchase tobacco advertising directly impacts the number of minors who buy cigarettes. A study published in May 2007 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 & Adolescent Med. 440-45 (May

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[19] *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.

2007).[20] A 2010 survey of 2,110 teens likewise found that those who regularly visited stores with point-of-sale tobacco ads were at least twice as likely to try smoking as those who visited infrequently. Henriksen, et al., *A Longitudinal Study of Exposure to Retail Cigarette Advertising and Smoking*, Pediatrics (July 19, 2010).[21]

Put simply, 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.'" NCI Monograph 19 at 84, 85.

2. Although the district court recognized that the majority of the FSPTCA promotional provisions at issue are well-tailored to advance the important public health interest in preventing underage tobacco use, the court struck down the ban on use of color and imagery in tobacco ads (§ 102(a)(2)). This provision also satisfies *Central Hudson*.

First, in restricting color and imagery in ads, Congress relied on abundant evidence that tobacco advertising uses vibrant imagery to "misleadingly portray[] the use of tobacco as socially acceptable and healthful to minors." FSPTCA § 2(17). The

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[20] *Available at* http://archpedi.ama-assn.org/cgi/reprint/161/5/440.

[21] *Available at* http://pediatrics.aappublications.org/cgi/content/abstract/peds.2009-3021 v1.

industry has "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. For example, tobacco companies have for many years marketed menthol cigarettes to youth with advertisements depicting "cool" lifestyles and images of young people having fun. *Id.* at 158. These and similar images appeal to youth by suggesting themes of "rugged independence, rebelliousness, love of life, adventurousness, confidence, self-assurance, and belonging to the 'in' crowd." *Id.* at 676.

Young people are more susceptible to these forms of image advertising and are thus much more likely than adults to smoke branded cigarettes. FSPTCA § 2(23); NCI Monograph 19, at 158. The Joe Camel ad campaign, perhaps the most famous example of the targeted campaigns, demonstrates the susceptibility of the youth market. After appellant 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.* Similarly, Lorillard successfully capitalized on the youth market by advertising its Newport brand with images of "attractive, vibrant young adults enjoying recreational activities," and

Marlboro appealed to adolescent males with images of the "rugged, masculine Marlboro man." *Philip Morris*, 449 F. Supp. 2d at 863-64.

Congress's conclusion that deterring minors from smoking requires "comprehensive advertising restrictions," FSPTCA § 2(25), and that narrow restrictions—such as a ban on cartoon animals or cowboys—would be inadequate is well justified. "Tobacco manufacturers are some of the best marketers 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. Industry documents show that tobacco companies conducted focus groups and surveys of teenagers and devoted "decades of research and development of strategic plans designed to capture the youth market." NCI Monograph 19, at 157. A targeted ban on specific kinds of images would not stop tobacco companies from devising new ways to target youth.

Singling out specific kinds of image ads for regulation would be particularly difficult because tobacco companies' use of imagery can be subtle. Image advertising is designed to associate the brand with positive emotions and to "appeal to the psychological needs of adolescents." *Philip Morris*, 449 F. Supp. 2d at 863. Advertising targeting teenage girls, for example, has successfully used images of attractive, thin women smoking to associate cigarettes with improved appearance and

losing weight. NCI Monograph 19, at 219-20. The industry has also successfully used color, standing alone, to convey product characteristics. *Id*. at 64-65 (finding, for example, that light blue conveys health). Moreover, tobacco companies have a history of publicly insisting that they were committed to reducing youth smoking at the same time they were designing ads tailored to "teenage behaviors and preferences." *Philip Morris*, 449 F. Supp. 2d at 862. In the face of this history of subtlety and deception, Congress's ban on color and imagery is a tailored means of preventing minors from being enticed to use tobacco products. At the same time, tailoring the restriction to fit the governmental interest, the FSPTCA allows color advertisements in adult-focused media, thereby leaving the industry room to communicate to adults.

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In sum, 45 years after the industry adopted a voluntary "Cigarette Advertising Code" prohibiting ads directed at youth,[22] despite 24 years of mandated package warnings, *see* 15 U.S.C. § 1333 (1965 & as amended 1970, & as amended 1984), 15 years of experience with a statute giving states incentives rigorously to enforce prohibitions against tobacco sales to minors, 42 U.S.C. § 330x-26 (1992), and 12 years of the MSA, industry marketing to minors—and consequently tobacco use by minors—continues. Noting the failure of these prior efforts and with the benefit of

[22]*See* http://legacy.library.ucsf.edu:8080/t/b/m/ tbm09c00/Stbm09c00.pdf.

