UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO CO., *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:11-cv-1482 (RJL)

MEMORANDUM OF AMICI CURIAE 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, CAMPAIGN FOR TOBACCO-FREE KIDS, AND PUBLIC CITIZEN IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Plaintiff tobacco companies in this case seek a preliminary injunction against enforcement of the enhanced warnings required by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which mandates that cigarette packaging and advertising include "color graphics depicting the negative health consequences of smoking." Pub. L. No. 111-31, § 201(a). Amici curiae submit this brief to highlight three related points important to the balance of harms and of the public interest required by the preliminary-injunction analysis. First, tobacco use is this nation's number one preventable cause of premature death and disease, and Congress thus has a uniquely strong interest in ensuring effective warnings. Second, overwhelming evidence demonstrates that existing warnings have failed to inform the public adequately of the risks of tobacco use, and that the industry has intentionally undermined those warnings by misrepresenting the health consequences of smoking and marketing their products to children. Third, evidence also establishes that the large, graphic warnings required by the FSPTCA are effective both at raising public awareness of the risks of smoking and at reducing tobacco use. That evidence includes numerous consumer surveys, scientific studies, and a consensus of the most respected national and international authorities in the field—including the Surgeon General, the President's Cancer Panel, the National Cancer Institute, the Institute of Medicine, and the World Health Organization. Taken together, these considerations weigh heavily against plaintiffs' motion for a preliminary injunction.

INTEREST OF AMICI

Amici curiae are ten nonprofit 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 have broad knowledge about the history of tobacco regulation and the tobacco industry's promotional techniques and are particularly well qualified to assist the Court in understanding

the substantial public interest advanced by the provisions of the FSPTCA challenged here. A description of each organization is included in the motion for leave to file this brief. All parties have consented to the filing of this memorandum.

BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) responds to what the Supreme Court has described as "perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). The statistics are grim: An estimated 443,000 people in this country die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease. FDA, *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628, 36,629 (June 22, 2011) (final rule); CDC, *Smoking and Tobacco Use: Fast Facts* (March 2011).[1] These numbers make cigarettes the "leading cause of preventable death and disease" in the United States, "resulting in more deaths each year than AIDS, alcohol, illegal drug use, homicide, suicide, and motor vehicle crashes combined." FDA, *Required Warnings for Cigarette Packages and Advertisements*, 75 Fed. Reg. 69,524, 69,526 (Nov. 12, 2010) (notice of proposed rulemaking). Since the first Surgeon General's report on the hazards of smoking was issued in 1964, more than 12 million people in the United States have died from smoking cigarettes. President's Cancer Panel, *Annual Report: Promoting Healthy Lifestyles* 61 (2006-2007) (President's Cancer Panel Report).[2]

The FSPTCA adopts a comprehensive set of rules governing marketing of tobacco products, but this case challenges the FDA's implementation of only one aspect of the law—its

[1] *Available at* http://www.cdc.gov/tobacco/data_statistics/fact_ sheets/fast_facts/index.htm.

[2] *Available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp06rpt/pcp06rpt.pdf.

requirement of graphic warnings on cigarette packages and advertisements. Specifically, the Act requires tobacco companies to print one of nine textual warnings on the top half of the front and back of cigarette packaging. FSPTCA § 201(a) (amending 15 U.S.C. § 1333). The statute requires warnings to be in 17-point type and appear either in black text on a white background or white text on a black background. *Id.*

Most importantly for this case, the FSPTCA required the FDA, by June 2011, to "issue regulations [for cigarette packaging] that require color graphics depicting the negative health consequences of smoking." *Id.* (amending 15 U.S.C. § 1333(d)). In implementing this requirement, the FDA examined graphic warnings used in other countries and consulted with "experts in the fields of health communications, marketing research, graphic design, and advertising" to develop a set of proposed warnings. 75 Fed. Reg. at 69,534. In November 2010, the FDA published in the Federal Register and on the agency's website 36 proposed graphic warnings that "depict[] the negative health consequences of smoking" and "illustrate[] the message conveyed by the accompanying textual warning statement." 76 Fed. Reg. at 36,636. The notice set forth much of the extensive evidence on which Congress relied in passing the law, demonstrating both that existing warnings have failed to adequately inform consumers about the health risks of tobacco and that larger, graphic warnings used in other countries have been much more effective at accomplishing that goal. 75 Fed. Reg. at 69,529-35.

