ORAL ARGUMENT SCHEDULED APRIL 10, 2012

No. 11-5332

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,
Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants.

On Appeal from the U.S. District Court
for the District of Columbia

BRIEF 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, CITIZENS' COMMISSION TO PROTECT THE TRUTH, PUBLIC CITIZEN, AND THE TOBACCO CONTROL LEGAL CONSORTIUM IN SUPPORT OF DEFENDANTS-APPELLANTS

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CERTIFICATE AS TO PARTIES, RULING, AND RELATED CASES

Parties and Amici. Except for the following, all parties, intervenors, and amici appearing before the district court and in this court are listed in the Brief for Appellant: Citizens' Commission to Protect the Truth and the Tobacco Control Legal Consortium appear in this Court as amici curiae in support of the defendants-appellants.

Rulings Under Review. References to the rulings at issue appear in the Brief for Appellant.

Related Cases. In a case brought by several of the plaintiffs here, the district court in *Commonwealth Brands v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010), *cross-appeals pending sub nom. Discount Tobacco City & Lottery v. United States*, Nos. 10-5234 & 10-5235 (6th Cir.), rejected a First Amendment challenge to the statutory provision at issue in this case.

/s/Gregory A. Beck
Gregory A. Beck

CORPORATE DISCLOSURE STATEMENT

Amici 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, Citizens' Commission to Protect the Truth, Public Citizen, and the Tobacco Control Legal Consortium are non-profit organizations that have no parents, subsidiaries, or affiliates that have issued shares or debt securities to the public. The general purpose of the amici organizations is to advocate for the public's health and for the protection of consumers. More detailed information about each organization is set forth in the addendum to this brief.

/s/Gregory A. Beck
Gregory A. Beck

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Cases

Statutory and Regulatory Materials

* Authorities upon which we chiefly rely are marked with asterisks.

Other Authorities

GLOSSARY

CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
IOM	Institute of Medicine
FSPTCA	Family Smoking Prevention and Tobacco Control Act
WHO	World Health Organization

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Appellant.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The district court in this case granted a preliminary injunction against enforcement of the enhanced warnings required by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which, among other things, 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 points to which the district court failed to give adequate weight in its decision to grant the injunction.

First, by limiting its review of the record to two FDA studies, the court ignored all the evidence on which Congress relied when it passed the FSPTCA. That evidence—which includes numerous consumer surveys, scientific studies, and a consensus of the most respected national and international authorities in the field—overwhelmingly establishes that existing warnings fail to adequately inform the public of the risks of tobacco use, and that the large, graphic warnings required by the FSPTCA are effective both at raising public awareness of the risks of smoking and promoting public health by reducing tobacco use.

Second, the court gave no weight to Congress's interest in ensuring that consumers are effectively informed about the health consequences and addictive impact of cigarettes. Federal and state regulations routinely require disclosure of products' threats to health and safety. Given that tobacco is the "leading cause of

preventable death and disease" in the United States, 75 Fed. Reg. 69,524, 69,534 (2010) (notice of proposed rulemaking), it is difficult to imagine any product for which the Congress has a stronger interest in ensuring effective warnings.

Third, the district court enjoined all nine of the FDA's graphic warnings on the ground that they are not "factual," but made no effort to examine the truthfulness of any of the *specific* images depicted on the warnings. In fact, each of the warnings illustrates a well-established consequence of using cigarettes. To the extent that some of the images are disturbing, it is because they truthfully depict the disturbing consequences of smoking.

INTEREST OF AMICI[1]

Amici curiae are twelve 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

[1] This brief was not authored in whole or in part by counsel for a party. No person or entity other than amicus curiae or its counsel made a monetary contribution to preparation or submission of this brief.

more detailed description of each organization is included in the appendix to this brief. All parties have consented to the filing of this brief.

BACKGROUND

The 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. 76 Fed. Reg. 36,628, 36,631 (June 22, 2011) (final rule); CDC, *Smoking and Tobacco Use: Fast Facts*.[2] An overwhelming majority of adult smokers started smoking before age 18. *See* President's Cancer Panel, *Promoting Healthy Lifestyles* 64 (2007) (President's Cancer Panel Report).[3] And half of the children who become regular smokers will die prematurely from a tobacco-related disease. *Id.*

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*,

[2] *Available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

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

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. *Id.* at 852. 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);[4] *Philip Morris*, 449 F. Supp. 2d at 676.

