

[ORAL ARGUMENT SCHEDULED FOR APRIL 10, 2012]

No. 11-5332

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

R.J. REYNOLDS TOBACCO COMPANY et al.,

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION et al.,

Defendants-Appellants.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

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BRIEF FOR APPELLANTS

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## **CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**

### **A. Parties and Amici**

Plaintiffs are R.J. Reynolds Tobacco Company; Lorillard Tobacco Company; Commonwealth Brands, Inc.; Liggett Group LLC; and Santa Fe Natural Tobacco Company, Inc. Defendants are the United States Food and Drug Administration (“FDA”); FDA Commissioner Margaret Hamburg; and Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services. The following groups participated in district court as *amicus curiae* in support of the government: the American Academy of Pediatrics, the American Cancer Society, the American Cancer Society Action Network, Cancer Action Network, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Public Health Association, the Campaign for Tobacco-Free Kids, and Public Citizen. The following groups participated as *amicus curiae* in support of plaintiffs: the Association of National Advertisers, Inc., the American Advertising Federation, and the Washington Legal Foundation.

### **B. Rulings Under Review**

The ruling under review was issued on November 7, 2011, by the Hon. Richard J. Leon in Civ. No. 11-1482 (D.D.C.). The district court held that the cigarette health disclosures required by the Family Smoking Prevention and

Tobacco Control Act of 2009 (“Tobacco Control Act”) are subject to strict scrutiny under the First Amendment and concluded that the warnings are not narrowly tailored to advance a compelling governmental interest. In an order styled as a preliminary injunction, the court enjoined enforcement of the Tobacco Control Act’s health warnings until 15 months after the district court issues final judgment in this case.

### **C. Related Cases**

Several plaintiffs here (R.J. Reynolds Tobacco Company; Lorillard Tobacco Company; and Commonwealth Brands, Inc.) are also plaintiffs in another case that presents a First Amendment challenge to the same cigarette health warning requirements that are at issue in this case. *See 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.). The district court in *Commonwealth Brands* upheld the health warning requirements but invalidated certain restrictions on tobacco advertising not at issue here. Cross-appeals are pending before the Sixth Circuit, which heard oral argument on July 27, 2011.

In *United States v. Philip Morris USA, Inc., et al.*, No. 11-5145 (D.C. Cir.), defendant cigarette manufacturers, including some of the plaintiffs in this case, urge this Court to vacate the injunctive relief that this Court affirmed in *United*

*States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010) (“the RICO case”), on the ground that the Tobacco Control Act eliminates the basis for injunctive relief. The district court (Hon. Gladys Kessler) rejected that contention, in part because the cigarette manufacturers are challenging the constitutionality of Tobacco Control Act requirements including the health warning requirements at issue here. *See United States v. Philip Morris USA, Inc., et al.*, Civ. No. 99-2496, 6/1/2011 Op. 12 (Docket #5937). This Court has scheduled oral argument in that appeal for April 20, 2012 before Chief Judge Sentelle, Circuit Judge Brown, and Senior Circuit Judge Silberman. The same panel will hear argument the same day in another appeal that arises out of the same RICO injunction and that concerns the cigarette manufacturers’ obligation to disclose disaggregated marketing data to the federal government. *See Appeal No. 11-5146.*

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---

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H.R. Rep. No. 111-58(I) (2009)..... 6

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Australia Department of Health and Ageing, Fact Sheet: Graphic Health  
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David Hammond et al., *Effectiveness of Cigarette Warning Labels  
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David Hammond, *Health Warnings Messages on Tobacco Products:  
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Department of Health and Human Services, *Preventing Tobacco  
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Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007), available at [http://www.nap.edu/catalog.php?record\\_id=11795](http://www.nap.edu/catalog.php?record_id=11795)..... 6, 29, 36

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S. David Leonard et al., *Comprehension and Memory*, in *WARNINGS AND RISK COMMUNICATION* 149 (Michael S. Wogalter et al. eds. 1999). ..... 33

Stanley Fish, *The Tobacco Horror Show*, NY Times Opinionator (Nov. 14, 2011), <http://opinionator.blogs.nytimes.com/2011/11/14/the-tobacco-horror-show/?scp=7&sq=stanley%20fish&st=cse>..... 49

Steven Young & Michael Wogalter, *Comprehension and Memory of Instruction Manual Warnings: Conspicuous Print and Pictorial Icons*, 32(6) Human Factors 637 (1990). ..... 34

U.K. Health Department, *Picture Warnings on Tobacco Products*, <http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/PublicHealth/Healthimprovement/Tobacco/Picturewarningsontobaccoproducts/pressimages/index.htm>..... 14

Victoria White et al., *Do Graphic Health Warning Labels Have an Impact on Adolescents’ Smoking-Related Beliefs and Behaviors?*, 103 *Addiction* 1562 (2008). ..... 32

---

\* Authorities chiefly relied upon are marked with an asterisk.

W. Howard Levie & Richard Lentz, *Effects of Text Illustrations: A Review of Research*, 30 *Educ. Comm. & Tech. J.* 195 (1982)..... 37

Wendy A. Rogers et al., *Warning Research: An Integrative Perspective*, 42 *Human Factors* 102 (Spring 2000), available at <http://hfs.sagepub.com/content/42/1/102.full.pdf>. .... 33, 34

World Health Organization, *Framework Convention on Tobacco Control*, <http://www.who.int/fctc/en/>. .... 30

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## GLOSSARY

|                     |                                                                                             |
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| APA                 | Administrative Procedure Act                                                                |
| FDA                 | Food and Drug Administration                                                                |
| FDCA                | Federal Food, Drug, and Cosmetic Act                                                        |
| HHS                 | Department of Health and Human Services                                                     |
| IOM Report          | Institute of Medicine, <i>Ending the Tobacco Problem: A Blueprint for the Nation</i> (2007) |
| RICO                | Racketeer Influenced and Corrupt Organizations Act                                          |
| Tobacco Control Act | Family Smoking Prevention and Tobacco Control Act of 2009                                   |

## **JURISDICTIONAL STATEMENT**

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331.

The district court entered a preliminary injunction on November 7, 2011.

Defendants filed a timely notice of appeal on November 29, 2011. This Court has appellate jurisdiction under 28 U.S.C. § 1292(a).

## **STATEMENT OF THE ISSUES**

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), revised the text and format of the health warnings that are required on cigarette packaging and advertising. The questions presented are:

1. Whether the district court erred in holding that the health warnings required under the Tobacco Control Act are subject to strict scrutiny under the First Amendment and in declaring the warnings invalid on that basis.
2. Whether the district court independently erred in issuing an injunction that, although styled as "preliminary," enjoins enforcement of the Act's health warning requirements for 15 months after the district court issues final judgment.

## **STATUTORY AND REGULATORY PROVISIONS**

Pertinent provisions are reproduced in the addendum to this brief.

## STATEMENT OF THE CASE

1. The Tobacco Control Act regulates the manufacture and sale of cigarettes and other tobacco products. As relevant here, the Act revised the content and format of the health warnings that have been required for decades on cigarette packaging and advertising. Congress specified the text of nine new health warnings that must appear on each cigarette package and advertisement; provided that the warnings shall comprise the top half of the front and back panels of cigarette packages and 20% of the area of cigarette advertisements; and directed the Secretary of Health and Human Services (“HHS”) to “issue regulations that require color graphics depicting the negative health consequences of smoking” to be included as part of each warning. 15 U.S.C. § 1333 Note. Congress directed the Secretary to issue the regulations identifying the particular graphics by June 22, 2011, and provided that the Tobacco Control Act’s revised health warnings will take effect 15 months after issuance of the regulations, *i.e.*, on September 22, 2012. *See ibid.*

Pursuant to that statutory directive, the Secretary, acting through the Food and Drug Administration (“FDA”), published for public comment thirty-six proposed images. *See* 75 Fed. Reg. 69,524, 69,526 (Nov. 12, 2010). FDA selected the final set of nine images, one for each statement, by regulations issued



on June 22, 2011. *See* 76 Fed. Reg. 36,628 (June 22, 2011). FDA concluded that the required warnings (reproduced in the addendum to this brief, *see* Add. 6–7) “will effectively communicate the negative health consequences of smoking to a wide range of population groups.” 76 Fed. Reg. at 36,636.

2. The plaintiff cigarette manufacturers challenge the Tobacco Control Act’s revisions to the cigarette health warnings on First Amendment grounds.<sup>1</sup> Several plaintiffs here (R.J. Reynolds, Lorillard, and Commonwealth Brands) are also plaintiffs in another case that presents a First Amendment challenge to the same warning requirements, as well as challenges to other Tobacco Control Act provisions. *See 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.).<sup>2</sup> On cross-motions for summary judgment, the district court in *Commonwealth Brands* upheld the health warning requirements, *see id.* at 528–32, but invalidated certain restrictions on tobacco advertising not at issue here. Cross-appeals are pending before the Sixth Circuit, which heard oral argument on July 27, 2011.

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<sup>1</sup> Although plaintiffs also presented an APA claim, the district court did not address that claim because the court concluded that “plaintiffs prevail on their First Amendment claim.” JA 17 n.3.

<sup>2</sup> Plaintiff Santa Fe Natural Tobacco Company is a corporate affiliate of plaintiff R.J. Reynolds; both are owned by Reynolds American, Inc.