The agency received more than 1,700 comments "from cigarette manufacturers, retailers and distributors, industry associations, health professionals, public health or other advocacy groups, academics, State and local public health agencies, medical organizations, individual consumers, and other submitters." 76 Fed. Reg. at 36,629. Based on the comments and on its

own research on the effectiveness of the proposed images, the FDA selected nine graphic warnings to illustrate each of the nine textual warnings written by Congress. *Id.* at 36,636.

Before the FDA had published its final rule on the graphic warnings, however, several tobacco companies—including many of the plaintiffs here—sued the FDA in the U.S. District Court for the Western District of Kentucky to enjoin eleven provisions of the Act, including the warning requirements. In *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 528-32 (2010), the court rejected the plaintiffs' challenge to the warnings and granted summary judgment to the government on that issue. The court found "Congress's decision to revise the content and format of the tobacco warnings justified" by evidence that the pre-FSPTCA warnings were largely ignored by consumers and "fail[ed] to convey relevant information in an effective way." *Id.* at 530-31 (quoting Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 291 (2007) (IOM Report)).[3] The court also rejected the plaintiffs' argument that "the new warnings are too large and too prominent," noting the "international consensus" that had developed behind similar warnings. *Id.* at 531. The decision is on appeal to the Sixth Circuit.

ARGUMENT

I. The Government Has a Strong Interest in More Effectively Informing Consumers About the Deadly Effects of Tobacco.

As *Commonwealth Brands* recognized in rejecting the tobacco companies' challenge to the statutory warning requirement, Congress has a strong interest in ensuring that consumers are effectively informed about the health consequences and addictive impact of cigarettes. 678 F. Supp. 2d at 531-32. Indeed, given that tobacco is the "leading cause of preventable death and

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

disease" in the United States, 75 Fed. Reg. at 69,526, it is difficult to imagine any product for which the government has a stronger interest in ensuring effective warnings to consumers.

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 Report);[4] President's Cancer Panel Report 61. Cigarette smoke can accurately be described as poison. It contains 7,000 chemicals, 250 of which cause cancer or are otherwise toxic. U.S. Department of Health and Human Services, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking Attributable Disease: A Report of the Surgeon General* iii (2010).[5] A recent figure estimates that 158,000 people in the United States die each year from lung and bronchial cancer caused by smoking. CDC, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses–United States, 2000-2004* (2008).[6] Smoking also 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 USA, Inc.*, 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* FSPTCA § 2(2). And exposure to secondhand smoke causes heart disease and lung cancer, as well as other health problems. CDC, *Health Effects of Secondhand Smoke* (2011) (reporting that, each year, secondhand smoke causes approximately 46,000 non-smokers to die prematurely, mostly as a result of heart disease; causes 3,400 nonsmokers to die of lung cancer;

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[4] *Available at* http://www.who.int/tobacco/mpower/en/.

[5] *Available at* http://www.surgeongeneral.gov/library/tobaccosmoke/report/full_report.pdf.

[6] *Available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.

and increases the risk of sudden infant death).[7] The FDA cited evidence that, in total, 443,000 people in this country die each year from tobacco-related illnesses. 76 Fed. Reg. at 36,629.

The need for more effective warnings is especially critical in light of tobacco's impact on youth. Although the tobacco industry for decades denied that it targeted youth in its advertising, the industry's own documents show that, early on, it understood the value of creating sophisticated advertising messages directed toward young people and devoted "decades of research and development of strategic plans designed to capture the youth market." National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*, Smoking and Tobacco Control Monograph No. 19 (June 2008), at 157;[8] *Philip Morris*, 449 F. Supp. 2d at 676 (finding the industry's claim that it did not target youth to be false). It is thus no surprise that Congress found that "virtually all" new tobacco users are minors. FSPTCA § 2(4). Every day, almost 3,900 children under the age of 18 try smoking for the first time; and every day, almost 1,000 begin a daily smoking habit. Substance Abuse and Mental Health Servs. Admin., *Results from the 2008 National Survey on Drug Abuse and Health* (2009);[9] *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). Nearly one-half of the children who become regular smokers will die prematurely from a tobacco-related disease. President's Cancer Panel Report, at 64.

By hooking new smokers when they are young and vulnerable to sophisticated advertising messages, the industry creates lifelong customers. Nicotine's strongly addictive nature causes acute withdrawal symptoms and makes quitting very difficult. IOM Report, at 80.

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[7] *Available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/.