In the FSPTCA, Congress adopted a comprehensive set of rules governing the marketing of tobacco products. Plaintiffs in this case challenge 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). 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. 75 Fed. Reg. at 69,534 (notice of proposed rulemaking). In November 2010, the FDA published in the Federal Register and on the agency's website 36 proposed

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

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 the conclusions of 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 the agency's 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, 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 the warning requirements and other provisions of the Act. 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)).[5] The court also rejected the plaintiffs' argument that "the new warnings are too large and too prominent," noting the weight of authority behind similar warnings. *Id*. at 531. The decision is on appeal to the Sixth Circuit.

Plaintiffs filed this second challenge to the warning requirements soon after the FDA announced its final rule, seeking injunctive relief and a declaratory judgment that the warnings infringe their First Amendment rights. The district court granted a preliminary injunction, concluding that the warnings constitute "compelled commercial speech." App. 27. The court rejected the government's

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

argument that the warnings present important factual information about the health risks of smoking, holding instead that the warnings are not "purely factual and uncontroversial" because they are "unquestionably designed to evoke emotion." *Id.* at 28. The court subjected the warnings to a strict-scrutiny standard of review, concluding that the government had failed to prove that the warnings were narrowly tailored to advance a compelling government interest. *Id.* at 30-35.

ARGUMENT

I. Overwhelming Evidence Supports the Revised Warning Requirements.

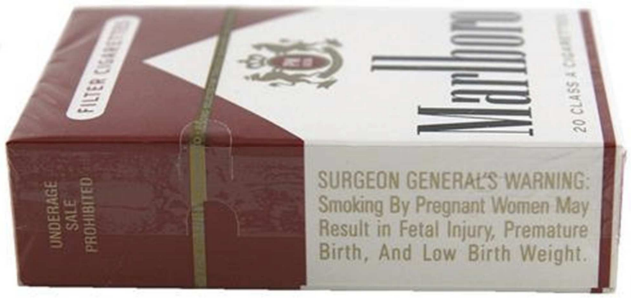
In concluding that the government had not demonstrated that graphic warnings are necessary to achieving Congress's goal, the district court ignored the entirety of the record on which Congress relied in enacting the warning requirement. The record as a whole, along with Congress's findings and years of experience documenting the effectiveness of large, graphic warnings, amply support Congress's conclusion that current warnings have failed to adequately inform consumers, and that requiring larger, graphic warnings is necessary to accomplishing that goal.

A. The Evidence Demonstrates that Large, Graphic Warnings Are Necessary 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—are small and easy to ignore. *Id.* at 69,530. These warnings occupy only half of the narrow side of cigarette packages and are not visible when the packages are on display:



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." 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).[6] At the same time, in Canada, where a warning appears on the front of the package, 83% of students mentioned the warnings. *Id.*

Reviewing the available evidence, the Surgeon General concluded in 1994 that empirical studies "consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." Surgeon General's Report, *Youth & Tobacco: Preventing Tobacco Use Among Young People* 168 (1994).[7] Similarly, the Institute of Medicine 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.

2. Extensive research and the FDA's findings demonstrate that—despite the existing warnings—tobacco users in the United States fail to appreciate the extent of the health risks associated with tobacco use and, in fact, greatly *underestimate*

[6] *Available at* http://www.tobaccolabels.ca/factshee/article_.
[7] *Available at* http://profiles.nlm.nih.gov/ps/access/NNBCLQ.pdf.

their personal risk. *See* Weinstein, *Public Understanding of the Illnesses Caused by Cigarette Smoking*, 6 Nicotine & Tobacco Res. 349, 349 (2004) ("[E]ven 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."); 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").

Although smokers generally understand that smoking *can* cause lung cancer, they are less likely to understand the degree of risk. 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; *see* Weinstein, 6 Nicotine & Tobacco Res. at 349 (finding 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). Smokers are also much less aware of the risk of different forms of cancer and of other health risks caused by tobacco use. 76 Fed. Reg. at 36,632. 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.* Knowledge about the health risks of smoking is particularly low 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 can accurately identify statistical risks of smoking are unlikely to appreciate their *own* risk of disease. *Id.* 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.* 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 smokers' understanding of their personal risk "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. *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.

