

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 SUPPORT OF DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION
FOR SUMMARY JUDGMENT**

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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 tobacco warnings challenged here. A description of each organization is included in the motion for leave to file this memorandum. 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). An estimated 443,000 people in this country die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, making cigarettes the leading cause of preventable death in the United States. FDA, *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628, 36,631 (2011) (final rule); CDC, *Smoking and Tobacco Use: Fast Facts* (updated Mar. 2011).¹ An overwhelming majority of adult smokers started smoking before age 18. President's Cancer Panel, *Promoting Healthy Lifestyles* 64 (2007) (President's Cancer Panel Report).² Because cigarettes are highly addictive, many young smokers become addicted at a time when they do not fully understand addiction or its impact on

¹Available 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/pcp07rpt/pcp07rpt.pdf>.

their ability to quit. *See* Slovic, *Smoking: Risk, Perception, and Policy* 121-23 (2001). Nearly half of the children who become regular smokers will die prematurely from a tobacco-related disease. President’s Cancer Panel Report at 64.

The FSPTCA adopts a comprehensive set of rules governing the marketing of tobacco products, but this case challenges only one aspect of the law—its requirement that the FDA “issue regulations [for cigarette packaging] that require color graphics depicting the negative health consequences of smoking.” Pub. L. No. 111-31, § 201(b) (amending 15 U.S.C. § 1333). In implementing that requirement, the FDA consulted with “experts in the fields of health communications, marketing research, graphic design, and advertising” to develop a set of proposed warnings. FDA, *Required Warnings for Cigarette Packages and Advertisements*, 75 Fed. Reg. 69,524, 69,534 (2010) (notice of proposed rulemaking). 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 educate the public about the health risks of tobacco and that larger, graphic warnings used in other countries have been much more effective than text-only labels at informing consumers. 75 Fed. Reg. at 69,529-34. 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.

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 these 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.

ARGUMENT

This brief highlights three points relevant to the Court’s evaluation of the evidence on summary judgment. First, overwhelming evidence demonstrates both that existing warnings have failed to inform the public adequately of the risks of tobacco use, and that the large, graphic warnings required by the FSPTCA are effective at raising public awareness of the risks of smoking. Second, the specific graphic warnings chosen by the FDA truthfully illustrate health consequences of tobacco that are well-established and undisputed by plaintiffs. Third, plaintiffs’ discussion of the evidence is limited to narrow portions of the FDA’s rulemaking that were not intended to prove the warnings’ effectiveness, and ignores almost the entirety of the extensive record on which Congress and the FDA relied. That record, taken as a whole, amply supports the warnings and the government’s motion for summary judgment.

I. Overwhelming Evidence Demonstrates That Large, Graphic Warnings on the Front and Back of Cigarette Packaging Are Most Effective at Informing Consumers About the Risks of Tobacco Use.

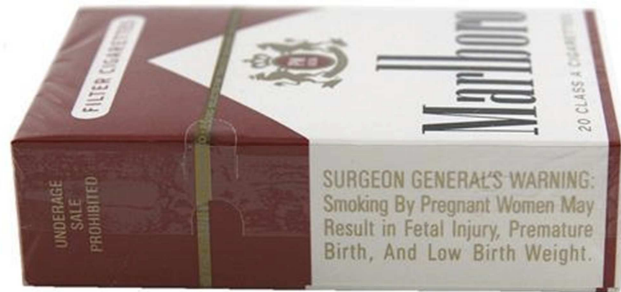
Much of plaintiffs’ argument hinges on their assertions that the FSPTCA’s graphic warnings are unnecessary because the existing warnings are sufficient and that Americans are “well aware of the health risks of smoking.” Mem. in Supp. of Pls.’ Mot. for Summ. J. at 14. The evidence, however, refutes these assertions. 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—establish both that current warnings have failed to adequately inform consumers, and that graphic warnings are much more effective at accomplishing that goal.

A. The Existing Warnings Fail to Adequately Inform Consumers of the Risks of Smoking.

For almost fifty 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, Congress and the FDA found that the public remains misinformed about the risks of smoking. 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 69,529.