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

[9] *Available at* http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm.

Although about 40 percent of smokers try to quit every year, the success rate is only two to five percent. *Id.* at 82. Yet, as Judge Kessler found in 2006, "[w]hile nicotine shares certain key attributes of heroin, cocaine, and other drugs," tobacco companies lied to the public for years, "assert[ing] that smoking is no more addictive than coffee, chocolate, and exercise." *Philip Morris*, 449 F. Supp. 2d at 209.

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, at 88. Congress has a strong interest in ensuring that future consumers—and especially youth—are fully informed about the risks they will face *before* they begin experimenting with a dangerous and highly addictive drug, that current users understand the consequences and relative risk of continuing to smoke, and that those who have quit are reminded of the risks of again taking up the habit.

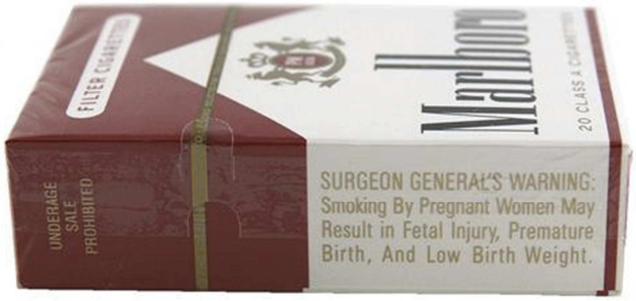
II. Current Warnings Have Failed To Inform Consumers Effectively About the Risks of Tobacco Use.

Much of plaintiffs' argument hinges on their assertions that the FSPTCA's graphic warnings are unnecessary because the existing warnings are sufficient and that Americans are "well aware of the health risks of smoking." Mem. in Supp. of Pls.' Mot. for Summ. J. at 14. The overwhelming evidence, however, refutes these assertions.

For more than 50 years, Congress and the federal government have attempted to better inform the American public about the health consequences of cigarette smoking—adopting three prior sets of warning labels, issuing repeated reports on the health consequences of smoking, and seeking to curtail the industry's deceptive health claims. Despite these efforts, numerous consumer surveys, scientific studies, and a consensus of the most respected national and international authorities in the field—including the Surgeon General, the President's Cancer Panel, the National Cancer Institute, the Institute of Medicine, and the World Health

Organization—have found that the public remains misinformed about the risks of smoking. Moreover, the findings contained in the 1600-page decision of the U.S. District Court in *United States v. Philip Morris* establish that the tobacco industry itself has undermined the existing warnings by denying the dangers of smoking and repeatedly misleading the public about the health hazards of their products. 449 F. Supp. 2d 1. Examining this complete record, Congress and the FDA found that prior efforts have been inadequate to inform the American public fully. As the FDA concluded, "[r]esearch has repeatedly illustrated that the current warnings … frequently go unnoticed or fail to convey relevant information regarding health risks." 75 Fed. Reg. at 69,539.

A. The existing warnings—which were last updated in 1984 and have remained unchanged for more than 25 years—are small and easy to ignore. These warnings occupy only 50% of the narrow side of cigarette packaging (not visible when the packages are on display) and 5% of cigarette advertisements:



As a result, the warnings go largely unnoticed by consumers. IOM Report, at 291.

Studies show that "small text warnings are associated with low levels of awareness and poor recall." David Hammond, *Health Warning Messages on Tobacco Products: A Review*, *Tobacco Control* 3 (2011). In one study on how well students could recall the contents of cigarette packaging, only seven percent of students in the United States mentioned health

warnings. David Hammond, *Tobacco Packaging and Labeling: A Review of Evidence* 5 (2007).[10] At the same time, in Canada, where a warning appeared on the front of the package, 83 percent of students mentioned the warnings. *Id.* Other studies show similar results for advertising. A study of adolescents viewing tobacco advertisements found that more than 40% did not even look at the warning statement included in the advertisement, while only about 35% looked at the warning long enough to read any words in it. 75 Fed. Reg. 69,530. After viewing the ads, adolescents were unable to recall the content of the warnings or even to recognize the warnings in a list. *Id.*

Reviewing the available evidence, the Surgeon General concluded in 1994 that empirical studies of "the visibility of cigarette warnings in advertising ... consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." Surgeon General's Report, at 168. Similarly, the Institute of Medicine concluded that text warnings in the United States receive little notice by smokers. IOM Report, at C-3. The Institute described the warnings as "woefully deficient," and the Chair of the Institute's Committee on Reducing Tobacco Use described them as "invisible" to consumers. *Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Comm. on Energy and Commerce*, 110th Cong. 42 (2007) (testimony of Richard Bonnie).