Here, as in *Commonwealth Brands*, plaintiffs do not challenge the accuracy or validity of the text of the Tobacco Control Act's warnings, which require that cigarette packaging and advertising bear statements such as "Smoking can kill you"; "Cigarettes are addictive"; "Tobacco smoke can harm your children"; and "Quitting smoking now greatly reduces serious risks to your health." Plaintiffs contend, however, that the format of the warnings—their size, placement, and the graphics that Congress mandated be part of the warnings—transforms them into "compelled speech" subject to strict scrutiny under cases like *Wooley v. Maynard*, 430 U.S. 705 (1977). See JA 209 (Joint Comments of R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, Commonwealth Brands, Inc., at 2 ("Joint Comments")).

The district court accepted plaintiffs' argument. The court concluded that the size and placement of the warnings and the graphic component demonstrate that the warnings do not communicate health information about smoking but, instead, require plaintiffs to promote a controversial anti-smoking agenda. JA 34. The court held that the warnings are therefore subject to strict scrutiny under the *Wooley* line of cases, JA 30, and concluded that the warnings are not narrowly tailored to advance a compelling government interest, JA 35. The court issued an order, styled as a preliminary injunction, that bars implementation of the Tobacco

Control Act warning requirements for at least 15 months after the district court enters final judgment in this case. JA 45.

## STATEMENT OF FACTS

### A. Statutory Background

1. The Tobacco Control Act regulates the manufacture and sale of cigarettes and other tobacco products. Congress crafted the provisions of the statute on the basis of evidence gathered over decades by all three branches of government regarding the health risks posed by cigarettes and the tobacco industry's marketing of its products.

*First*, “tobacco use, particularly among children and adolescents, poses 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). Smoking “kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.” *Id.* at 134–35 (quoting 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996)); *see also* 75 Fed. Reg. 69,524, 69,526 (Nov. 12, 2010) (same). The Surgeon General testified before Congress that, “[e]ach year, 440,000 people die of diseases caused by smoking or other forms of tobacco use—that is about 20 percent of all deaths in our nation.” Statement of Vice Admiral Richard H.

Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009).<sup>3</sup> Because cigarettes are inherently dangerous when used as intended by their manufacturers, they would be banned outright if they were subject to regulation as drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”). *Brown & Williamson*, 529 U.S. at 136. Moreover, in light of current knowledge, cigarettes “would not be allowed to enter the marketplace” if they “were being introduced for the first time” today. Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation*, at 152 (2007) (“IOM Report”)<sup>4</sup> (discussed in H.R. Rep. No. 111-58(I) (2009)).

*Second*, “the magnitude of public health harm caused by cigarettes is inextricably linked” to nicotine addiction. 75 Fed. Reg. at 69,528. “The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine,” *ibid.*, and the force of nicotine addiction is illustrated by the failure rate of individual smoking cessation efforts. Data for 2004, for example, showed “that although approximately 40.5 percent of adult smokers reported attempting to quit in that year, only between 3 and 5 percent were successful.” *Id.* at 69,529.

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<sup>3</sup> All citations to the Congressional Record are to the daily editions and can be found at <http://www.gpoaccess.gov/crecord/09crpgs.html>.

<sup>4</sup> Available at [http://www.nap.edu/catalog.php?record\\_id=11795](http://www.nap.edu/catalog.php?record_id=11795).

Tobacco companies “have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction.” Legislative Finding 49.<sup>5</sup> Although the companies “engineered their products around creating and sustaining this addiction,” they “denied and distorted the truth as to the addictive nature of their products for several decades” and “concealed much of their nicotine-related research.” *United States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095, 1107, 1124 (D.C. Cir. 2009) (citation and internal quotation marks omitted), *cert. denied*, 130 S. Ct. 3501 (June 28, 2010); Legislative Finding 49.

*Third*, the cigarette industry has long depended on recruiting underage users who become addicted before age 18. According to a 2008 study, *each day* nearly 4,000 Americans under the age of 18 experiment with cigarettes for the first time, and approximately 1,000 children become new daily smokers. 75 Fed. Reg. at 69,526–27. Congress found that, despite laws prohibiting the sale of tobacco products to minors, the “overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18.” Legislative Finding 31; *see also* 75 Fed. Reg. at 69,526 (“more than 80 percent of established

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<sup>5</sup> The Tobacco Control Act findings are codified at 21 U.S.C. § 387 Note.

adult smokers began smoking before age 18”); *United States v. Philip Morris USA, Inc., et al.*, 449 F. Supp. 2d 1, 562 (D.D.C. 2006) (“over 80% of smokers start smoking before they turn eighteen”), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009) (*per curiam*), *cert. denied*, 130 S. Ct. 3501 (2010); *J.T.I. MacDonald Corp. v. Canada*, 2007 SCC 30, ¶14 (Canadian S. Ct. 2007) (“Most smokers begin as teenagers, between the ages of 13 and 16.”). Congress additionally found that “[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth.” Legislative Finding 15; *see also Philip Morris*, 449 F. Supp. 2d at 572 (“[t]he central purpose of the tobacco companies’ image advertising is motivating adolescents to smoke”); *J.T.I. Macdonald*, 2007 SCC 30, ¶74 (“much of the industry’s advertising is in fact aimed at youth,” and “persuading teenagers to take up smoking was a calculated and deliberate industry advertising strategy”).

2. Since 1966, Congress has required that cigarette manufacturers warn consumers and potential consumers of the health risks of smoking. *See* Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965). Before enactment of the Tobacco Control Act, Congress had not revised the content or format of the cigarette health warnings since 1984. *See*

Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984). The 1984 health warnings appear on the side panel of a cigarette pack and comprise only 4% of packaging and advertising space. *See* 76 Fed. Reg. at 36,678; 75 Fed. Reg. at 69,531.

As early as 1994, the Surgeon General reported that empirical studies consistently indicated that these warnings “are given little attention or consideration by viewers.” Department of Health and Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* 168 (1994) (“1994 Surgeon General’s Report”). Evidence before Congress in 2007 showed that the current warnings “fail to convey relevant information in an effective way.” IOM Report at 291. The Chair of the Institute of Medicine’s Committee on Reducing Tobacco Use advised Congress that the current warnings are essentially “invisible.” *Family Smoking Prevention & Tobacco Control Act: Hearing on H.R. 1108 Before the House Subcommittee on Health of the House Committee on Energy and Commerce*, 110 Cong. Rec. 42 (2007) (testimony of Richard Bonnie).

In the decades since the cigarette health warnings were last revised, regulators’ understanding of the force of nicotine addiction and the health risks of smoking has increased dramatically. This enhanced understanding has resulted in

significant part from the exposure of the cigarette industry's concerted campaign to discredit public health officials and minimize consumer concerns about the health consequences and addictiveness of smoking.

For many decades, the cigarette industry sought to convince consumers that they might reasonably choose to smoke because sufficient doubt existed as to the risks of smoking and the nature of nicotine addiction. As this Court explained in affirming a judgment of RICO liability against the major cigarette manufacturers, the “[e]vidence at trial revealed that at the same time Defendants were disseminating advertisements, publications, and public statements denying any adverse health effects of smoking and promoting their ‘open question’ strategy of sowing doubt, they internally acknowledged as fact that smoking causes disease and other health hazards.” *Philip Morris*, 566 F.3d at 1106. This Court concluded, when it rejected the companies’ First Amendment defenses, that the public statements by the cigarette manufacturers were “clearly and deliberately false,” and that the manufacturers “knew of their falsity at the time and made the statements with the intent to deceive.” *Id.* at 1123–24. Indeed, the industry’s joint public relations representative admitted internally that the industry’s “‘basic position in the cigarette controversy is subject to the charge, and may be subject to



a finding, that we are making false or misleading statements to promote the sale of cigarettes.” *Id.* at 1120 (citation omitted).

3. In the Tobacco Control Act, Congress revised the text and format of the health warnings that are required on cigarette packaging and advertising in order to convey more effectively factual information about the health risks of smoking. The Act provides that product packaging and advertisements for cigarettes shall bear one of nine statements:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

15 U.S.C. § 1333 Note.

Congress directed the Secretary of Health and Human Services to “issue regulations that require color graphics depicting the negative health consequences of smoking” to be part of each warning. *Ibid.* Congress “informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada” that had proven significantly more effective in conveying the risks of

smoking than the warnings used in the United States. *Commonwealth Brands*, 678 F. Supp. 2d at 531.

The Act also requires that the warnings comprise the top 50% of the front and rear panels of cigarette packs and 20% of the area of each cigarette advertisement. 15 U.S.C. § 1333 Note.

The effective date of the revised cigarette health warnings is set by the Tobacco Control Act. The Act directed the Secretary to issue final regulations identifying the graphic component of the warnings by June 22, 2011, and provided that the revised health warnings will take effect 15 months after promulgation of those regulations, *i.e.*, by September 22, 2012. *See* 15 U.S.C. § 1333 Note.

#### **B. FDA's Rulemaking**

Pursuant to the statutory directive, FDA published for public comment thirty-six proposed images. *See* 75 Fed. Reg. at 69,534. The final set of nine images, one for each warning statement, was established by regulations issued on June 22, 2011. *See* 76 Fed. Reg. 36,628 (June 22, 2011).