3. In contrast to existing warnings, the effectiveness of large, graphic warnings is extensively documented in 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, 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* 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 at 530.

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);[8] *see* IOM Report at 290-96. Images more effectively draw attention to the message and make it more memorable, while prompting consumers to think about the consequences of smoking. *See* Hammond, *Tobacco Packaging and Labeling* 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 consider 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; *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 followed 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, and Switzerland. *See* Canadian

[8] *Available at* http://www.who.int/tobacco/mpower/2008/en/index.html.

Cancer Society, *Cigarette Package Health Warnings* 3 (2010).[9] 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. There is strong evidence that these warnings have been effective both in educating consumers and in reducing smoking. *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 (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). 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.

B. The District Court's Exclusive Focus on FDA Studies Ignores the Overwhelming Weight of Evidence Demonstrating the Warnings' Effectiveness.

The district court ignored the entirety of the record on which Congress relied in adopting the new warning requirements. Instead, it singled out for criticism a

[9] *Available at* http://tobaccofreecenter.org/files/pdfs/en/WL_status_report_en.pdf.

regulatory-impact analysis and consumer study conducted by the FDA to help it choose specific images to illustrate the textual warnings. But those studies were conducted after Congress had already adopted the graphic warning requirement, were not designed to assess whether the warnings are necessary, and do not undermine the overwhelming weight of evidence supporting the effectiveness of graphic warnings.

1. The district court concluded that the FDA's regulatory-impact analysis failed to establish that tobacco use in Canada declined after that country adopted graphic warnings similar to those required by the FSPTCA. App. 19-20 & nn.9-10. The agency's analysis, however, was never designed 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.* The agency's best estimate was that the warnings would cause 213,000 people to quit smoking by 2013. *Id.*

Moreover, the FDA's difficulty in quantifying the impact of the rule on smoking prevalence does not undermine the other extensive evidence—set forth in detail in the FDA's notice of proposed rulemaking and final rule, but ignored by the district court—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.*

There is also strong evidence that pictorial warnings in Canada have been effective in deterring children from taking up smoking. Approximately six 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, 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. *See generally* Hammond, 20 Tobacco Control 327. 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. Other studies have found similar effects of graphic warnings in other countries. *See, e.g.*, Fathelrahman, *Smokers' Responses Toward Cigarette Pack Warning Labels in Predicting Quit Intention, Stage of Change, and Self-Efficacy*, 11 Nicotine & Tobacco Res. 248 (2009) (Malaysia); Vardavas, *Adolescents Perceived Effectiveness of the Proposed European Graphic Tobacco Warning Labels*, 19 Eur. J. Pub. Health 212 (2009) (European Union).

2. The district court also singled out the FDA's consumer research for criticism, concluding that it failed to demonstrate "whether any singular graphic warning was effective on its own terms." App. 32. Like the agency's regulatory-impact analysis, however, 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 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.* Far from casting doubt on the graphic warning requirement, the warnings' ability to create *any* measurable effect on smokers' beliefs and intention to quit after only one viewing powerfully demonstrates the warnings' effectiveness.

II. The District Court Failed to Give Weight to Congress' Interest in More Effectively Informing Consumers About the Health Effects of Smoking.

A. 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 more effectively inform consumers about the risk of serious injury and death caused by their products. 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.

Numerous other 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); *see also 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).

The First Amendment does not prohibit the government from compelling such warnings. In *Zauderer*, for example, the Supreme Court upheld the constitutionality of a state bar disciplinary rule requiring attorneys who advertised contingent-fee representation to disclose 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 affect consumers' decisions. 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.*

B. The district court here discounted the government's "information goal" on the ground that, "[a]s best as [it could] discern … the Government's primary purpose is not, as it claims, merely to inform." App. 31-32. In refusing to credit the

government's interest, the court failed to consider the powerful evidence demonstrating 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, 18 Tobacco Control at 358. 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.

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

The district court did not question the accuracy of the new textual 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. Instead, the court held that the graphic images accompanying the textual warnings "cross the line from information to advocacy" because they are "designed to evoke emotion." App. 35 n.28. Yet the specific graphic warnings chosen by the FDA—like the textual warnings they accompany—truthfully convey the health consequences of smoking. Each image "illustrate[s] the message conveyed by the accompanying textual warning statement" by depicting smoking risks that are "well-established in the scientific literature." 76 Fed. Reg. at 36,636, 36,641.