1. Congress’s decision to require large, graphic warning labels was based on decades of experience with the failure of less prominent, textual warnings to accomplish their purpose. The United States first began requiring cigarette warning labels in 1966 and has revised the warnings twice since then. *Id.* at 69,529-30. The existing warnings—which were last updated in 1984 and have remained unchanged for more than 25 years—are small and easy to ignore. *Id.* at 69,530. These warnings occupy only half of the narrow side of cigarette packaging, where they are not visible when the packages are on display, and 5% of cigarette advertisements:



As a result, the warnings go largely unnoticed by consumers. Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 291 (2007) (IOM Report).³

Studies show that “small text warnings are associated with low levels of awareness and poor recall.” Hammond, *Health Warning Messages on Tobacco Products: A Review*, 20 *Tobacco Control* 327, 329 (2011). In one study on how well students could remember the contents of cigarette packaging, only 7% of students in the United States mentioned health warnings. Hammond, *Tobacco Packaging and Labeling: A Review of Evidence* 5 (2007).⁴ At the same time, in Canada, where a warning appeared on the front of the package, 83% of students mentioned the warnings. *Id.* Other studies show similar results for warnings required in advertisements. 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. at 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

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

⁴ Available at http://www.tobaccolabels.ca/factshee/article_.

General's Report, *Youth & Tobacco: Preventing Tobacco Use Among Young People* 168 (1994).⁵ Similarly, the Institute of Medicine—the medical arm of the National Academy of Sciences—concluded that text warnings in the United States receive little notice by smokers. IOM Report at 290-91. The Institute found that existing warning labels have been “woefully deficient” at informing consumers of the consequences of smoking, and recommended the adoption of large, graphic warning labels. *Id.* at 291. In his testimony to Congress, the Chair of the Institute's Committee on Reducing Tobacco Use described the existing warnings as “invisible” to consumers. *Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcomm. 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 anyone under age 18, one in five high school students smokes cigarettes. CDC, *Cigarette Use Among High School Students* (July 2010).⁶

2. 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 fail to appreciate the extent of the health risks associated with tobacco use and, in fact, greatly *underestimate* their personal risk.

⁵ Available at <http://profiles.nlm.nih.gov/ps/access/NNBCLQ.pdf>.

⁶ Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm>.

Although smokers generally understand that smoking can cause lung cancer, they are less likely to understand the degree of risk involved. 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, most smokers do not know that smoking 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 demographic groups, 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.*

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 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 relevant risks salient.” 76 Fed. Reg. at 36,633.

These problems are particularly serious among youth. Evidence shows that “adolescent smokers underestimate[] 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 danger of addiction, the likelihood that they will suffer tobacco-related disease, and the degree to which smoking can shorten their lives. *Id.* at 89-90.

Plaintiffs rely on three studies that they say show that smokers are already fully aware of the dangers of smoking, but these studies actually reached the opposite conclusion. Mem. in Supp. of Pls.’ Mot. for Summ. J. at 26 & n.19. For example, plaintiffs rely on 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 *Nicotine & Tobacco Res.* 349, 349 (2004) (emphasis added). 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 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); Cummings, *Are Smokers Adequately Informed about the Health Risks of Smoking and Medicinal Nicotine?*, 6 *Nicotine & Tobacco Res.* 1, 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 their health risks”).

3. 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 USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), 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. The scheme was highly successful: Sales of purportedly “low-tar” and “low-nicotine” brands increased from 2% of total cigarette sales in 1967 to 92.7% in 2006. *Id.* at 508; FTC, *Cigarette Report for 2006*, at 7 (2009).⁷

Moreover, 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* 157 (2008);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).

* * *

Nearly fifty years of experience with less prominent warnings 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 options. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). In concluding that the current warnings are inadequate, Congress and the FDA reasonably relied on the evidence showing the ineffectiveness of those warnings at both educating the public and changing consumer behavior.

⁷ Available at <http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf>.

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

B. The Evidence Demonstrates the Effectiveness of Large, Graphic Warnings.

In contrast to existing warnings, the effectiveness of large, graphic 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 Tobacco Products*, 20 *Tobacco Control* at 327. “[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 the court in *Commonwealth Brands, Inc. v. United States* recently held in rejecting a tobacco-industry challenge to the FSPTCA’s warning requirement, “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 instance.” 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010).

Experts 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” World Health Organization, *Report on the Global Tobacco Epidemic* 34 (2008) (WHO Report);⁹ *see* IOM Report at 290-96. 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*, *supra*, at 10. One study showed that 90% 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

⁹ Available at <http://www.who.int/tobacco/mpower/2008/en/index.html>.

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; *see also id.* at C-3 (noting that current warnings “require a college reading level” and thus “may be inappropriate for youth and Americans with poor reading abilities”).