In addition to failing to inform consumers about the risks of tobacco use, the current warnings fail to change consumers' decisionmaking or behavior. Although more than 400,000 people in the United States die every year from tobacco use, more than 45 million Americans continue to smoke. And despite laws in all 50 states banning the sale of tobacco products to

[10] *Available at* http://www.tobaccolabels.ca/factshee/article_.

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).[11]

B. Despite plaintiffs' contention that the public "overestimates" the risks of smoking, Mem. in Supp. of Pls.' Mot. for Summ. J. at 14, extensive research and the FDA's findings demonstrate that tobacco users in the United States actually fail to appreciate the extent of the health risks associated with tobacco use and, in fact, greatly *underestimate* their personal risk.

Although smokers generally understand that smoking can cause lung cancer, they are less likely to understand the *degree* of risk involved. For example, one study found that more than a quarter of smokers did not believe that smoking increased the risk of getting cancer "a lot." 76 Fed. Reg. at 36,632. Smokers are also much less aware of the risk of different forms of cancer and of other health risks caused by tobacco use. For example, fewer than half of smokers knew that tobacco use causes stomach ulcers, infertility, osteoporosis, and sudden infant death syndrome. *Id.* Indeed, one survey found that, "more than half of the respondents were unable to name a smoking-related illness other than lung cancer." *Id.* Up to a third of smokers also believe that activities like exercise or taking vitamins can "undo" most of the negative effects of smoking. *Id.* And knowledge about the health risks of smoking is even lower in some demographics, including low-income Americans and those with fewer years of education. *Id.* Based on this evidence, the FDA concluded that, "[w]hile most smokers understand that smoking poses certain statistical risks to their health, many fail to appreciate the severity and magnitude of those risks." *Id.* at 36,632.

Even smokers who correctly recognize the risks of tobacco use in the abstract are much less likely to appreciate their *own* risk of disease. One study found that only 40% of smokers

[11] *Available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm.

believed they had a higher-than-average risk of cancer, and only 29% believed they had a higher-than average risk of heart disease. *Id.* Even among smokers who smoke 40 or more cigarettes per day, less than half believed they were at increased risk of those diseases. *Id.* Smokers are also more than twice as likely as nonsmokers to doubt that tobacco use, even for as long as 30 to 40 years, would cause death. IOM Report, at 90. And the FDA found that, even among smokers who accurately understand their personal risk, "that understanding may be too abstract to be thought of at the time of purchase" when warnings fail "to make the risks salient." 76 Fed. Reg. at 36,633.

These problems are particularly serious among youth. Evidence shows that "adolescent smokers underestimated their personal risk, even if they had an accurate sense of the statistical risk." *Id.* at 36,632. The Institute of Medicine explained that "adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior." IOM Report, at 93. Although adolescents overestimate the risks of lung cancer, they underestimate the likelihood that they will suffer tobacco-related disease and the degree to which smoking can shorten their lives. *Id.* at 89-90. Adolescents also "typically underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose." President's Cancer Panel Report, at 64; *see also* IOM Report, at 89, 91. Although fewer than 5 percent of daily smokers in high school think that they still will be smoking at all in 5 years, more than 60 percent are still regular daily smokers 7 to 9 years later. 76 Fed. Reg. at 36,633.

Plaintiffs rely on three studies that they say show that smokers are already fully aware of the dangers of smoking, but these studies reached the opposite conclusion. Mem. in Supp. of Pls.' Mot. for Summ. J. at 26 & n.19. For example, plaintiffs rely on Neil D. Weinstein, *Public*

Understanding of the Illnesses Caused by Cigarette Smoking, but that study found that "lung cancer was the *only* illness that could be identified by a clear majority of respondents," and that—even as to lung cancer—people underestimated the fatality rate and overestimated length of life. 6:2 Nicotine & Tobacco Res. 349, 349 (2004). The study concluded that, "even though people recognize that smoking can lead to adverse health consequences, they do not have even a basic understanding of the nature and severity of these consequences." *Id.* The other studies on which plaintiffs rely reached similar conclusions. *See* David Hammond, *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings From the International Tobacco Control (ITC) Four Country Survey*, 15 Tobacco Control iii19, iii19 (2006) (concluding that smokers "exhibited significant gaps in their knowledge of the risks of smoking," but that smokers in countries with larger, graphic warnings had more knowledge of the risks); K. Michael Cummings, *Are Smokers Adequately Informed about the Health Risks of Smoking and Medicinal Nicotine?*, 6:2 Nicotine & Tobacco Res. 1 (2004) (finding that "smokers are misinformed about many aspects of the cigarettes they smoke … and that they want more information about ways to reduce the health risks").