In selecting the final nine images that would be part of the required warnings, FDA reviewed well over a thousand public comments, including the joint comments submitted by plaintiffs R.J. Reynolds, Lorillard, and

Commonwealth Brands. *See id.* at 36,629.<sup>6</sup> FDA also reviewed the results of an 18,000-person consumer study that tested the relative effectiveness of the thirty-six proposed images at conveying information about the health risks of smoking. *See* FDA, Experimental Study of Graphic Cigarette Warning Labels, Final Results Report (Dec. 2010) (“FDA Study Report”).<sup>7</sup> The study participants were randomly assigned to view either a cigarette pack or advertisement with one of the proposed images along with the corresponding warning statement, or a text-only control. *See id.* at 1-3. FDA used several measures to test the relative efficacy of each proposed pictorial warning, including “three measures to assess the salience (*i.e.*, noticeability and readability) of the proposed required warnings: Emotional reactions, cognitive reactions, and whether the warning was difficult to look at.” 76 Fed. Reg. at 36,696. FDA explained that “[u]se of these [salience] measures is well-established in the scientific literature.” *Id.* at 36,696–97. “As discussed in the study report” and comments on the study, “risk information is most readily conveyed by warnings that elicit strong responses on these measures—eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and

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<sup>6</sup> Plaintiffs Santa Fe Natural Tobacco Company and Liggett did not submit comments to FDA.

<sup>7</sup> Available at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0568-0008>.

information processing, which helps to ensure that the warnings are better understood and remembered.” *Id.* at 36,697.

FDA also emphasized “the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.*, photographic versus illustrative), themes, and human images (*e.g.*, race, gender, age).” *Id.* at 36,636. That diversity is necessary to ensure that “the final set of required warnings effectively communicates risk information to a diverse range of audiences,” including audiences, like youth, that “have been targeted by tobacco industry marketing efforts.” *Ibid.*

The images FDA selected to be part of the required health warnings are “generally consistent with the graphic health warnings used in other countries.” *Id.* at 36,647. For instance, images similar to the ones selected by FDA have appeared on cigarette packs in Canada for more than a decade. *See* Health Canada, *Graphic Health Warnings* (Aug. 3, 2010).<sup>8</sup> Similar warnings have also appeared on cigarette packs in Australia since 2006 and in the United Kingdom since 2008.<sup>9</sup> *See also* European Commission Directorate General For Health and

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<sup>8</sup> The Canadian cigarette warnings in place at the time Congress enacted the Tobacco Control Act are reproduced in the addendum to this brief (Add. 8–12).

<sup>9</sup> Australia Department of Health and Ageing, Fact Sheet: Graphic Health Warnings, <http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/fact-sheet-health-warnings> (last visited Dec. 12, 2011); U.K. Health

Consumers, Pictorial Health Warnings, [http://ec.europa.eu/health/tobacco/law/pictorial/index\\_en.htm](http://ec.europa.eu/health/tobacco/law/pictorial/index_en.htm) (last visited Dec. 12, 2011).

Under 21 U.S.C. § 387f(d), FDA also required the warnings to bear the phone number of the National Cancer Institute's "Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1-800-QUIT-NOW." 76 Fed. Reg. at 36,681.

### **C. Proceedings Below**

The plaintiff cigarette manufacturers contend that the cigarette warnings required under the Tobacco Control Act and implementing regulations violate the First Amendment. Plaintiffs do not dispute the accuracy or validity of the mandated text. They nevertheless urge that the size and placement of the warnings, as well as the use of color graphics to depict the negative consequences of smoking, render the warnings "compelled speech" subject to strict scrutiny under the reasoning of such cases as *Wooley v. Maynard*, 430 U.S. 705 (1977). Applying that standard, plaintiffs argue that the warnings are unconstitutional.

The district court determined that plaintiffs' likelihood of success on the merits of their First Amendment challenge depends on whether the warnings are

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Department, Picture Warnings on Tobacco Products, <http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publichealth/Healthimprovement/Tobacco/Picturewarningsontobaccoproductspressimages/index.htm> (last visited Dec. 12, 2011).

subject to strict scrutiny. JA 35, 27–28. Accepting plaintiffs’ analysis, the court concluded that the size and placement of the warnings and the nature of the images demonstrate that the warnings are not designed to convey accurate information but, instead, require plaintiffs to promote an anti-smoking agenda. JA 28, 34. The court declared that “[a]ppropriating the top 50% of the front *and* back of all cigarette packages manufactured and distributed in the United States is hardly a directive narrowly designed to achieve the Government’s purpose (whatever it might be),” JA 33–34, and opined that “the dimensions *alone* strongly suggest” that the warnings advance the government’s “obvious anti-smoking agenda!” JA 34. The court also declared that “the fact *alone* that some of the graphic images appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of ‘purely factual.’” JA 28.

The court observed that, in FDA’s consumer study, the agency measured the “salience” of the combined images and text in part by the viewer’s emotional reaction. *Ibid.* In the court’s view, this salience measure “further undercuts the Government’s argument that the images are purely factual and not controversial.” *Ibid.* The court declared it “abundantly clear from viewing these images that the emotional response that they were crafted to induce is calculated to provoke the

viewer to quit, or never to start, smoking: an objective wholly apart from disseminating purely factual and uncontroversial information.” *Ibid.*

The district court issued an order, styled as a preliminary injunction, that blocks implementation of the revised warnings for at least 15 months after the issuance of final judgment in this case. JA 45. The court rejected the argument that such relief is not a “preliminary” injunction and declared that it has “inherent equitable power” to issue such relief. JA 24.

### **SUMMARY OF ARGUMENT**

I. The Tobacco Control Act revised the health warnings on cigarette packaging and advertising for the first time since 1984. In the intervening decades, public health officials have acquired a far more comprehensive understanding of the health consequences of smoking, tobacco use among children and adolescents, and the tenacity of nicotine addiction. Congress found that the “overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18.” Legislative Finding 31. Because smoking is not only deadly but addictive, “tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public

health in the United States.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

The Act replaced the current Surgeon General health warnings with nine new health warnings. The accuracy of the statements in each of these warnings is undisputed. Cigarettes *are* addictive and they *do* cause cancer, strokes, and heart disease; smoking *does* cause fatal lung disease in non-smokers; and smoking during pregnancy *can* harm your baby. Congress also legislated a new format for the warnings that reflects the guidelines adopted by the World Health Organization’s Framework Convention on Tobacco Control. Congress’s judgment was informed, in particular, by the health warnings adopted by Canada in 2000 which, like the warnings required by Congress, comprised the top 50% of the front and rear panels of cigarette packaging and included color graphics depicting the negative health consequences of smoking.

Regulations of commercial speech are generally reviewed under the standard set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), and are upheld if proportionate to the substantial government interest they are designed to serve. The Supreme Court has repeatedly recognized, however, that consumer disclosure requirements impinge less significantly on commercial speech than outright restrictions on such



speech. Accordingly, rules requiring accurate disclosures are sustained if they are “reasonably related” to an identified governmental interest, and are not so “[u]njustified or unduly burdensome” as to “chill[] protected speech.” *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339–40 (2010) (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985)).

The health warnings mandated by Congress and implemented by FDA readily meet either of these standards, and the district court did not conclude otherwise. The evidence before Congress demonstrated that the current Surgeon General warnings are ineffective and virtually invisible. The size and placement of the new warnings, and the inclusion of images as part of the warnings, reflect the overwhelming consensus of regulators and scientists in the United States. Ample evidence demonstrates the superiority of the revised warnings over the current Surgeon General warnings in their ability to effectively communicate the undisputed health consequences of smoking. Congress’s judgment is properly accorded deference, even in the context of a First Amendment challenge, *see Turner Broadcasting System, Inc. v. FCC*, 520 U.S. 180, 196 (1997), and no basis exists for setting aside that judgment here.

The court did not suggest that FDA departed in any way from Congress's directive. The agency proposed thirty-six images for public comment and, in the final rulemaking, selected nine of those images to accompany the nine warning statements mandated by Congress. In so doing, the agency explained in detail the reasons for each selection, noting that the images were "were designed to correlate with [the] warning statements," 76 Fed. Reg. at 36,637, and, as Congress intended, were "generally consistent with the graphic health warnings used in other countries," *id.* at 36,647.

The district court nevertheless held that none of the images selected, nor indeed any of the other images considered by FDA, would pass First Amendment scrutiny. The court also concluded that the size and placement of the warnings was constitutionally impermissible.

This ruling rests on the seriously mistaken premise that the cigarette health warnings are subject to strict scrutiny on the theory that they "compel speech" and are thus analogous to the requirements invalidated in cases such as *Wooley v. Maynard*, 430 U.S. 705 (1977), and *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943). Those cases involved attempts by the government to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein."

*Zauderer*, 471 U.S. at 651 (internal quotation marks omitted). Such regulations bear no relationship to the product disclosures at issue here. The district court cited no instance in which the Supreme Court has subjected a regulation of commercial speech to strict scrutiny based on this line of cases.

Even apart from this fundamental error, the court's recharacterization of the cigarette health warnings as an ideological message is untenable. The court offered no explanation for its assertion that "the dimensions *alone* strongly suggest" that the warnings were designed to advance the government's "obvious anti-smoking agenda!" JA 34. Nor did the court acknowledge the overwhelming evidence demonstrating that the warnings' current dimensions render them largely ineffective. The court similarly erred in misapprehending the concept of "salience" and holding that the final rule was unconstitutional because FDA had considered the salience of the warnings in measuring their efficacy. JA 28. As FDA explained in its rulemaking, salience is measured by individuals' emotional and cognitive reactions to a warning and reflects the likelihood that the warning will be recalled and processed. Thus, the images were selected by FDA to help convey the message of the accompanying textual warnings. In rejecting salience as a valid metric, the court did not suggest that the images will cause viewers to abstain from smoking for irrational reasons unrelated to its fatal consequences.