In adopting larger, graphic warnings, the United States joined a growing consensus among nations that graphic warnings covering a substantial portion of the front and back 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 39 countries 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 (2010).¹⁰ Thirty-two countries require at least half of the front and back panels of a cigarette container to be used for warnings. *Id.* at 4. 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.

II. The Graphic Warnings Truthfully Inform Consumers of the Risks of Smoking.

Plaintiffs do not challenge the text of the new warnings required by Congress, which truthfully state, among other things, that cigarettes are addictive; that they cause cancer, fatal lung disease, strokes, and heart disease; and that “[q]uitting smoking now greatly reduces serious threats to your health.” FSPTCA § 201(a). As *Commonwealth Brands* held, these statements are “objective and [have] not been controversial for many decades.” 678 F. Supp. 2d at 531-32.

¹⁰ Available at http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_en.pdf.

Instead, plaintiffs challenge the FDA’s choice of graphic images to accompany the textual warnings, arguing that the images “cross the line into anti-smoking advocacy.” Mem. in Supp. of Pls.’ Mot. for Summ. J. at 1. But to the extent that some of the images are disturbing, it is because they truthfully depict the disturbing consequences of smoking. Each image “illustrate[s] the message conveyed by the accompanying textual warning statement”—which plaintiffs do not dispute—by depicting smoking risks that are “well-established in the scientific literature.” 76 Fed. Reg. at 36,636, 36,641. The “salience” of these images is critical to ensuring that consumers notice and understand them. *Id.* at 36,697-98; *see* IOM Report at C-3. As the FDA explained, the “overall body of scientific literature indicates that health warnings that evoke strong emotional reactions enhance an individual’s ability to process the warning information.” 76 Fed. Reg. at 36,641. By “eliciting strong emotional and cognitive reactions,” the warnings “enhance[] recall and information processing, which helps to ensure that the warning is better processed, understood and remembered,” and increases understanding of “the extent to which an individual could personally experience a smoking-related disease.” *Id.* at 36,641, 36,642. The graphics thus fulfill the purpose of the warnings: “to increase consumer knowledge and understanding of the health risks of smoking.” *Id.* at 36,642.

A. “Smoking can kill you.”

To illustrate the warning “smoking can kill you,” the FDA chose an image of a body on an autopsy table. The image truthfully illustrates the uniquely dangerous nature of cigarettes, which, unlike any other consumer product, kill up to half of the people who use them as they are intended to be used. WHO Report at 8; President’s Cancer Panel Report at 61. Tobacco kills an estimated 443,000 people in the United States every year—more “than AIDS, alcohol, illegal drug use, homicide, suicide, and motor vehicle crashes combined.” 75 Fed. Reg. at 69,526. Plaintiffs argue that most people who die of smoking-related diseases do not receive autopsies,

but that objection, even if true, is not material to the message conveyed by the warning—that smoking causes death. Given that cigarettes are the leading cause of preventable death in the United States, defendants cannot dispute the FDA’s conclusion that the image of a corpse depicts “a realistic outcome of the negative health consequences caused by smoking.” 76 Fed. Reg. at 36,655.

B. “Cigarettes are addictive.”

The graphic illustrating the statement “cigarettes are addictive” shows a man holding a cigarette and blowing smoke from a tracheostomy hole in his throat. This image also depicts the realistic consequences of smoking. First, doctors use tracheostomies to relieve obstructions of the airway caused by cancer of the larynx, pharynx, or esophagus—all of which are caused by smoking. Surgeon General’s Report, *The Health Consequences of Smoking* 62-67 (2004).¹¹ Second, the image graphically conveys a well-documented fact about cigarettes—they are so addictive that many smokers are unable to break the habit even while suffering the effects of smoking-related illness. Seven studies summarized in a 2006 medical paper followed patients who had been smokers after surgery for lung cancer. Nearly half smoked at some point during the first year after surgery, and 37% were smokers a year later. Walker, *Smoking Relapse During the First Year After Treatment for Early-Stage Non-Small-Cell Lung Cancer*, 15 *Cancer Epidemiology Biomarkers & Prevention* 2370, 2370 (Dec. 2006). Other studies have also found that large numbers of smokers continue smoking after a cancer diagnosis.¹² Overall, although about 40% of smokers try to quit every year, the success rate is only 2 to 5%. IOM Report at 82.

¹¹ Available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

¹² See Cooley, *Smoking Cessation Is Challenging Even for Patients Recovering from Lung Cancer Surgery With Curative Intent*, 66 *Lung Cancer* 218 (Nov. 2009); Cox, *Nicotine Dependence Treatment for Patients With Cancer*, 98 *Cancer* 632 (Aug. 2003).