C. Plaintiffs' argument that the risks of smoking are well-known is particularly troubling given that much of the public's failure to understand those risks is directly attributable to the industry's deliberate misrepresentations. Although for many years the tobacco industry feigned ignorance of the addictive nature of its products, the FDA's tobacco rulemaking in 1995 and 1996, and the extensive findings of Judge Kessler in *United States v. Philip Morris*, 449 F. Supp. 2d 1, found overwhelming evidence that the industry's public statements were lies. 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," or "low-nicotine" cigarettes were less harmful than regular cigarettes—claims that the industry knew to be false. *Id.* at 445, 468, 531. To discourage smokers from quitting, the companies promoted their low-tar brands to those who were concerned about cigarettes' health hazards or considering quitting. *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);[12] *see also Philip Morris*, 449 F. Supp. 2d at 507-08 (companies "continue to make[] false and misleading statements regarding low-tar cigarettes in order to reassure smokers and dissuade them from quitting").

* * *

More than fifty years of experience with less prominent warnings, and the industry's history of undermining those warnings by misrepresenting the risks of its products, demonstrate that—unlike commercial speech restrictions held unconstitutional in other cases—Congress did not adopt the FSPTCA warnings as a "first resort," without exploring the feasibility of other

[12] *Available at* http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf.

options. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). In concluding that the current warnings are inadequate, Congress reasonably relied on the overwhelming evidence showing the ineffectiveness of those warnings at either educating the public or changing consumer behavior.

III. Substantial Evidence Supports the Revised Warning Requirements.

A. The Evidence Demonstrates That Large, Graphic Warnings on the Front of Cigarette Packaging Are Most Effective at Reducing Smoking and Informing Consumers About the Risks of Tobacco Use.

In adopting larger, graphic warnings, the United States joined a growing consensus among nations that graphic warnings covering a substantial portion of the front panels of cigarette packages are the most effective means of informing consumers about the risks of smoking. *Commonwealth Brands*, 678 F. Supp. 2d at 531. At least 25 countries now require graphics on cigarette packaging, including Canada, Brazil, Great Britain, Australia, India, Thailand, Chile, and Switzerland. *See* Canadian Cancer Society, *Cigarette Package Health Warnings* 3 (2008).[13] 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. Citing the success of warnings in these countries, the World Health Organization 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 Report, at 34; *see also Commonwealth Brands*, 678 F. Supp. 2d at 531.

The effectiveness of such warnings is documented in extensive independent research. A recent review of ninety-four separate studies on tobacco warnings concluded that "the impact of health warnings depends on their size and design." Hammond, *Health Warning Messages on*

[13] http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_en.pdf.

Tobacco Products: A Review, *supra*, at 1. "[W]hereas obscure text-only warnings appear to have little impact, prominent health warnings on the face of packages serve as a prominent source of health information for smokers and non-smokers, can increase health knowledge and perceptions of risk and can promote smoking cessation." *Id.* As *Commonwealth Brands* held in rejecting the industry's arguments, "the government's goal is not to stigmatize tobacco products on the industry's dime; the goal is to ensure that the health risk message is actually *seen* by consumers in the first place." 678 F. Supp. 2d at 530 (emphasis in original).

Experts also agree that package warnings are more effective—particularly among youth—when they involve imagery. "[P]ictures with graphic depictions of disease and other negative images [have] greater impact than words alone … ." WHO Report, at 34. Use of images more effectively draws attention to the message and makes it more memorable, while prompting consumers to think about the consequences of smoking. *See* Hammond, *Tobacco Packaging and Labeling: A Review of Evidence*, *supra*, at 10. One study showed that 90 percent of young people surveyed thought that picture warnings were informative and made smoking seem less attractive. *Id.* 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. Graphic warnings are also important for communicating with consumers with low levels of education, given evidence that those consumers "are less likely to recall health information in text-based messages." IOM Report, at 295, C-3 (noting one study showing that current warnings "require a college reading level" and thus "may be inappropriate for youth and Americans with poor reading abilities.").