Judge Kessler's detailed findings, Congress enacted the 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 the historical facts, Congress's conclusion that "advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use," FSPTCA § 2(27), is beyond dispute.

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

The district court correctly rejected the companies' challenge to the FSPTCA provisions revising the requirements for health warnings in advertisements and on product packaging. "[T]he 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 Supreme Court 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. Likewise, the Federal 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 thousands of existing regulations). Indeed, cigarette packaging has been subject to compelled health warnings for more than four decades. *See* 15 U.S.C. § 1333.

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. They are thus uniquely positioned for effectiveness. Hammond, *Tobacco Packaging and Labeling: A Review of Evidence* 4-5 (2007) ("[T]he extent to which smokers read and think about[] and act upon the warnings is highly dependent on their size, position, and design.").[23]

Prior to the FSPTCA, the United States required only a small, text-only warning on the side of the package. *Id*. at 4. In a 1995 study on how well students could recall the contents of cigarette packaging, only seven 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; R.100 at 27. Thus, the evidence shows that the FSPTCA warnings will be far more effective than the small U.S. warning has been.

Experts also agree that package warnings are more effective—particularly among youth—when those labels involve imagery. The World Health Organization

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[23] *Available at* www.tobaccolabels.ca/factshee/article_.

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, *supra*, at 10. One study showed that 90 percent of youth thought that picture warnings were informative and made smoking seem less attractive. Hammond, *supra*, 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. R.100 at 26. 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).[24] Twenty-four countries require at least 50 percent of the front and back panels (combined) of a cigarette container 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; *see also* R.100 at 26. This recommendation

[24]http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_ en.pdf.

advocates precisely the type of warning label requirement that Congress enacted in the FSPTCA.

III. The Provisions Aimed At Preventing Tobacco Companies From Misleading Consumers About Health Risks Easily Pass First Amendment Scrutiny.

Two provisions at issue in this case involve Congress's effort to prevent tobacco companies from misleading consumers about the health risks of tobacco products: the application requirement for making reduced-risk claims and the prohibition on manufacturer promotional statements that mislead consumers into believing that tobacco products are safe because of FDA regulation.

A. The District Court Properly Upheld The Review Requirement For Products Marketed As Posing A Reduced Risk.

Based on the industry's history of misrepresentation, as documented by the court in the *Philip Morris* case and a 2001 National Cancer Institute monograph on the risks of "light" cigarettes,[25] Congress found that the only way effectively to protect the public from the dangers of unsubstantiated reduced-risk claims is to create a system of pre-market review to ensure that the evidence cited to support such claims is verifiable. FSPTCA § 2(36-43). The application requirement for claims that a

[25]Nat'l Cancer Inst., *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13 (Oct. 2001), *available at* http://cancercontrol.cancer.gov/tcrb/monographs/13/index.html (NCI Monograph 13).

product is a reduced-risk tobacco product is consistent with the FDA's long-established authority over the content of drug and medical device labeling and advertising and the review requirement for health claims made for foods. Like the regulatory schemes for these other products, the provision addressing reduced-risk tobacco products serves as a check against unproven and misleading health claims about tobacco use.

i. The MRTP Provision Is Supported By The FDCA's Long-Standing Regulation Of Health Claims For Drugs, Medical Devices, And Foods.

The "modified risk tobacco product" (MRTP) provision provides, in essence, that if a tobacco company wants to promote a tobacco product as less hazardous than other tobacco products, it must submit evidence for FDA review. Although the tobacco companies' brief presents the MRTP provision as an extraordinary restraint on speech, it in fact mirrors the statutory schemes that have long provided for FDA regulation of health claims made for drugs, medical devices, and foods.