II. Because the cigarette health warnings are constitutional, plaintiffs are not entitled to any relief. Even apart from this central legal error, the district court exceeded its authority in ordering “preliminary” relief that is in no sense “preliminary” and that is not required to avoid imminent, irreparable injury.

The health warning requirements of the Tobacco Control Act take effect on September 22, 2012. Plaintiffs are not currently required to display the revised health warnings on their packaging or advertising, and the new warnings requirements are, of course, not being enforced by FDA or any other agency. There is thus no imminent government action to which a preliminary injunction could be directed.

Instead, the order purports to enjoin the government from enforcing the statute when it becomes effective, barring enforcement for at least 15 months after the court issues a final judgment. That is not a preliminary injunction, which, by definition, remains in effect only until a final judgment is rendered or the complaint is dismissed. The court justified its extraordinary ruling, in part, by invoking the principle that “the harm flowing from a First Amendment violation is *per se* irreparable.” JA 38. That reasoning underscores the anomaly of its order: at this time the statute neither requires nor limits speech. The court’s mistaken constitutional analysis, even on its own terms, provides no support for an order

that purports to excuse future compliance with the statute regardless of the outcome of this litigation.

### STANDARD OF REVIEW

The legal rulings on which a preliminary injunction rests are subject to de novo review in this Court. *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009). The district court's balancing of the harms is reviewed for abuse of discretion. *Ibid.*

### ARGUMENT

#### **I. Plaintiffs Have Not Demonstrated a Likelihood of Success on the Merits of Their Challenge to the Cigarette Health Warnings.**

The Tobacco Control Act specifies the text of nine new cigarette health warning statements and prescribes the size and placement of the warnings on cigarette advertisements and packaging. Congress directed the Secretary of Health and Human Services to “issue regulations that require color graphics depicting the negative health consequences of smoking” to accompany the textual warnings mandated by Congress. 15 U.S.C. § 1333 Note.

Congress's authority to require health warnings on cigarette packaging is not disputed. Nor is there any question that these warnings can properly include the text mandated by the Act. Each of the warnings statements incontrovertibly describes the consequences of using plaintiffs' products as intended. *See*

JA 24–25 (“[P]laintiffs do not quarrel with the substance of the nine new textual messages Congress created by statute.”).

The district court nevertheless concluded that the size and placement of the health warnings do not pass constitutional muster, and that the color graphics included in the warnings to depict the negative health consequences of smoking likewise impinge impermissibly on plaintiffs’ First Amendment rights. This decision rests on the mistaken premise that the health warnings are subject to strict scrutiny, because they compel speech in the same way as the provisions at issue in cases such as *Wooley v. Maynard*, 430 U.S. 705 (1977). We discuss the errors underlying the court’s analogy to cases such as *Wooley* at Point C, *infra*. First, however, we demonstrate that the statute and implementing regulation readily withstand review under the level of scrutiny applicable to regulations of commercial speech.

**A. Regulations of commercial speech are generally subject to intermediate scrutiny, and required disclosures of accurate information are subject to a more relaxed standard of review.**

There can be no question that the statute and rule at issue regulate quintessential commercial speech, *i.e.*, advertisements proposing the sale of a product, and product packaging. *See, e.g., Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010); *Bad Frog Brewery, Inc. v. N.Y. State*

*Liquor Auth.*, 134 F.3d 87, 97 (2d Cir. 1998) (explaining that product labels “are a form of advertising”). In general, a regulation of commercial speech is upheld if it “directly advances the governmental interest asserted [and] is not more extensive than is necessary to serve that interest.” *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). A more relaxed standard is appropriate, however, when a regulation does not restrict commercial speech but, instead, requires sellers to make accurate disclosures about their products.

In the context of commercial speech, required disclosures are sustained as long as they are “‘reasonably related’” to an identified governmental interest, and are not so “[u]njustified or unduly burdensome” as to “chill[] protected speech.” *Milavetz*, 130 S. Ct. at 1339–40 (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985)). This relatively relaxed standard of review reflects the “material differences between disclosure requirements and outright prohibitions on speech.” *Zauderer*, 471 U.S. at 650. Unlike restrictions on commercial speech, disclosure requirements, including warnings, do not prevent sellers “from conveying information to the public”; they require sellers only to provide “more information than they might otherwise be inclined to present.” *Ibid.* “Thus,” the Supreme Court observed, “in virtually all our commercial speech decisions to date, we have emphasized that because

disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, 'warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception.'" *Id.* at 651 (citations omitted).

The federal and state governments routinely require commercial sellers to disclose health and safety risks associated with their products, and such requirements have never been thought to offend the First Amendment. Even outside the realm of health and safety regulation, disclosure requirements are commonplace in the context of commercial speech, and their validity has seldom been called into doubt. Applying the *Zauderer* standard, the Supreme Court in *Milavetz* rejected the contention that it should subject to intermediate scrutiny a requirement that attorneys providing consumer bankruptcy services "clearly and conspicuously disclose in any advertisement" the statement: "We are a debt relief agency. We help people file for bankruptcy relief under the Bankruptcy Code." *Milavetz*, 130 S. Ct. at 1330 (citing 11 U.S.C. § 528(a)(3)–(4)).

The district court implicitly recognized that the textual statements to be included in the health warnings accurately describe the health consequences of using plaintiffs' products and are subject to review under the *Zauderer* standard applicable to required disclosures in the context of commercial speech. Although



the court described the size and placement of the warnings as evidence of an “anti-smoking agenda,” it did not, and could not, suggest that the prominence of the warnings made them less accurate. And, as we discuss below, the court plainly erred in concluding that the warnings are made less accurate by inclusion of images along with the text. As the Supreme Court observed in *Zauderer*, “[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [plaintiffs’] constitutionally protected interest in not providing any particular factual information in [their] advertising is minimal.” 471 U.S. at 651 (citing *Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)).

**B. The cigarette health warnings readily withstand review under *Central Hudson* and *Zauderer*.**

**1. Abundant evidence shows that larger cigarette warnings that include images communicate health information far more effectively than the warnings currently used in the United States.**

The cigarette health warnings readily withstand review under either the intermediate scrutiny of *Central Hudson* or the less demanding scrutiny of *Zauderer*.

The district court did not question the strength of the government’s interest

in ensuring that consumers generally, and adolescents in particular, understand the health consequences of using cigarettes. The indisputably accurate content of the nine warning statements underscores the paramount importance of conveying that information effectively. Cigarettes *are* addictive, and they *do* kill smokers when used as intended by their manufacturers, by causing cancer, fatal lung disease, strokes, and heart disease. And secondhand smoke *does* kill family and friends. It is likewise uncontroversial that “[q]uitting smoking now greatly reduces serious risks to your health.” 15 U.S.C. § 1333 Note. Indeed, “tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.” *Brown & Williamson*, 529 U.S. at 161. It “kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined.*” *Id.* at 134–35 (internal quotation marks omitted) (emphasis added).

The size and placement of the warnings, and the inclusion of color images to illustrate the warning statements, are tailored to advance the government’s substantial interest in effectively communicating health information. Before the 2009 legislation, the content and the format of cigarette health warnings had not been revised since 1984. *See Comprehensive Smoking Education Act of 1984*,

Pub. L. No. 98-474, 98 Stat. 2200 (1984). As early as 1994, however, the Surgeon General reported that empirical studies “consistently indicate that the Surgeon General’s warnings are given little attention or consideration by viewers.” 1994 Surgeon General’s Report at 168; *see also ibid.* (describing an eye-tracking study of adolescents showing that “more than 40 percent of subjects did not even view the warning” on cigarette advertisements and “[a]n additional 20 percent looked at the warning but failed to actually read it”). Evidence presented to Congress showed that the current warnings “fail to convey relevant information in an effective way,” IOM Report at 291, and are essentially “invisible,” *Hearing Before the House Subcommittee on Health, supra*, 110 Cong. 42. *See also* 75 Fed. Reg. at 69,530–31 (discussing additional evidence of the ineffectiveness of the current cigarette warnings).

Regulators’ understanding of nicotine addiction, consumption patterns, and the health risks of smoking has increased significantly since 1984, as has their understanding of how to communicate health-risk information to consumers. Based on this fuller understanding, an international consensus has developed regarding the minimum requirements for warnings that will effectively convey the health risks of smoking. These standards are reflected in the World Health Organization’s Framework Convention on Tobacco Control and include “warnings

that are rotating, ‘large, clear, visible and legible,’” that “occupy 50 percent or more of the principal display areas,” and “may be in the form of or include pictures or pictograms.” *Id.* at 69,525 (citation omitted).<sup>10</sup> “Worldwide, over 30 countries/jurisdictions have implemented pictorial warnings on tobacco packages and requirements for pictorial warnings are pending in several other countries/jurisdictions.” *Ibid.*

When Congress enacted the revised cigarette warnings, it looked in particular to the Canadian disclosure requirements that went into effect in 2000. *See* JA 18 n.5 (“It is no secret that the Congress was greatly influenced in the drafting and passage of this aspect of the legislation by the example of our northerly neighbors.”). Like the warnings required by Congress, those warnings comprised the top 50% of the front and rear panels of cigarette packaging and included color images depicting the negative health consequences of smoking.<sup>11</sup>

Ample evidence shows that this size and placement attracts and retains the attention of consumers far more effectively than the current U.S. Surgeon General warnings, particularly when the warnings include not only a textual statement but

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<sup>10</sup> *See* World Health Organization, Framework Convention on Tobacco Control, <http://www.who.int/fctc/en/> (last visited Dec. 12, 2011).