Finally, there is also strong scientific evidence demonstrating the value of including the national quitline number, 1-800-QUIT-NOW, in the graphic warnings to inform consumers

about the availability of assistance if they want to quit. As the Institute of Medicine found, quitlines have proven "effective … in helping individuals to stop smoking"—increasing smoking abstinence by as much as 30 to 50 percent. *Id.* at 237. Based on a careful review of the evidence, the U.S. Public Health Service similarly concluded that smokers who use telephone quitlines are significantly more successful at quitting than those who get little or no counseling. U.S. Pub. Health Serv., *Clinical Practice Guidelines, Treating Tobacco Use and Dependence: 2008 Update* 91-92 (2008).[14] The Public Health Service's guidelines accordingly recommend that "clinicians and health care delivery systems should both ensure patient access to quitlines and promote quitline use." *Id.* at vii. These conclusions are consistent with well-established evidence confirming that by providing a direct and immediate cue for action, quitlines significantly increase the likelihood of changes in behavior. *See, e.g.*, David B. Abrams, *et al.*, *Boosting Population Quits Through Evidence-Based Cessation Treatment and Policy*, 38 Am J. Prev. Med. Supp. S351-363 (2010).

B. Plaintiffs' Criticism of the FDA's Rulemaking Fails to Rebut the Overwhelming Weight of Evidence Demonstrating the Warnings' Effectiveness.

Plaintiffs ignore the entirety of the record on which Congress relied in adopting the new warning requirements. Instead, they single out for criticism a regulatory-impact analysis and consumer study conducted by the FDA to help it choose specific images to include in the warnings. The rulemaking record as a whole, however, along with Congress's findings and years of experience documenting the effectiveness of large, graphic warnings, amply support the chosen graphic warnings.

[14] *Available at* http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

1. The FDA's Regulatory-Impact Analysis Does Not Undermine the Evidence on Which Congress Relied.

Plaintiffs argue that the agency's regulatory-impact analysis fails to establish that tobacco use in Canada declined after that country adopted graphic warnings similar to those required by the FSPTCA. Mem. in Supp. of Pls.' Mot. for Summ. J. at 19-22. The analysis, however, was never intended to carry that burden. As the FDA explained, its regulatory-impact analysis was subject to a "large uncertainty" because it was based on "very small data sets" and depended on unmeasurable differences between the "social and policy climate of the U.S. and Canada." 76 Fed. Red. at 36,721. Although, based on this limited data, the agency could "not reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate," it also could not reject the possibility that the rule would lead to significant reductions in tobacco use and thus savings to the American public. *Id.* Regardless, the FDA's difficulty in quantifying the impact of the rule on smoking prevalence does nothing to undermine the extensive evidence—set forth in detail in the FDA's notice of proposed rulemaking and final rule, but ignored by plaintiffs—that Canada's warnings were effective both in substantially reducing tobacco use and in effectively communicating information to consumers.

Studies show that Canadian smokers who have read, thought about, and discussed graphic labels were more likely to have quit, tried to quit, or reduced their smoking. IOM Report, at 295. One-fifth of Canadian smokers said that they smoked less, and one-third said they were more likely to quit, because of the warnings. *Id.* Former smokers also identified the pictorial warnings as important factors in quitting and in subsequently remaining nonsmokers. *Id.* Moreover, there is evidence that pictorial warnings in Canada have been effective in deterring children from taking up smoking. Approximately 6 years after the introduction of pictorial warnings, more than 90% of surveyed Canadian youth agreed that pictorial warnings on

Canadian cigarette packages had provided them with important information about the health consequences of smoking and made it less likely that they would smoke. Given this and other evidence, the Canadian Supreme Court unanimously rejected a challenge to the warnings by tobacco companies there, concluding that "[t]he benefits flowing from the larger warnings are clear." *Canada v. JTI-Macdonald Corp.*, [2007] S.C.C. 30 ¶ 139.