For example, under the Food, Drug, and Cosmetic Act (FDCA), a pharmaceutical company cannot sell a new drug until the product has been evaluated by the FDA. *See generally* 21 U.S.C. § 355; *see also id.* § 360c (approval of medical devices). To obtain approval, a drug company must first submit a "new drug application" (NDA) that includes, among other things, information about the clinical

trials that demonstrates the safety and effectiveness of the product, and proposed labeling. *Id*. § 355(a), (b), (d). After reviewing the application, the FDA will approve the drug for marketing if it finds that the drug is safe and effective for its intended use or uses and that the labeling is not false or misleading. *Id*. § 355(c)(1)(A). FDA review includes approval of the labeling, which specifies the approved uses of the products, as well as warnings, precautions, and other information. 21 C.F.R. §§ 201.56, 201.57, 201.80. After a drug is approved for sale, the manufacturer is permitted to market it only for the specific use for which the company sought and obtained approval. 21 U.S.C. § 331(a), (d); *id.* § 352(a). If the company wants to promote the product for an additional use, it must submit an application and again receive FDA approval before doing so. 21 U.S.C. § 314.70. Similar to the MRTP provision, the FDCA's drug provisions were enacted because Congress was "concerned about unsafe drugs and fraudulent marketing." *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009).

Like the FDCA's drug provisions, the MRTP provision does not bar truthful speech, but rather provides a mechanism for objective pre-marketing evaluation of health and safety claims for a category of products that pose great potential for harm. Even health claims for standard foods, however—which have far less potential than drugs and tobacco to cause harm—must await FDA's evaluation of a company's

application before making such claims. Under the food labeling provisions of the FDCA, food manufacturers may make health claims for their products only after obtaining FDA authorization and subject to substantive and procedural criteria set forth in the statute. 21 U.S.C. § 343(r)(1), (3).[26] Under this scheme, a food company can assert, for example, that its high-fiber cereals may reduce the risk of some types of cancer only because the FDA has determined that the claim is valid. 21 C.F.R. § 101.76. And dairy companies are permitted to advertise that milk may reduce the risk of osteoporosis because the FDA has cleared that claim. *Id*. § 101.72.

The MRTP provision falls comfortably in line with these other well-established regulatory schemes. The MRTP provision allows companies to market tobacco products without any FDA review, but a company must apply for an FDA order before touting a tobacco product as healthy or healthier than others. Appellants'

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[26]Specifically, the FDCA permits FDA approval of food health claims only when the agency "determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 U.S.C. § 343(r)(3)(B)(i). In addition, the FDA sometimes chooses to allow "qualified" health claims that cannot satisfy the statutory standard ("significant scientific agreement"). *See* 68 Fed. Reg. 41387 (2003). In these instances as well, the FDA requires that the health claim be submitted to it in advance, along with all supporting documentation, and that the claim be made only after FDA authorization and only with a disclaimer approved by the agency. *Id.*

presentation of the MRTP provision as outside the mainstream of long-established regulatory schemes is off-base.

ii. The MRTP Provision Imposes A Permissible Check On False Or Misleading Speech.

"Light" and "lowered tar and nicotine" cigarettes are not any safer than regular cigarettes. As the National Cancer Institute reported in 2001, although changes in cigarette design reduced the amount of tar and nicotine measured by smoking machines, machine measurements do not accurately show how much tar and nicotine smokers actually take in. *See* NCI Monograph 13 at 1, 4. In reality, there is no meaningful difference in exposure from smoking low-tar brands as compared to regular brands, and therefore no difference in disease risk. *Id.* at 10. Although "many smokers switch to lower yield cigarettes out of concerns for their health believing these cigarettes to be less risky or to be a step towards quitting," *id.*, "current evidence does not support either claims of reduced harm or policy recommendations to switch to these products." *Id.*

Although NCI's Monograph 13 is only nine years old, the industry has been aware for decades that smoking machines do not accurately measure the behavior of actual smokers. As a 1982 R.J. Reynolds report stated, "smokers compensate to obtain a consistent amount of nicotine. Relevant to this, it should be noted that all

cigarettes experienced a marked reduction in nicotine filter efficiency under human smoking conditions compared to the nicotine filter efficiencies obtained under standard FTC conditions." *Philip Morris*, 449 F. Supp. 2d at 468. Nonetheless, tobacco companies decided to use labels touting "light" and "lowered tar and nicotine" cigarettes, and fostered and then exploited widespread public misperception about both the true exposure to tar and nicotine, and the relative health risks of products. For example, R.J. Reynolds tailored its advertising for "low-tar" cigarettes to smokers "seriously concerned about the alleged hazards of smoking." *Id*. at 531. Moreover, such conduct is not simply history. The *Philip Morris* court found that tobacco companies such as plaintiffs R.J. Reynolds and Lorillard "were reasonably likely" to continue their deceptive conduct in the future "because they continued to make false and misleading statements at the time of trial." *Philip Morris*, 566 F.3d at 1109.[27]

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[27] Indeed, the *Philip Morris* court found overwhelming evidence of a "scheme to defraud smokers and potential smokers" by denying the health effects of smoking, denying the addictiveness of nicotine, "falsely representing that light and low-tar cigarettes deliver less nicotine and tar and therefore present fewer health risks than full flavor cigarettes," "falsely denying that they market to youth," "falsely denying that secondhand smoke causes disease," and "suppressing documents, information, and research to prevent the public from learning the truth about these subjects and to avoid or limit liability in litigation." 566 F.3d at 1108.