C. “Tobacco smoke can harm your children.”

The graphic warning the FDA chose to illustrate the statement “tobacco smoke can harm your children” depicts a man smoking while holding a baby. The warning visually conveys the risks of smoking around children, which, together with the text, conveys an undeniable truth. The Surgeon General found that exposure to secondhand smoke harms children by causing sudden infant death syndrome, slow lung growth, respiratory infections, ear problems, and asthma attacks, among other problems. Surgeon General’s Report, *The Health Consequences of Involuntary Exposure to Tobacco Smoke* 13-14 (2006).¹³ Plaintiffs do not deny that their products cause these illnesses. Instead, they complain that the image chosen by the FDA “employs actors and technological manipulation to create a stylized plume of smoke approaching a baby.” Compl. ¶ 59(a). But that complaint, once again, is not material to the warning’s message, and it would defy reason to require the FDA to expose a real baby to tobacco smoke to illustrate the risk of smoking.¹⁴

D. “Smoking during pregnancy can harm your baby.”

The FDA chose a cartoon image of a baby in an incubator to illustrate the warning “smoking during pregnancy can harm your baby.” Again, the image accurately illustrates the text of the warning and depicts a realistic consequence of smoking. Smoking “causes poor birth outcomes such as prematurity, low birth weight, [and] respiratory problems in the newborn,” among other problems. IOM Report at 29; Surgeon General’s Report (2006) at 13-14. As the graphic suggests, an incubator is a common form of treatment for babies born with these kinds of

¹³ Available at http://www.cdc.gov/tobacco/data_statistics/sgr/2006/index.htm.

¹⁴ Plaintiffs’ complaint about the use of actors to *accurately* depict the risks of tobacco use is particularly disingenuous given that the industry has for years used actors—from athletic teenagers to the rugged Marlboro man—to falsely suggest that tobacco is associated with a healthy lifestyle. See *Philip Morris*, 449 F. Supp. 2d at 863-64.

problems. Tobacco use is also responsible for other serious complications, resulting in 1,900 to 4,800 infant deaths from perinatal or pre-birth disorders and 1,200 to 2,200 deaths from sudden infant death syndrome. See DiFranza, *Effect of Maternal Cigarette Smoking on Pregnancy Complications and Sudden Infant Death Syndrome*, 40 J. Family Practice 385, 385 (Apr. 1995). In addition, 19,000 to 141,000 miscarriages each year are attributable to smoking. *Id.*

E. “Cigarettes cause cancer.”

The warning “cigarettes cause cancer” is illustrated by an image of oral cancer. Like the other graphic warnings, this image is a truthful representation of one likely consequence of smoking. According to the Centers for Disease Control and Prevention, smoking is the primary risk factor for approximately 75% of oral cancer cases in the United States. CDC, *Preventing and Controlling Oral and Pharyngeal Cancer* (August 1998).¹⁵ The warning communicates a risk of smoking of which many smokers and potential smokers are unaware. Although most young people may know that cigarettes cause lung cancer, they typically do not understand the risk of other forms of cancer, including oral cancer. See Weinstein, *Public Understanding of the Illnesses Caused by Cigarette Smoking*, 6 *Nicotine & Tobacco Res.* at 352.

F. “Cigarettes cause fatal lung disease.”

The warning “cigarettes cause fatal lung disease” is illustrated by the side-by-side images of diseased and healthy lungs. The images truthfully illustrate the risk of lung cancer, emphysema, and a variety of other lung diseases caused by smoking. See Surgeon General’s Report (2004) at 61, 508. Indeed, the side-by-side images of healthy and diseased lungs closely resemble an image in the Surgeon General’s 2010 report illustrating the effects of emphysema

¹⁵ Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00054567.htm>.

caused by smoking. Surgeon General's Report, *How Tobacco Smoke Causes Disease* 449 (2010).¹⁶

Overall, nearly 129,000 people in the United States die each year from smoking-related lung and bronchial cancer. CDC, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004* (2008).¹⁷ Smoking increases the risk of death from emphysema and bronchitis by a factor of 10, and the risk of death from lung cancer by a factor of 22 among men and a factor of nearly 12 among women. CDC, *Tobacco-Related Mortality* (updated Mar. 2011).¹⁸ Among youth, smoking causes health effects even before it becomes a lifelong habit, including respiratory symptoms, reduced physical fitness, and stunted lung growth. President's Cancer Panel Report at 64.