<sup>11</sup> *See* Physicians for a Smoke-Free Canada, *Canada’s Graphic Health Warnings*, <http://www.smoke-free.ca/warnings/canada-warnings.htm> (last visited Dec. 12, 2011).

also illustrative images. *See, e.g.*, 75 Fed. Reg. at 69,531 (describing focus group research in which young adults in the United States “reported that the Canadian [graphic] warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States.”); *id.* at 69,532 (“National surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information.”).

The Australian experience similarly demonstrates that the health risks identified in a warning statement are communicated more effectively when the warning also includes images. From 1995 to 2005, Australia required cigarette manufacturers to display large, text-only warnings that covered the top quarter of the front panel and the top third of the back panel of cigarette packages. *See* David Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers about the Risks of Smoking*, 15 *Tobacco Control* iii19, iii20 (2005).<sup>12</sup> After Australia introduced larger pictorial warnings in 2006, a longitudinal study of youth “found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented.” David

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<sup>12</sup> Available at [http://tobaccocontrol.bmj.com/content/15/suppl\\_3/iii19.full.pdf](http://tobaccocontrol.bmj.com/content/15/suppl_3/iii19.full.pdf).

Hammond, *Health Warnings Messages on Tobacco Products: A Review*, 20 Tobacco Control 327, 330 (2011)<sup>13</sup> (citing Victoria White et al., *Do Graphic Health Warning Labels Have an Impact on Adolescents' Smoking-Related Beliefs and Behaviors?*, 103 Addiction 1562 (2008)). That study also found that “adolescents who were experimenting with smoking or were established smokers indicated that they thought more about forgoing cigarettes after graphic warnings appeared on cigarette packages in 2006.” 75 Fed. Reg. at 69,532 (citing White, *supra*, 103 Addiction 1562).

Studies from around the world have confirmed the findings from Canada and Australia. A recent review that summarized the results of 15 studies concluded that “significant proportions of adult and youth smokers report that large text and pictorial health warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit and increased the likelihood of remaining abstinent following a quit attempt.” Hammond, 20 Tobacco Control at 331. Similarly, a study comparing the European Union’s large, text-only warnings to its new pictorial warnings concluded that the results “clearly demonstrate[] that visual messages, as opposed to text warnings, are more effective.” Karine Gallopel-Morvan et al., *The Use of*

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<sup>13</sup> Available at <http://tobaccocontrol.bmj.com/content/20/5/327.full.pdf>.

*Visual Warnings in Social Marketing: The Case of Tobacco*, 64 J. Business Research 7, 7 (2011).<sup>14</sup> Research also “suggests that larger pictorial warnings sustain their effects longer” than their text-only counterparts. Hammond, 20 Tobacco Control at 333.

These results should not be surprising. It is axiomatic in cognitive psychology that “pictures are easier to remember than words.” S. David Leonard et al., *Comprehension and Memory*, in WARNINGS AND RISK COMMUNICATION 149, 158 (Michael S. Wogalter et al. eds. 1999). The brain has distinct coding systems for words and for images, and information in the “image” memory system is more likely to be retained and is more easily retrieved. *Ibid.* This is particularly the case for “abstract concepts.” *Ibid.* Information that is coded in both systems is particularly easy to remember “because theoretically more ‘paths’ are created in memory, making the information more accessible (more likely to be cued) at later times.” *Ibid.* Thus, even apart from tobacco-specific research, studies have “found that pictorials in combination with conspicuous print facilitated recollection of warning contents,” and that “the enhanced memory was directly related to the fact that the warning was noticed in the first place[.]” Wendy A. Rogers et al., *Warning Research: An Integrative Perspective*, 42 Human Factors

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<sup>14</sup> Available at [http://goodhealth.freeservers.com/SR\\_GRE01\\_10\\_article\\_public%20nov\\_%2009.pdf](http://goodhealth.freeservers.com/SR_GRE01_10_article_public%20nov_%2009.pdf).

102, 114 (Spring 2000)<sup>15</sup>; *see also, e.g.*, Steven Young & Michael Wogalter, *Comprehension and Memory of Instruction Manual Warnings: Conspicuous Print and Pictorial Icons*, 32(6) *Human Factors* 637, 646 (1990) (comparing the relative effectiveness of instruction-manual warnings with and without pictorials, and finding that “warnings that have both conspicuous print and illustrative pictorial icons enhance comprehension and memory of the warnings’ message content”); Hammond, *supra*, 20 *Tobacco Control* at 329–30 (“A wide variety of research has demonstrated the effectiveness of using pictures and imagery in health communications. These studies suggest that health warnings with pictures are significantly more likely to draw attention, result in greater information processing and improve memory for the health message.” (citations omitted)).

Moreover, communicating information about the health consequences of smoking poses special difficulties that make the use of images as part of the health warning particularly appropriate.

*First*, although the health consequences of smoking are severe, they generally do not become manifest for many years. Because of that time lag, smokers—and adolescents in particular—tend to disregard or discount discomfoting factual information about the long-term consequences of using

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<sup>15</sup> Available at <http://hfs.sagepub.com/content/42/1/102.full.pdf>.



plaintiffs' products. Dr. Paul Slovic has explained that, "[a]lthough most smokers acknowledge a high degree of risk associated with many years of smoking, many believe they can get away with some lesser amount of smoking before the risk takes hold." Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, in *SMOKING: RISK, PERCEPTION & POLICY* 97, 109 (Paul Slovic ed., 2001); *Philip Morris*, 449 F. Supp. 2d at 577 (noting the obstacles to conveying effectively the health risks of smoking to adolescents in particular) (citing Dr. Slovic's testimony).

*Second*, new consumers, who are not already addicted, are primarily children and adolescents who "are particularly vulnerable to cigarette marketing because they are not capable of making a fully informed decision whether to start or continue smoking for a variety of reasons, including the fact that they underestimate personal risks and lack the judgment which can only be developed through experience." *Philip Morris*, 449 F. Supp. 2d at 578. Dr. Slovic explained that "[m]any young smokers, in particular, believe that smoking for only a few years poses negligible risk," and "are more prone to believe in the safety of short-term smoking than are young non-smokers." Slovic, *Cigarette Smokers*, *supra*, at 109.

*Third*, this failure to fully appreciate the risks of tobacco smoking is compounded by the powerful nature of nicotine addiction, which starts to take hold “within days to weeks of the onset of occasional use of tobacco.” *Ibid*.

*Fourth*, smoking rates, and knowledge of smoking risks, are closely correlated with education levels. FDA noted that “49.1 percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree.” 76 Fed. Reg. at 36,630. Moreover, “research shows that knowledge of smoking risks is lower among people with lower incomes and fewer years of education.” *Id.* at 36,633. Thus, warnings that include images may be particularly important for communicating with consumers of low levels of education, particularly given evidence that such smokers “are less likely to recall health information in text-based messages than people with more education.” IOM Report at 295.

Including images in health warnings is also important in ensuring that information is effectively communicated to underage viewers, who, by definition, have both lower education levels and less cognitive development than adults. Summarizing the results of more than 50 youth studies, one review explained that “[i]llustrations can help learners understand what they read, can help learners

remember what they read, and can perform a variety of other instructional functions.” See W. Howard Levie & Richard Lentz, *Effects of Text Illustrations: A Review of Research*, 30 *Educ. Comm. & Tech. J.* 195, 226 (1982).

**2. The images FDA selected work in tandem with the textual statements in the warnings to communicate the health consequences of smoking.**

The FDA rule is consistent with Congress’s directive that the new warnings include color images depicting the undisputed health risks of smoking described in the warning statements. The images that FDA selected work in tandem with the textual statements in the warnings to further the government’s interest in effectively communicating the health risks of smoking. In selecting specific images, FDA reviewed extensive scientific literature, the experience of other countries, and more than a thousand comments. See 76 *Fed. Reg.* at 36,629. FDA also conducted a study to measure consumer responses to the thirty-six possible warnings that it published for comment in the proposed rulemaking.

The study randomly exposed study participants to a cigarette package or an advertisement that included either one of the prospective warnings containing both a textual statement and one of the images proposed by FDA or, instead, a control set of text-only warnings. FDA Study Report at 1-3, 4-1. The study then asked each participant to answer a series of questions about the warning. *Id.* at 1-3.

These included questions regarding “salience” designed to elicit participants’ immediate reactions to the warnings. These salience measures include “cognitive responses” (*e.g.*, belief that the warnings were, for example, informative, meaningful, or difficult to look at) and “emotional responses” (*e.g.*, worry, disgust, etc.). 76 Fed. Reg. at 36,638; FDA Study Report, app. A, at A-3. FDA recognized, based on a substantial body of scientific literature, that such cognitive and emotional responses reliably predict the likelihood that consumers will understand and appreciate the substance of the warnings. 76 Fed. Reg. at 36,640–41; FDA Study Report at 4-2.

FDA noted that some comments that it received during the rulemaking criticized specific images as “disturbing” or “eliciting emotions.” 76 Fed. Reg. at 36,696. These included the image “depicting a man smoking through a tracheostomy opening,” the image “depicting healthy lungs juxtaposed with lungs damaged by smoking,” the image “depicting a lesion consistent with that caused by oral cancer,” and the image “depicting a man with an autopsy scar.” *Ibid.* The public comments “did not assert, however, that the effects shown in the images are false, *i.e.*, that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death.” *Ibid.* As the agency emphasized, “[t]he fact that the images are disturbing or evoke emotion does not

mean that they are not factual representations of the effects of smoking.” *Ibid.* Indeed, “it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen.” *Ibid.* In short, viewers respond to the combination of text and image that meaningfully confronts them with the very real consequences of smoking.