In reaction to the industry's marketing campaign, over the past twenty-five years or so, most smokers in developed countries began to use "light" and "low-tar" products as a substitute for what they perceived to be riskier products. *See*, *e.g.*, Kozlowski, et al., *Smokers' Misperceptions of Light and Ultra-Light Cigarettes May Keep Them Smoking*, 15 Am. J. of Preventive Med. 9-16 (July 1998); *see generally* NCI Monograph 13 at ch. 1, ch. 6. In the United States, for example, 92.7 percent of cigarettes currently sold are low-tar brands marketed with descriptions such as "light" and "ultra-light." FTC, *Cigarette Report for 2006*, at 7.

These facts form the backdrop against which Congress enacted the MRTP provision. *See* FSPTCA § 2(36-43). This history—a history of the industry marketing "low-tar" and "low-nicotine" tobacco products in a way designed to foster and exploit a misconception that the products were less dangerous than other cigarettes to discourage smokers from trying to quit—shows that the MRTP provision is a means of preventing false or misleading commercial speech that has great potential for harm by an industry with a documented record of deceit.

a. In light of the industry's history of deceptive marketing of tobacco products falsely claimed to pose fewer health risks and the substantial public health concerns at issue, the Court should defer to Congress's determination that there is legitimate need for objective review of the accuracy of promotional health claims for specific

products before those claims are made to consumers. *See United States v. Edge Broad. Co.*, 509 U.S. 418, 434 (1993) ("Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments."). Like claims for other products with potentially significant health consequences, claims that some tobacco products pose a reduced health risk can lawfully be subject to pre-marketing FDA evaluation. *See Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[T]he State may ban commercial expression that is fraudulent or deceptive without further justification."); *Friedman v. Rogers*, 440 U.S. 1, 9-10, (1979) (government may restrict commercial speech that is "not provably false, or even wholly false, but only deceptive or misleading").

That the MRTP provision may delay some accurate reduced-risk promotional statements presents no First Amendment impediment. There is no way of knowing prior to FDA review which reduced-risk claims that a company wants to make will be substantiated. Again, the FDA's regulation of drug and health claims for foods demonstrates the point: The FDA has rejected applications to market drugs for particular uses because it determined that the applications did not substantiate that the products were safe and effective for those uses, and the FDA has denied requests from food companies seeking to make health claims that were not adequately supported. *See*, *e.g.*, FDA, Letter of Denial - Alkaline and Earth Alkaline Citrates

Minimizing the Risk of Osteoporosis (Docket Number 2007P-0301), Oct. 30, 2007;[28] FDA, Qualified Health Claims, Letters of Denial.[29]

Here, in light of its findings regarding the tobacco companies' history of misleading reduced-risk claims and the widespread misperception that they created, Congress required post-marketing studies to verify that the FDA's pre-marketing findings are backed up by post-marketing reality. 21 U.S.C. § 387k(i). But as Congress recognized, because of the potential for addiction and serious illness caused by ungrounded health claims for tobacco products, post-marketing review cannot alone adequately serve the substantial public interest.

The MRTP provision does not bar substantiated reduced-risk claims; it provides a route to making them. The public health imperative justifies the delay to allow the FDA to ensure that the companies do not make false or misleading claims.

b. Even if the MRTP provision were a restriction on non-misleading commercial speech, the provision would satisfy *Central Hudson* because the provision is narrowly tailored to directly advance a substantial government interest in protecting public health. Commercial speech restrictions may be justified by a record

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[28] *Available at* www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/ucm121764.htm.