Studies of warnings outside Canada back up this conclusion. For example, a study of graphic warnings introduced in Australia in 2006 found that the "self-reported impact" of tobacco use "increased significantly" after the country adopted the enhanced warnings. Ron Borland, *et al.*, *Impact of Graphic and Text Warnings on Cigarette Packs: Findings From Four Countries Over Five Years*, 18 *Tobacco Control* 358, 359-60 (2009). The study concluded that Australia's experience "strengthened the existing evidence that reactions to warnings predict subsequent quitting." *Id.* at 359; *see also* Victoria White, *et al.*, *Do Graphic Health Warning Labels Have an Impact on Adolescents' Smoking-Related Beliefs and Behaviors?*, 103 *Addiction Res. Report* 1562, 1562 (2008) (finding that the "introduction of graphic warning labels may help to reduce smoking among adolescents"). Other studies have found similar effects of graphic warnings in Malaysia, *see* Ahmed I. Fathelrahman, *Smokers' Responses Toward Cigarette Pack Warning Labels in Predicting Quit Intention, Stage of Change, and Self-Efficacy*, 11:3 Nicotine & Tobacco Res. 248 (2009), and the European Union, *see* Constantine I. Vardavas, *Adolescents Perceived Effectiveness of the Proposed European Graphic Tobacco Warning Labels*, 19 Eur. J. Pub. Health 212 (2009).

Even if the evidence that the revised warnings will lead to a reduction in smoking were not as compelling as it is, the First Amendment would not prohibit the government from requiring tobacco companies to inform consumers more effectively about the risk of serious

injury and death caused by their products. The primary purpose of warning labels is to communicate information to consumers. Because "the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, … 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 Supreme Court of Ohio*, 471 U.S. 626, 651 & n.4 (1985). Unlike prohibitions on speech, 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). Indeed, such "disclosure furthers, rather than hinders the First Amendment goal of the discovery of truth." *Id.* at 114.

In *Zauderer*, for example, the Supreme Court upheld the constitutionality of a state bar disciplinary regulation requiring attorneys that advertised contingent-fee representation to disclose in their advertisements that clients may still have to bear certain costs. *See* 471 U.S. at 633. Notably, the court did not require the state to show that the disclosures would make consumers less likely to hire the advertising attorney or would otherwise affect their decision about whom to hire. Rather, the Court held the disclosure to be justified because the average consumer might not understand the difference between fees and costs. *Id.* Similarly, the Court in *Milavetz, Gallop & Milavetz, P.A. v. United States* upheld a federal law requiring "debt relief agencies" to disclose, among other things, that their assistance "may involve bankruptcy relief." 130 S. Ct. 1324, 1339 (2010). Again, the Court did not require evidence that the disclosure would change consumer behavior. Noting that "the less exacting scrutiny described in *Zauderer* governs" when "the challenged provisions impose a disclosure requirement rather than an affirmative limitation on speech," the Court found the government's burden to be satisfied by

"[e]vidence in the congressional record demonstrating a pattern of advertisements that hold out the promise of debt relief without alerting consumers to its potential cost." *Id.*

Numerous other federal, state, and local laws require advertisers to include health and safety warnings that are necessary for consumers to understand the risks they will undertake if they heed the advertiser's commercial message. For example, the FDA mandates 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." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005). Such laws have been widely upheld by the courts. *See id.* at 113-16 (upholding Maine law requiring intermediaries between drug companies and pharmacies to disclose their conflicts of interest and financial arrangements); *see also, e.g., N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114 (2d Cir. 2009) (upholding a New York City law requiring disclosure of calories on menus and menu boards); *Envt'l Def. Ctr. v. EPA*, 344 F.3d 832, 848-851 (9th Cir. 2003) (upholding requirement that storm-sewer providers distribute information concerning the environmental hazards of stormwater discharges and steps the public can take to reduce pollutants); *Sorrell*, 272 F.3d 104 (upholding a Vermont law requiring manufacturers to inform consumers that products contain mercury and should be recycled or disposed of as hazardous waste). *Cf. UAW-Labor*

Employment & Training Corp. v. Chao, 325 F.3d 360, 365 (D.C. Cir. 2003) (upholding requirement that federal contractors post notices at all of their facilities informing employees of rights under federal labor law).

In this case, overwhelming evidence demonstrates that Canada's enhanced warnings have been highly effective at increasing public awareness about the risks of tobacco. In studies of Canadian smokers, "approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information," and more than half "reported that the pictorial warnings have made them more likely to think about the health risks of smoking." IOM Report, at 294. Moreover, in a recent study of more than 8,000 smokers from Canada, Australia, the United States, and the United Kingdom over a five-year period, 85% of Canadian respondents cited packages as a source of health information, compared to only 47% of U.S. smokers. Borland, *Impact of Graphic and Text Warnings*, *supra*, at 358. In many countries, more smokers report getting information about the health risks of smoking from warning labels than any other source except television. David Hammond, *Tobacco Labeling & Packaging Toolkit*: *A Guide to FCTC Article 11* (2009). Like the required disclosure in *Zauderer*, the warnings thus ensure that consumers are better informed about the products they are purchasing, thereby serving the same constitutional purpose as does the commercial speech doctrine itself.