**C. The district court invalidated the warnings mandated by Congress on the mistaken premise that they are subject to strict scrutiny.**

**1. The cigarette health warnings are not subject to review under the “compelled speech” line of cases.**

The district court concluded that the size and placement of the cigarette health warnings violates the First Amendment and that all of the images selected or considered by FDA are unconstitutional. In engaging in this wholesale invalidation, the court found it unnecessary to consider the evidence that the format of the current U.S. Surgeon General warnings renders them essentially invisible. Nor did the court review each of the nine images or FDA’s basis for selecting them.

The district court made clear that its analysis was dictated by its view that the warnings are subject to strict scrutiny: “Put simply, plaintiffs’ likelihood of success on the merits turns on the level of constitutional scrutiny which governs

the FDA's Rule mandating textual warnings and graphic images on cigarette packaging and advertisements." JA 27. The court thus accepted the position first advanced by plaintiffs Reynolds, Lorillard, and Commonwealth Brands in their joint comments to FDA on the proposed warnings, in which they argued that the agency should "order that the Tobacco Control Act's new textual warnings be displayed in the same manner in which the Surgeon General's warnings have been displayed for years"—in other words, without the changes to the size and placement of the warnings mandated by Congress in the statute, and without the images that depict the negative health consequences of smoking, which Congress required FDA to promulgate. JA 210–11.

In urging the district court to apply strict scrutiny, plaintiffs argued that images do not "simply convey information intended to enable smokers to make informed decisions about whether to smoke cigarettes," but instead convey "the Government's viewpoint that the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them and, therefore, that no one should use these lawful products." JA 209. Plaintiffs insisted that "the proposed warnings convey to smokers the Government's view that they should change in a significant way how they lead their lives," and argued that "[t]he viewpoint the Government proposes to be conveyed on the manufacturers' packaging and

advertising is thus every bit as ideological as the message at issue in *Wooley v. Maynard*, 430 U.S. 705 (1977): ‘Live Free or Die.’” *Ibid.* They asserted that, “[i]n effect, the message and viewpoint of FDA’s proposed graphic warnings is: ‘Live Smoke-Free or Die.’” *Ibid.* Accepting that reasoning, the district court held that the challenged cigarette health warnings implicate the “fundamental ten[e]t of constitutional jurisprudence . . . that the First Amendment protects ‘both the right to speak freely and the right to refrain from speaking at all,’” JA 27 (quoting *Wooley*, 430 U.S. at 714), and that “[a] speaker typically ‘has the autonomy to choose the content of his own message,’” *ibid.* (quoting *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573 (1995)).

The district court fundamentally misunderstood the *Wooley* line of cases, which involved attempts by the government to “‘prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.’” *Zauderer*, 471 U.S. at 651 (quoting *West Virginia State Bd. of Ed. v. Barnette*, 319 U.S. 624 (1943)). In *Wooley*, the Court likened the New Hampshire license plates at issue in that case to the requirement invalidated in *Barnette*, which “‘required public school students to participate in daily public ceremonies by honoring the flag both with words and traditional salute gestures.’” *Wooley*, 430 U.S. at 714. The Court noted that

“[c]ompelling the affirmative act of a flag salute involved a more serious infringement upon personal liberties than the passive act of carrying the state motto on a license plate, but the difference is essentially one of degree.” *Id.* at 715. In both cases, the government sought to “foster[] public adherence to an ideological point of view” and, in so doing, ““invade[d] the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control.”” *Ibid.*

Similarly, in *Hurley*, the Supreme Court held that the State could not “require private citizens who organize a parade to include among the marchers a group imparting a *message* the organizers do not wish to convey.” 515 U.S. at 559 (emphasis added). The Court emphasized that “[p]arades are public dramas of social relations, and in them performers define who can be a social actor and what subjects and ideas are available for communication and consideration.” *Id.* at 569 (internal quotation marks and citation omitted).

The district court identified no instance in which the Supreme Court has applied strict scrutiny to a regulation of commercial speech based on the reasoning of decisions such as *Wooley* and *Barnette*. The district court correctly noted that “[f]or corporations as for individuals, the choice to speak includes within it the choice of what not to say.” JA 27 (quoting *Pacific Gas & Elec. Co. v. Pub. Utils.*



*Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion)). The Court in *Pacific Gas & Electric* stressed, however, that the speech at issue there was *not* commercial speech. 475 U.S. at 8–9. That case concerned a newsletter that a utility company distributed with its monthly billing statements, which the Court found “[i]n appearance no different from a small newspaper.” *Id.* at 8. The newsletter “included political editorials, feature stories on matters of public interest, tips on energy conservation, and straightforward information about utility services and bills.” *Id.* at 5. It thus “extend[ed] well beyond speech that proposes a business transaction,” *id.* at 9 (citing *Zauderer*, 471 U.S. at 637; *Central Hudson*, 447 U.S. at 561–63), and “include[d] the kind of discussion of ‘matters of public concern’ that the First Amendment both fully protects and implicitly encourages,” *ibid.* (quoting *Thornhill v. Alabama*, 310 U.S. 88, 101 (1940)). Thus, there was “no doubt” that the newsletter should “receive[] the full protection of the First Amendment.” *Id.* at 8.

The district court erred in importing the analysis of *Wooley* and its progeny into the commercial speech context. In so doing, the court adopted a dichotomy without any basis in First Amendment doctrine. In the district court’s view, the cigarette health warnings are either subject to review under the relaxed standards applied in *Zauderer*, or, alternatively, subject to strict scrutiny under *Wooley*.

Because we are here dealing with commercial speech, the correct question is instead whether the warnings should be reviewed under *Zauderer* or under *Central Hudson*. This Court explained in *Philip Morris* that, “[a]lthough the standard for assessing burdens on commercial speech has varied, the Supreme Court’s bottom line is clear: the government must affirmatively demonstrate its means are ‘narrowly tailored’ to achieve a substantial government goal.” 566 F.3d at 1143 (citing *Central Hudson*, 447 U.S. at 566, *Zauderer*, 471 U.S. at 644, and other cases). As we have explained, the cigarette health warnings easily withstand review under the *Zauderer* and *Central Hudson* standards.

**2. The district court’s reasoning also fails on its own terms.**

Even on its own terms, the district court’s analysis fails at every step. The format for the size and placement of the warnings legislated by Congress reflects its informed judgment regarding the effective means for communicating the health risks of smoking. The district court owed considerable deference to that judgment, which finds ample support in empirical evidence of the effectiveness of similar warnings used in Canada, Australia, and the European Union. The Supreme Court has stressed that, “[e]ven in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures

adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy.” *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997).

The district court gave *no* deference to Congress’s reasoned determination that the dimensions of the revised health warnings are needed to effectively convey information about the risks of smoking to the public. And it disregarded the wealth of evidence demonstrating that the size and placement of the current U.S. Surgeon General warnings render them wholly ineffective, and the experience of public health regulators in other countries that demonstrates that the dimensions chosen by Congress will more effectively communicate the health risks of smoking. Instead, when the district court invalidated these requirements, it declared, without explanation, that “the dimensions *alone* strongly suggest” that the warnings were designed to advance the government’s “obvious anti-smoking agenda!” JA 34.

The district court similarly failed to give any deference to Congress’s judgment that warnings regarding the risks of smoking will be more effective if they include images depicting those risks, or to FDA’s selection of the specific images to be included. Instead, the district court dismissed these judgments out of hand.

With respect to FDA's choice of specific images, the court deemed the images unconstitutional because "their efficacy was measured by their 'salience,' which the FDA defines in large part as a viewer's emotional reaction." JA 28. The court misunderstood both the concept of salience and FDA's analysis. As the court noted, FDA conducted a study to measure consumer responses to the thirty-six warnings published for public comment in the proposed rulemaking. Participants in the FDA study viewed the proposed images along with the corresponding textual warning statements, or a text-only control. *See* FDA Study Report at 1-3. FDA used "three measures to assess the salience (*i.e.*, noticeability and readability) of the proposed required warnings: Emotional reactions, cognitive reactions, and whether the warning was difficult to look at." 76 Fed. Reg. at 36,696. The agency explained that the "[u]se of these measures is well-established in the scientific literature." *Id.* at 36,696-97.

As discussed in the study report and comments on the study, "risk information is most readily conveyed by warnings that elicit strong responses on these measures—eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warnings are better understood and remembered." *Id.* at 36,697. Thus, as FDA explained in responding to comments, its "use of these reaction measurements

does not demonstrate the Agency's intent to stigmatize tobacco products." *Ibid.*

"Rather, these measures are appropriate indicators of how effectively health warning messages are communicated, and were used in FDA's research study to provide valuable information regarding the relative ability of the 36 proposed required warnings to effectively convey the very real adverse health consequences of smoking to the public." *Ibid.*

The district court made no reference to the agency's analysis, and instead declared that the "emotional response [the images] were crafted to induce is calculated to provoke the viewer to quit, or never to start, smoking." JA 28. This purpose, the court stated, is "an objective wholly apart from disseminating purely factual and uncontroversial information." JA 28.

This reasoning is difficult to fathom. The goal of effectively communicating the risks of cigarette smoking is, of course, related to the viewer's decision to quit, or never to start, smoking. The warning on a package or in an advertisement that "cigarettes cause fatal lung disease"—whether or not it is accompanied by an image—is obviously intended to convey to consumers the entirely accurate message that using plaintiffs' products may destroy their lungs. The image of diseased lungs conveys the same message as the accompanying text and, as the evidence demonstrates, helps to communicate these long term consequence of

smoking more effectively. If the text and image convince the viewer to abstain from or quit smoking, that is the result of the accurate health information that the warning conveys.