[29] *Available at* www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072751.htm.

of abuse (such as the extensive record of the tobacco industry's conduct over many decades) and the government's interest in protecting the public (such as its substantial interest in protecting the public health). *See Went For It,* 515 U.S. at 627, 633-35 (historical evidence of abuse may justify broad prophylactic restraints on speech); *Friedman*, 440 U.S. at 15 (same); *Mainstream Mktg. Servs., Inc. v. FTC*, 358 F.3d 1228, 1233 (10th Cir. 2004) (restriction on commercial telemarketing justified by government's interest in combating abusive telemarketing). Here, the industry's history of deliberate misuse of evidence to support inaccurate health claims shows that requiring tobacco companies to demonstrate the validity of claims before presenting those claims to the public is a reasonable way to prevent further deception and public harm.

Appellants' opening brief does not take issue with the facts establishing that tobacco companies have long "used so-called brand descriptors such as 'light' and 'ultra light' to communicate reassuring messages that these are healthier cigarettes and to suggest that smoking low-tar cigarettes is an acceptable alternative to quitting," and they "used sophisticated marketing imagery" to reinforce the misconception that these "low-tar" brands were less harmful. *Philip Morris*, 449 F. Supp. 2d at 430. The issue then, as in many commercial speech challenges, is the fit between the governmental interest and the means chosen to accomplish it. In

discussing this aspect of the *Central Hudson* test, the Supreme Court has emphasized that the restriction should be "no more extensive than is necessary," 447 U.S. at 566, but that it need not be "perfect," only "reasonable." *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

Here, the history of promotional practices employed by the tobacco industry over the past 30 years shows the reasonableness of the fit between the substantial public interest and the MRTP provision. The facts more than justify Congress's conclusion that "[p]ermitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products . . . would be detrimental to the public health," FSPTCA § 2 (42), and demonstrate the reasonable fit between significant public health concerns and the MRTP provision. As the district court concluded, Congress's determination that pre-market review by the FDA is the "only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products," *id*. § 2(43), should be upheld.

B. The Prohibition On Manufacturers' Making Misleading Statements To Consumers That Would Mislead Them Into Believing That Tobacco Products Are Safer Because Of FDA Regulation Should Be Upheld.

Although the court below rightly held that the MRTP provision passes First Amendment scrutiny, it struck down another provision targeted directly at preventing

tobacco companies from misleading consumers about the purported health and safety of tobacco products. That provision, codified at 21 U.S.C. § 331(tt)(4), prohibits manufacturers' statements "directed to consumers" that would mislead consumers into believing that a tobacco product "is safe or less harmful by virtue of—(A) its regulation or inspection by the [FDA]; or (B) its requirements with regulatory requirements set by" the FDA.

The lower court enjoined enforcement of this prohibition because the court was concerned that the provision reached too broadly, encompassing speech by non-commercial actors, such as journalists. R.100 at 34. As Congress's findings make clear, however, that provision is intended to apply only to speech "manufacturers" "directed to consumers." FSPTCA § 2(46). Interpreting the provision in light of the congressional findings and legislative history to apply only to commercial speech, the provision raises no constitutional concerns. *Zadvydas v. Davis*, 533 U.S. 678 (2001) ("'[I]t is a cardinal principle' of statutory interpretation, however, that when an Act of Congress raises 'a serious doubt' as to its constitutionality, 'this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.'") (citations omitted).

CONCLUSION

For the foregoing reasons and the reasons stated in the brief of the appellees/cross-appellants United States, the decision below should be reversed with respect to the restriction on color and graphics in labeling and advertising and the prohibition against manufacturers making misleading statements to consumers implying that a tobacco product is safer because of FDA regulation. The decision should be affirmed in all other respects.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief of amici curiae Campaign for Tobacco-Free Kids, et al. is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare the brief (WordPerfect X3), the brief contains 8,121 words, not including the items not required to be counted.

/s/
Allison M. Zieve

ADDENDUM

The foregoing brief is submitted on behalf of the following organizations:

Campaign for Tobacco-Free Kids works to raise awareness that cigarette smoking is a public health hazard by advocating public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made. Tobacco-Free Kids has more than 100 member organizations, including health, civic, corporate, youth, and religious groups dedicated to reducing children's use of tobacco products.