2. The FDA's Consumer Research Was Not Intended to Prove By Itself the Effectiveness of Graphic Warnings.

Plaintiffs also criticize consumer research conducted by the FDA, arguing that the evidence fails to demonstrate that the chosen warnings increase awareness about the risks of smoking. Plaintiffs' criticism misstates the purpose of the study and its role in the FDA's decision making. Like the agency's regulatory-impact analysis, its consumer research was not

designed to provide independent proof of the effectiveness of graphic warnings, which had already been demonstrated by a large number of independent studies. Rather, the purpose of the study was to test only the "*relative* efficacy" of each of the 36 graphic warnings proposed in the agency's notice of proposed rulemaking. FDA, *Experimental Study of Graphic Cigarette Warning Labels* 1-1 (2010) (FDA Study) (emphasis added).

The study tested the effectiveness of each proposed graphic by exposing participants to a single viewing of one of the warnings and measuring both the participants' immediate reaction and their ability to recall the warning's content later. *Id.* at 1-3. Such measurements are relevant in evaluating the relative effectiveness of warnings because evidence demonstrates that a warning's effect on long-term changes in knowledge and behavior depends on the viewer's "immediate emotional and cognitive reactions" to the warning. *Id.* at 4-1. As the study's authors explained, a strong immediate reaction "enhances recall and processing of the health warning, which helps ensure that the warning is better processed, understood, and remembered." *Id.* At 1-2. These "immediate responses" lead to "later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke," and "eventually … to changes in intentions to quit/start smoking." *Id.*

The study concluded that "[m]ost of the [proposed] warning images elicited strong emotional and cognitive responses compared with controls," and that participants' recall of the images was strong—exceeding 70% even one week after viewing. *Id.* at 4-1, 4-2. Moreover, the images adopted by the FDA in its final rule were generally more likely than other proposed images to be memorable and to make an impact on the viewer. Of the graphics proposed to illustrate the warning "Cigarettes are addictive," for example, the FDA selected a warning

depicting a man blowing smoke through a hole in his throat, which the study found was the image most likely to elicit a strong reaction from the viewer. *Id.* at 3-2, 3-4, 4-2.

Although these findings suggest that the FDA's chosen warnings are likely to lead to long-term effects on consumers' attitudes and behavior, *id.* at 4-1, the study was not intended to detect or measure such long-term effects directly. The effectiveness of graphic warnings on tobacco packaging comes not from a single exposure, but from repeated exposure at the moment when the viewer is deciding whether to purchase or use tobacco. As the FDA explained, "pack-a-day smokers are potentially exposed to warnings more than 7,000 times per year." 76 Fed. Reg. at 36,631. But changes in behavior "are unlikely to be immediate or short-term," FDA Study at 1-2, and the study's design did "not allow for assessment of the effect [of] repetitive viewing of the graphic warning labels." *Id.* at 4-5.

Even given these limitations, the study found that, after only a single viewing, several of the images had a significant impact on beliefs about the health risks of smoking. *Id.* at 4-3. And although the study—as expected—did not find "strong evidence" that the warnings increased subjects' intention to quit smoking after a single viewing, several of the images showed a statistically significant impact on the intention to quit in at least one sample group. *Id.*

Taken as a whole, the strength of the evidence reflected in Congress's findings and the rulemaking record is unique among commercial-speech cases. That a single study—not designed for the purpose—does not on its own demonstrate the effectiveness of graphic warnings does nothing to undermine the overwhelming weight of evidence that prominent, graphic warnings are effective both at reducing tobacco use and at better informing consumers about the risks of smoking. On the contrary, the ability of warnings to create *any* measurable effect in smokers'

beliefs and intention to quit after only one viewing powerfully demonstrates the warnings' effectiveness.

CONCLUSION

For the foregoing reasons and the reasons stated in the government's memorandum, the motion for a preliminary injunction should be denied.

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Respectfully submitted,

/s/Gregory A. Beck
Gregory A. Beck
Allison M. Zieve
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
202-588-1000

Attorneys for Amici Curiae
American Cancer Society, *et al.*