The district court also asserted, without explanation, that the fact that “each warning brandishes the ‘1-800-QUIT-NOW’ smoking cessation hotline only enhances plaintiffs’ argument that the FDA has conscripted tobacco manufacturers into an anti-smoking brigade.” JA 35 n.28. The court did not address FDA’s explanation that “the reference to a smoking cessation resource will enhance the effectiveness of the warnings required under [the Act] at conveying information about the risks to health from smoking cessation-related information.” 76 Fed. Reg. at 36,681. Nor did the district court explain why the telephone number conveys anything more than the fact that quitting smoking is beneficial to one’s health, which is plainly permissible.<sup>16</sup> One of the warnings states that “Quitting smoking now greatly reduces serious risks to your health,” 15 U.S.C. § 1333 Note, and plaintiffs do not dispute the accuracy or validity of that message.

The district court’s limited discussion of particular images misses the point that is communicated by the image in tandem with the text. For example, in

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<sup>16</sup> Indeed, Lorillard’s website instructs consumers to use the same resource: “For help in quitting smoking call 1-800-QUITNOW (TTY 1-800-322-8615), which is a 24-hour toll-free number to the National Network of Tobacco Cessation Quitlines.” <http://www.lorillard.com/responsibility/smoking-and-health/addiction>.

discussing the image of a body on an autopsy table that accompanies the textual statement “Smoking can kill you,” the court objected that there is not “a single shred of evidence to support the proposition that smoking causes autopsies.”

JA 28–29 n.18. The relevant question, however, is whether the image of a cadaver, when viewed in conjunction with the textual statement “Smoking can kill you,” communicates the message that smoking can cause death. The court did not dispute that “smoking kills 443,000 Americans each year.” *Ibid.* Nor did it respond to FDA’s explanation that “[v]iewers will understand that the image shows someone who has died from a smoking-related cause,” particularly because “the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown.” 76 Fed. Reg. at 36,655.<sup>17</sup>

The district court also declared “the fact *alone* that some of the graphic images here appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of ‘purely factual.’”

JA 28. FDA responded to a similar comment regarding the image of a baby in an

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<sup>17</sup> See also Stanley Fish, *The Tobacco Horror Show*, NY Times Opinionator (Nov. 14, 2011), <http://opinionator.blogs.nytimes.com/2011/11/14/the-tobacco-horror-show/?scp=7&sq=stanley%20fish&st=cse> (“The image of the cadaver stands in for death, for the proposition that smoking kills. It is an example of metonymy, a figure of speech in which a thing or concept—in this case death—is not presented directly but by reference to something—the condition of being in a morgue—with which it is closely associated.”).

incubator that accompanies the text “Smoking During Pregnancy Can Harm Your Baby.” 76 Fed. Reg. at 36,696. FDA explained that “[t]he style of the depiction—here, a graphic illustration—does not make it less factual.” *Ibid.* There is no dispute that “smoking during pregnancy has negative effects, including increasing rates of preterm delivery and shortened gestation and increasing the likelihood of low birth weight infants.” *Ibid.* And, as FDA explained, “a diversity of styles (*e.g.*, photographic versus illustrative), themes, and human images (*e.g.*, race, gender, age)” is necessary to ensure that “the final set of required warnings effectively communicates risk information to a diverse range of audiences,” including audiences, like youth, that “have been targeted by tobacco industry marketing efforts.” *Id.* at 36,636.

The district court’s observation that some images “appear to be digitally enhanced or manipulated,” JA 28, refers to comments in the rulemaking that “some of the proposed images, including some now selected by FDA in this final rule, appear to use technologically-enhanced photographs to emphasize the effects of sickness and disease,” 76 Fed. Reg. at 36,696. As FDA explained, however, “the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking,” and noted that “the comments did not dispute this fact.” *Ibid.*



More generally, FDA stressed that “the addition of graphics to warnings for cigarettes is a difference in form only and does not change the fundamental content of the messages, which convey factual information about the health consequences of smoking.” *Ibid.* The images do not “alter the substance” of the warning messages. *Ibid.* “Rather, these images alter the effectiveness of the warnings by enhancing their ability to communicate factual information to consumers.” *Ibid.*

In sum, the government has a substantial—indeed, compelling—interest in communicating the health risks of smoking, and the format of the cigarette health warnings is designed to communicate that accurate health information effectively. The judgments made by Congress and FDA have strong support in the empirical record, and the district court had no basis to overrule those judgments and declare the cigarette health warnings unconstitutional.

**II. The District Court Independently Erred in Issuing a “Preliminary” Injunction that Blocks Implementation of the Tobacco Control Act Warnings Until 15 Months After the Court Issues Final Judgment.**

Because plaintiffs have demonstrated no constitutional flaw in the statutorily mandated cigarette health warnings, they are entitled to no relief. Even apart from this fundamental legal error, the court’s injunction cannot properly be sustained because the type of relief ordered is unauthorized and inappropriate. The court

exceeded its authority in ordering “preliminary” relief that is in no sense “preliminary” and that is not required to avoid imminent, irreparable injury.

A. The effective date of the revised health warnings is established by the Tobacco Control Act. Congress directed the Secretary to issue regulations selecting the images to be included in the warnings by June 22, 2011, and provided that the revised health warnings shall take effect 15 months after issuance of those regulations. 15 U.S.C. § 1333 Note. Accordingly, the revised health warnings will take effect on September 22, 2012.

At this time, therefore, plaintiffs are not required to display the new health warnings on packaging or advertising and are not threatened with enforcement action. The district court nevertheless declared that, regardless of the outcome of the litigation, plaintiffs will have no obligation to comply with the statute until 15 months after it issues a final judgment, and it enjoined enforcement of the statute’s health warning requirements until that (as yet undetermined) date. JA 45.

A preliminary injunction, by definition, remains in effect only “until a final judgment is rendered or the complaint is dismissed.” 11A Charles Alan Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* § 2947; see also Fed. R. Civ. P. 65; *Planned Parenthood of Cent. & N. Arizona v. Arizona*, 718 F.2d 938, 950 (9th Cir. 1983) (“A preliminary injunction is not a court order that

expires after the passage of a prescribed or fixed amount of time; it remains in effect until the district court can hold a full hearing on and decide the merits of the case.”). Similarly, the Administrative Procedure Act authorizes courts only to “postpone the effective date of an agency action or to preserve status or rights *pending conclusion of the review proceedings.*” 5 U.S.C. § 705 (emphasis added).

If the moving party prevails on the merits, the preliminary injunction dissolves or merges into the permanent injunction effected by the final judgment. *See Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 314 (1999). In the event of a loss on the merits, the losing party is, of course, not entitled to relief. A preliminary injunction is not an insurance policy against such a loss. The district court identified no authority for the proposition that a plaintiff may, at the outset of litigation, obtain an indefinite extension of a statutory compliance date in the event that its suit is unsuccessful. Nevertheless, this is precisely the relief the district court ordered in this case.

The court correctly observed that a party may “challenge the validity of a law before its enforcement to avoid irreparable injury.” JA 24. That well established principle, however, provides no basis for a court to enter relief under the guise of a preliminary injunction that is in no way preliminary.<sup>18</sup>

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<sup>18</sup> The decisions cited by the district court have no apparent bearing on its authority to issue this type of relief. In *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072,

**B.** The relief ordered by the court is particularly anomalous because it bears no relationship to the nature of the alleged First Amendment violation. The court declared that “plaintiffs appropriately argued at the September 21, 2011 hearing that the harm flowing from a First Amendment violation is *per se* irreparable.” JA 38. The cigarette health warnings do not become effective until September 2012. Even assuming, for purposes for argument, that compliance with the warning requirements would at that juncture implicate *Wooley* and *Barnette*, the current preparations for compliance cannot plausibly be said to be “*per se* irreparable” within the meaning of decisions cited by the district court. *See, e.g., Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) (holding in context of employees threatened with dismissal based on their failure to affiliate with a certain

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1084 (D.C. Cir. 1981), this Court held that, in an action by the Federal Trade Commission to enjoin a proposed merger, a district court has authority to issue preliminary relief that requires a company to hold separate the assets acquired in the merger. In *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 819 (D.C. Cir. 1984), this Court held that it was appropriate for a district court to issue “mandatory preliminary injunctive relief in a common law tort action in which the defendant has already been adjudicated liable but where a trial to determine the amount of liability will be so long delayed that, in the interim, the plaintiffs face irreparable injury.” In *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), the Supreme Court upheld a final order of restitution for overcharges that were made in violation of the Emergency Price Control Act of 1942. *See United States v. Philip Morris USA, Inc., et al.*, 396 F.3d 1190, 1197 (D.C. Cir. 2005) (discussing *Porter*).

political party that “[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”).

C. Plaintiffs identified no other injury that would warrant a preliminary injunction, even if there were present or imminent agency action to enjoin. The district court recognized that this Court “‘has set a high standard for irreparable injury.’” JA 36 (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)). “In addition to demonstrating an injury that is ‘both certain and great,’ the moving party ‘must show that the injury complained of is of such imminence that there is a ‘clear and present’” need for equitable relief to prevent irreparable harm.” *Ibid.* (quoting *Chaplaincy of Full Gospel Churches*, 454 F.3d at 297 (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985))). “Indeed, a plaintiff must show that it will suffer harm that is ‘more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.’” *Ibid.* (quoting *Gulf Oil Corp. v. Dep’t of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981)).