G. “Cigarettes cause strokes and heart disease.”

The warning “cigarettes cause strokes and heart disease” is illustrated by the depiction of a patient wearing an oxygen mask—a common treatment for heart disease. There is no question that smoking dramatically increases the risk of both heart disease and stroke. *See* Surgeon General's Report (2004) at 26-27, 363-419. Indeed, smoking triples the risk of dying from heart disease among middle-aged men and women. CDC, *Tobacco-Related Mortality*, *supra*.

H. “Tobacco smoke causes fatal lung disease in nonsmokers.”

The FDA illustrated the warning “tobacco smoke causes fatal lung disease in nonsmokers” with the image of a woman crying. The image illustrates the social and emotional costs of secondhand smoke. Exposure to secondhand smoke increases the risk of developing lung

¹⁶ Available at http://www.surgeongeneral.gov/library/tobaccosmoke/report/full_report.pdf.

¹⁷ Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>.

¹⁸ Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm.

cancer by 20 to 30%. CDC, *Health Effects of Secondhand Smoke* (updated Jan. 12, 2010).¹⁹ The pain of losing a loved one, and the suffering from smoking-induced illnesses, are part of smoking's real consequences, but “[s]urveys have demonstrated that individuals have little knowledge of the reality of the pain, suffering and despair” caused by tobacco use. *Philip Morris*, 449 F. Supp. 2d at 578. There is nothing misleading about depicting those consequences.

I. “Quitting smoking now greatly reduces serious risks to your health.”

The final graphic warning illustrates the statement “quitting smoking now greatly reduces serious risks to your health.” The image chosen by the FDA for this warning depicts a man wearing a tee-shirt with the words “I quit” and the image of a cigarette crossed out. Nobody—including plaintiffs—disputes that quitting greatly reduces health risks. As the Surgeon General concluded, “quitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general.” Surgeon General’s Report (2004) at 25. Indeed, the major tobacco companies make almost identical statements on their own websites.²⁰

This warning and others also include the phone number for the national quitline, 1-800-QUIT-NOW. The phone number is not, as plaintiffs suggest, a form of advocacy; it is a resource for those who choose to quit. Strong scientific evidence demonstrates the value of informing consumers about the availability of assistance to help them quit. As the Institute of Medicine found, quitlines have proven “effective ... in helping individuals to stop smoking”—increasing

¹⁹ Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm.

²⁰ For example, Lorillard’s website states: “Although quitting smoking can be very difficult, smokers who want to quit should try to do so. Quitting greatly reduces the health effects of cigarette smoking.” <http://www.lorillard.com/responsibility/smoking-and-health/>. Similarly, R.J. Reynolds’s website states: “Quitting cigarette smoking significantly reduces the risk for serious diseases.” <http://www.rjrt.com/prinbeliefs.aspx>.

smoking abstinence by as much as 30 to 50%. IOM Report 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).²¹ 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., Abrams, Boosting Population Quits Through Evidence-Based Cessation Treatment and Policy*, 38 *Am. J. Preventative Med. Supp.* S351 (2010).

III. 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 illustrate the textual 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.

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

1. 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

²¹ Available at http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

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. Reg. 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 other 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 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 smoking seem less attractive. Hammond, *Health Warning Messages on Tobacco Products: A Review*, 20 Tobacco Control at 330. 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. Borland, *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* White, *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* Fathelrahman, *Smokers’ Responses Toward Cigarette Pack Warning Labels in Predicting Quit Intention, Stage of Change, and Self-Efficacy*, 11 *Nicotine & Tobacco Res.* 248 (2009); the European Union, *see* Vardavas, *Adolescents Perceived Effectiveness of the Proposed European Graphic Tobacco Warning Labels*, 19 *Eur. J. Pub. Health* 212 (2009); and other countries. *See* Hammond, *Health Warning Messages on Tobacco Products*, 20 *Tobacco Control* 327.

2. 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 who 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 held 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); *Env'tl 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 graphic warnings are 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*, 18 Tobacco Control 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. 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.

B. 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 decisionmaking. 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 study found that the FDA’s chosen image of a man blowing smoke from a tracheostomy hole was 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 the warnings to create *any* measurable effect in smokers’ beliefs and intention to quit after only one viewing powerfully demonstrates the warnings’ effectiveness.

CONCLUSION

The defendants' motion for summary judgment should be granted, and the plaintiffs' motion for summary judgment should be denied.

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Respectfully submitted,

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