The First Amendment does not prohibit mandatory warnings that may make consumers uncomfortable. The requirement that drug companies disclose side effects in prescription-drug advertisements, for example, does not violate the First Amendment because it requires discussion of conditions that may disgust some consumers, *see* 21 C.F.R. § 202.1(e), and the required skull-and-crossbones warning on bottles of poison is not unconstitutional because it is intended to deter inappropriate use, *see* 16 C.F.R. § 1500.14. On the contrary, the evidence on which the FDA relied demonstrates that the "salience" of graphic warnings is critical to the warnings' effectiveness. 76 Fed. Reg. at 36,697-98; *see* IOM Report at C-3. As the agency 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 district court focused on the warnings' inclusion of the national quitline, 1-800-QUIT-NOW, as an example of prohibited "advocacy." App. 35 n.28. A phone number, however, is not a form of advocacy; it is information for consumers about the availability of assistance to help them quit. Strong scientific evidence demonstrates the value of providing this information. As the Institute of Medicine found, quitlines have proved "effective … in helping individuals to stop smoking"—increasing smoking abstinence by as much as 30 to 50%. IOM Report at 237. 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).[10] These conclusions are consistent with well-established evidence confirming that by

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

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).

In addition to the quitline, each of the graphic warnings provides undisputed factual information about the health risks of smoking:

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.

The district court did not question these well-established facts, instead criticizing the government for failing to introduce "evidence that smoking causes autopsies." App. 28-29 n.18. But whether smokers receive autopsies after they die 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, plaintiffs cannot dispute 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. 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] The image graphically conveys a well-documented fact about cigarettes—they are so addictive that many smokers are unable to break the habit even after undergoing surgery for a smoking-related illness. *See, e.g.*, Cooley, *Smoking Cessation Is Challenging Even for Patients Recovering from Lung Cancer Surgery With Curative Intent*, 66 Lung Cancer 218 (Nov. 2009); Walker, *Smoking Relapse During the First Year After Treatment for Early-Stage Non-Small-Cell Lung Cancer*, 15 Cancer Epidemiology Biomarkers & Prevention 2370, 2370 (2006).

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. This

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

warning visually conveys the risks of secondhand smoke on children. 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).[12]

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 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 (1995).

[12] *Available at* http://www.cdc.gov/tobacco/data_statistics/sgr/2006/index.htm.

E. "Cigarettes cause cancer."

The warning "cigarettes cause cancer" is illustrated by an image of oral cancer. 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).[13] The warning communicates a risk of smoking of which many smokers and potential smokers are unaware. Although most young people 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 warning closely resembles images in the Surgeon General's 2010 report illustrating the effects of emphysema caused by smoking. Surgeon General's Report, *How*

[13] *Available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00054567.htm.

Tobacco Smoke Causes Disease 449 (2010).[14] 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).[15] 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*.[16] 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.

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

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

[16] *Available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm.

Smoking triples the risk of death from heart disease among middle-aged men and women. CDC, *Tobacco-Related Mortality*.

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, illustrating the societal and emotional costs of secondhand smoke. Exposure to secondhand smoke increases the risk of developing lung cancer by 20 to 30%. CDC, *Health Effects of Secondhand Smoke*.[17] 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 depicts a man wearing a tee-shirt with the words "I quit" and the image of a crossed-out cigarette. Nobody—including the 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."

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

Surgeon General's Report (2004) at 25. Indeed, the major tobacco companies make almost identical statements on their own websites.[18]

* * *

In sum, each of the graphic warnings illustrates a well-documented health consequence of smoking in an easy-to-understand and memorable way. The graphics thus fulfill the purpose of the warnings: "to increase consumer knowledge and understanding of the health risks of smoking." 76 Fed. Reg. at 36,642.

CONCLUSION

The district court's decision granting a preliminary injunction should be reversed.

Respectfully submitted,

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[18] 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.

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

I certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times New Roman font, and the word count is 6,900.

/s/Gregory A. Beck
Gregory A. Beck

CERTIFICATE OF SERVICE

I certify that on December 19, 2011, I caused the foregoing to be filed through the Court's ECF system, which will serve notice of the filing on counsel for all parties.

/s/Gregory A. Beck
Gregory A. Beck