The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of AAP has grown from the original group of 60 physicians specializing in children's health to 60,000 primary care physicians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 80 years, AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to working with hospitals and clinics, as well as with state and federal governments to protect the well-being of America's children. AAP has engaged in broad and continuous efforts to prevent harm to the health of

children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

The American Cancer Society, Inc. (ACS) has more than three million volunteers nationwide, including 50,000 physicians. The organization works to eliminate cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy, and service. Since its founding in 1913, ACS has conducted groundbreaking research to identify the use of tobacco products as a major cause of cancer and worked to educate the public about its deadly effects. The American Cancer Society Cancer Action Network is the advocacy affiliate of ACS, helping to educate public officials on ACS's views on public policy. ACS Cancer Action Network has more than 350,000 grassroots advocates, many of whom worked to help pass the FSPTCA.

The American Heart Association (AHA) is a voluntary health organization founded in 1924 to reduce death and disability from cardiovascular diseases and stroke—two of the top three causes of death among Americans. AHA is one of the world's premier health organizations, with 22.5 million volunteers and supporters in nearly 2,000 community organizations in the 50 states as well as in Washington, D.C., and Puerto Rico. The association invested more than $473.5 million in fiscal year 2004-05 for research, professional and public education, community service and

advocacy so people across America can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters.

The American Legacy Foundation is dedicated to building a world where young people reject tobacco and anyone can quit. The foundation was established in March 1999 as a result of the Master Settlement Agreement reached between the attorneys general in 46 states and five U.S. territories and the tobacco industry. The foundation develops programs that address the health effects of tobacco use through grants, technical assistance and training, youth activism, strategic partnerships, counter-marketing and grass roots marketing campaigns, research, public relations, and outreach to populations disproportionately affected by the toll of tobacco.

The American Lung Association (ALA) is the nation's oldest voluntary health organization, with 450,000 volunteers and affiliates in all 50 states and the District of Columbia. Because cigarette smoking is a major cause of lung cancer and chronic obstructive pulmonary disease, ALA has long been active in research, education and public policy advocacy on the adverse health effects of tobacco products. ALA has advocated for the regulation of tobacco products for more than two decades.

The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally,

through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy making process. The AMA seeks to promote the science and art of medicine and the betterment of public health. The AMA has long had an interest in the regulation of tobacco products and the tobacco industry. As an institution, it has developed expertise in the pharmacology of nicotine, the toxic effects of cigarette smoke, and the societal implications of tobacco usage. The AMA seeks to appear as amicus curiae in this case on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition of the AMA and the medical societies of each state and the District of Columbia, and was formed to represent the viewpoint of organized medicine in the courts.

The American Public Health Association (APHA) is a national organization devoted to protecting Americans and their communities from preventable serious health threats. Founded in 1872, APHA is the world's oldest and most diverse public health organization. APHA represents a broad array of health providers, educators, environmentalists, policymakers, and health officials at all levels working both within and outside governmental organizations and educational institutions. APHA

advocates for national tobacco control measures to protect the public's health from the adverse effects of tobacco products.

The Kentucky Medical Association (KMA) is a Kentucky, non-profit, non-stock, membership organization. Initially organized in 1851, the KMA was first incorporated in 1929. The KMA currently includes among its membership more than 4,000 physicians actively engaged in the practice of medicine in Kentucky. Among its purposes is the enlightenment of public opinion with regard to matters of great import to Kentucky physicians and their patients.

Oncology Nursing Society (ONS), the largest professional oncology association in the world, is composed of more than 37,000 registered nurses and other healthcare providers, including 455 in Kentucky, dedicated to excellence in patient care, education, research, and administration in oncology nursing. Because tobacco use is responsible for one in three cancer deaths in the United States, ONS has long supported the federal regulation of tobacco products to help reduce and prevent tobacco-related disease, disability, and death. ONS maintains a steadfast commitment to supporting federal, state, and local policies, programs, and other efforts that seek to reduce adult and youth tobacco use, promote tobacco cessation, protect nonsmokers against secondhand smoke, and help increase access to tobacco use prevention and cessation services.

Public Citizen is a consumer advocacy organization founded in 1971, with approximately 150,000 members and supporters nationwide. Public Citizen's members are consumers who are concerned that their children and grandchildren will be enticed into experimenting with tobacco products by the promotional efforts of the tobacco industry and that they may become addicted to tobacco products as a result. Public Citizen has long been active before Congress, regulatory agencies, and the courts in matters relating to public health in general and regulation by the Food and Drug Administration in particular. In addition, Public Citizen has substantial expertise on commercial speech doctrine, as its lawyers argued, among other cases, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748 (1976), the first case in which the United States Supreme Court recognized that commercial speech is entitled to some level of First Amendment protection.

CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of August, 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/
Allison M. Zieve