The district court recognized that plaintiffs’ asserted compliance costs do not meet this standard. JA 37. Plaintiffs’ “aggregate, estimated cost of compliance represents approximately ‘twelve one-hundredths of one percent of plaintiffs’ combined annual sales as reported for 2010.’” *Ibid.* Indeed, Congress found that

the tobacco industry's expenditures on marketing alone amounted to \$13 billion in 2005. *See* Legislative Finding 16.

The district court nonetheless believed that plaintiffs had established a level of irreparable harm that would warrant preliminary relief because their compliance costs cannot be recovered from FDA. *See* JA 37. Compliance costs, however, are generally not recoverable. Nothing distinguishes plaintiffs' claims of injury from the type of allegations that can be made by any regulated entity facing new regulatory obligations. Under the district court's reasoning, therefore, compliance costs would regularly be regarded as sufficient to demonstrate irreparable injury. And preliminary injunctions that postpone the effective dates of distant statutory deadlines would move, in one step, from unprecedented to routine. *See A.O. Smith Corp. v. FTC*, 530 F.2d 515, 527–28 (3d Cir. 1976) (“Any time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone, would satisfy the requisite for a preliminary injunction.”).

For all of these reasons, the district court's entry of a preliminary injunction cannot be sustained.

**CONCLUSION**

For the foregoing reasons, the preliminary injunction should be vacated.

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

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/s/ Alisa B. Klein

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Alisa B. Klein



**CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of December, 2011, I caused the foregoing brief to be filed with the Court in hard copy and electronically and served through the Court's CM/ECF system.

/s/ Alisa B. Klein

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Alisa B. Klein

**ADDENDUM**

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**15 U.S.C. § 1333 Note**

(a) Label requirements

(1) In general

It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health.

(2) Placement; typography; etc.

Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word "WARNING" shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

(3) Does not apply to foreign distribution

The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(4) Applicability to retailers

A retailer of cigarettes shall not be in violation of this subsection for packaging that--

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) Advertising requirements

(1) In general

It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2) Typography, etc.

Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under

subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital "W" of the word "WARNING" in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that--

(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

### (3) Matchbooks

Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

### (4) Adjustment by Secretary

The Secretary may, through a rulemaking under section 553 of Title 5, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type

sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) Marketing requirements

(1) Random display

The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(2) Rotation

The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(3) Review

The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan--

(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(4) Applicability to retailers

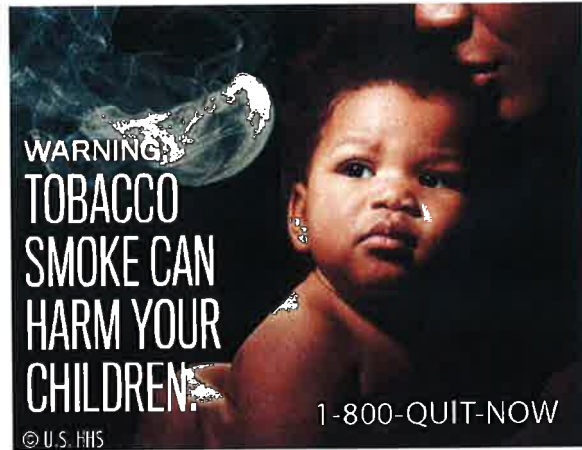
This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

(d) Graphic label statements

Not later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.



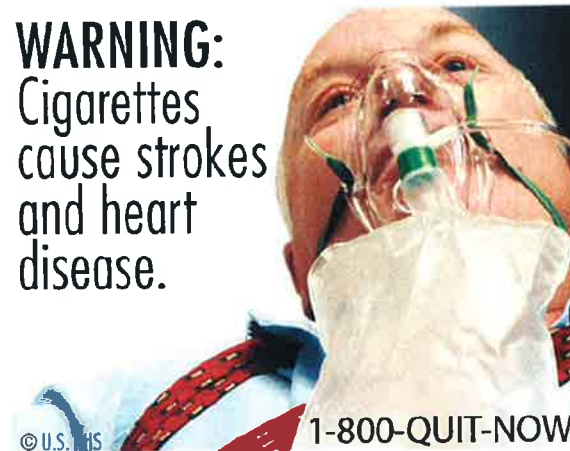
**Revised U.S. Health Warnings for Cigarette Packages and Advertisements**



**WARNING:** Cigarettes cause fatal lung disease.



**WARNING:** Cigarettes cause cancer.

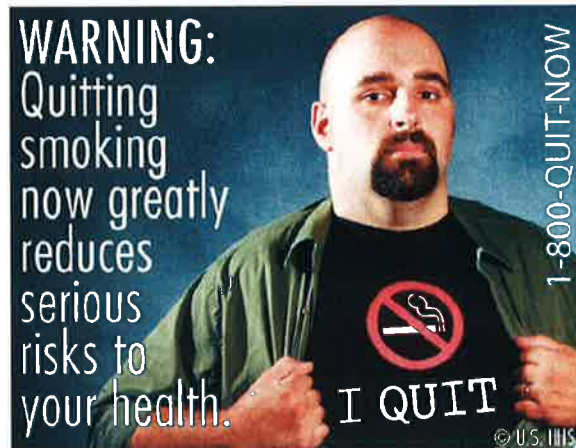




© U.S. HHS  
**WARNING:**  
Smoking can kill you.



**WARNING:**  
Tobacco smoke  
causes fatal  
lung disease  
in nonsmokers.



**WARNING:**  
Quitting  
smoking  
now greatly  
reduces  
serious  
risks to  
your health.

Source: <http://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM259401.pdf>



Home > Health Concerns > Tobacco > Legislation > Tobacco Product Labelling > Graphic Health Warnings

## Health Concerns

### Graphic Health Warnings

- See also: other [health effects](#)

Tobacco product packaging also displays [health information](#) messages on diseases caused by tobacco use or tips on quitting smoking which are printed on the inside slider or leaflet. The [regulations](#) that allowed for these images became law in June 2000, making Canada the first country in the world to implement such strong labelling and reporting measures.



Studies have shown that tobacco can be **harder to quit** than heroin or cocaine. [The facts behind this label](#)



Your [children](#) are **twice as likely** to smoke if you do. Half of all premature deaths among life-long smokers result from tobacco use. [The facts behind this label](#)



Tobacco use during pregnancy **reduces the growth of babies** during [pregnancy](#). These smaller babies may not catch up in growth after birth, and the risks of infant **illness, disability, and death** are increased. [The facts behind this label](#)



Cigarettes may cause sexual impotence due to **decreased blood flow** to the penis. This can prevent you from having an erection. [The facts behind this label](#)



Second-hand smoke contains **carbon monoxide, ammonia, formaldehyde, benzo[a]pyrene and nitrosamines**. These chemicals can harm your children. [The facts behind this label](#)



Tobacco use during pregnancy increases the risk of preterm birth. Babies born preterm are at an increased **risk of infant death, illness and disability**. [The facts behind this label](#)



Tobacco smoke can **cause the arteries in your brain to clog**. This can block the blood vessels and cause a stroke. A stroke can cause disability and death. [The facts behind this label](#)

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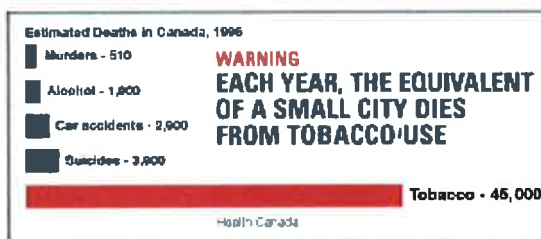




Cigarette smoke causes **oral cancer, gum diseases and tooth loss**. [The facts behind this label](#)

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Permission to use this image may be requested from the British Columbia [Intellectual Property Program](#).



Murders -- 510; Alcohol -- 1,900; Car accidents -- 2,900; Suicides - 3,900; **Tobacco - 45,000**. [The facts behind this label](#)



Tobacco use causes crippling, **often fatal lung diseases** such as **emphysema**. [The facts behind this label](#)



Tobacco use can result in the clogging of arteries in your heart. Clogged arteries cause **heart attacks** and can cause death. [The facts behind this label](#)

- Note: Health Canada is not the copyright owner of the photograph used in the label shown above. Therefore, reproducing or downloading this image is prohibited.



Every cigarette you smoke increases your chance of getting [lung cancer](#). [The facts behind this label](#)



85% of lung cancers are caused by smoking. 80% of [lung cancer](#) victims die within three years. [The facts behind this label](#)

- Note: Health Canada is not the copyright owner of the photograph used in the label shown above. Therefore, reproducing or downloading this image is prohibited.



Smoke from a lit cigarette contains **toxic substances** like hydrogen cyanide, formaldehyde and benzene. **Second-hand smoke can cause death** from lung cancer and other diseases. [The facts behind this label](#)



Tobacco smoke contains [hydrogen cyanide](#). It can cause **headaches, dizziness, weakness, nausea, vertigo, and stomach aches** in smokers and non-smokers. [The facts behind this label](#)



The smoke from a cigarette is not just inhaled by the smoker. It becomes **second-hand smoke**, which contains more than 50 cancer-causing agents. [The facts behind this label](#)

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Lung and brain images courtesy of the Australian National Tobacco Campaign

High-resolution JPG [images](#) can be downloaded for non-commercial purposes.

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Date Modified: 2010-08-03