UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Acting Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

KAREN E. SCHIFTER
Senior Counsel
U.S. Department of Health & Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

TONY WEST
Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

MAAME EWUSI-MENSAH FRIMPONG
Acting Deputy Assistant Attorney General

DRAKE CUTINI
DANIEL K. CRANE-HIRSCH
Attorneys, Consumer Protection Branch

MARK B STERN
ALISA B. KLEIN
SARANG V. DAMLE
DANIEL TENNY
LINDSEY POWELL
Attorneys, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: **Page**

* Authorities chiefly relied upon are marked with an asterisk.

* Authorities chiefly relied upon are marked with an asterisk.

* Authorities chiefly relied upon are marked with an asterisk.

Statutes:

Regulations:

* Authorities chiefly relied upon are marked with an asterisk.

Executive Orders:

Legislative Materials:

Other Authorities:

---

* Authorities chiefly relied upon are marked with an asterisk.

* Authorities chiefly relied upon are marked with an asterisk.

* Authorities chiefly relied upon are marked with an asterisk.

INTRODUCTION AND SUMMARY

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), gives the Food and Drug Administration ("FDA") authority to regulate the manufacture and sale of tobacco products, including cigarettes and smokeless tobacco. Among other things, the Act specifies the language for nine different textual warning statements, which include messages such as "Cigarettes cause cancer." Congress directed the Secretary to "issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the new textual warning statements. 15 U.S.C. § 1333(d).

Shortly after the Act was signed into law, several manufacturers of cigarettes and smokeless tobacco filed suit in the United States District Court for the Western District of Kentucky, claiming that this provision of the statute, as well as several others, violate the First Amendment. *See Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010), *appeals pending sub nom. Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir.). The *Commonwealth Brands* plaintiffs included three of the plaintiffs here—R.J. Reynolds, Lorillard, and Commonwealth Brands (which is owned by Imperial Tobacco, the United Kingdom's largest cigarette manufacturer).

After denying a motion for preliminary relief, the district court granted summary judgment to the government in 2010 on all but two provisions of the Act. As directly relevant here, the district court rejected plaintiffs' claim that "the Act's warning requirement is unconstitutional because it 'unjustifiably and unduly burden[s] Plaintiffs' commercial speech ... [and] unconstitutionally compel[s] Plaintiffs to disseminate the Government's anti-tobacco message.'" 678 F. Supp. 2d at 528. The court rejected plaintiffs' contention that "the public already appreciates the health risks associated with using tobacco products" and that the health warnings therefore did not advance a

legitimate government purpose. *Id.* at 530. It noted that Congress "informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada," which had proven demonstrably more effective in conveying the risks of smoking than the current U.S. health warnings. *Id.* at 531. Studies also demonstrated that "graphical warnings 'may be particularly important for communicating' with consumers with low levels of education" and underage consumers. *Ibid.* (citation omitted). Both sides appealed, and the Sixth Circuit heard oral argument on July 27, 2011.

On June 22, 2011, FDA, after notice-and-comment rulemaking, issued the final rule containing the new images required by the statute. This rule, by operation of statute, will become effective on September 22, 2012. Pub. L. No. 111-31, § 201(b). On August 16, plaintiffs filed this action, arguing that the final rule violates their First Amendment rights and does not comply with the Administrative Procedure Act.

Plaintiffs' new suit reprises arguments already considered and rejected in *Commonwealth Brands.* Plaintiffs do not claim that the rule is inconsistent with the governing statute, which required FDA to select "color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333. Plaintiffs' consistent position—in their comments in the rulemaking, in *Commonwealth Brands*, and in this suit—is that *any* color graphics of the kind required by Congress violate the First Amendment.

Plaintiffs repeatedly quote a sentence fragment from the rule's 65-page regulatory impact statement to claim that the health warnings will have no effect on smoking rates. The impact statement actually predicts that the new warnings likely *will* decrease smoking rates. More important, the impact statement has no bearing on the validity of the rule: Congress itself balanced the costs and benefits of requiring new health warnings and did not make issuance of the rule

contingent on any cost-benefit analysis by FDA. Even more fundamentally, Congress was not constitutionally required to predict the extent to which new health warnings, considered in isolation from other regulatory efforts, would reduce smoking rates. The evidence before Congress demonstrated that the new warnings will convey information about health risks more effectively than the current warnings, and that is sufficient to establish that the statute furthers a significant government purpose.

Plaintiffs have also failed to demonstrate that the balance of harms and the public interest require a preliminary injunction. Indeed, the relief they seek is not even "preliminary." Plaintiffs do not ask the Court to stay agency action pending final judgment. They ask, instead, for a ruling that will postpone the effective date of the regulation for a period of 15 months *after* final judgment. In any event, plaintiffs' asserted economic injury does not constitute irreparable harm. Even taking plaintiffs' untested allegations at face value, their alleged cost of preparing the revised warnings represents approximately one-tenth of one percent of their annual net sales, which is not sufficient to establish an entitlement to preliminary relief.

The public interest strongly militates against delaying health warnings that more effectively convey the extraordinary, undisputed health risks created by the use of plaintiffs' products. *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. 69,524, 69,526–27 (Nov. 12, 2010). Of those who become regular smokers, about half eventually will die from a tobacco-related disease. *Ibid.* The Supreme Court observed in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 156 (1967), that when a stay of an FDA regulation "would be detrimental to the public health or safety," it is "scarcely to be doubted that a court would refuse to postpone [its] effective date." That principle requires rejection of plaintiffs' invocation of the Court's equitable powers.

STATEMENT

A. Statutory Background.

1. Congress crafted the provisions of the Tobacco Control Act on the basis of evidence gathered over decades by all three branches of government regarding the health risks posed by tobacco products and the industry's marketing of those products. Four crucial features of tobacco use and marketing that emerged from these intensive investigations are essential to an analysis of plaintiffs' claims here, just as in *Commonwealth Brands*.

First, when used as intended by the manufacturers, tobacco products are deadly. "In the United States, cigarette smoking is the leading cause of preventable death and disease, resulting in more deaths each year than AIDS, alcohol, illegal drug use, homicide, suicide, and motor vehicle crashes combined." 75 Fed. Reg. at 69,526 (citations omitted); *see also FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000) (finding that FDA had "amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States").

The Surgeon General testified before Congress that "[e]ach year, 440,000 people die of diseases caused by smoking or other form 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).[1] The Institute of Medicine ("IOM") of the National Academies, in a report cited by Congress, concluded in 2007 that, in light of current knowledge, if cigarettes "were being introduced for the first time," they "would not be allowed to enter the marketplace." Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation*, at

[1] All citations to the Congressional Record are to the daily editions, and can be found at http://www.gpoaccess.gov/crecord/09crpgs.html.

152 (2007) ("IOM Report") (discussed in H.R. Rep. No. 111-58(I) (2009)).[2]

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," *id.*, and the force of nicotine addiction is illustrated by the failure rate of individual smoking cessation efforts. Data for 2004, for example, indicated "that although approximately 40.5 percent of adult smokers reported attempting to quit in that year, only between 3 and 5 percent were successful." 75 Fed. Reg. at 69,529.

The tobacco industry has for decades appreciated the importance of nicotine addiction to their sales. An internal R.J. Reynolds memo from 1972, quoted by Congressman Ganske in 2000, acknowledged: "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiologic effects." 146 Cong. Rec. H1849 (April 5, 2000).

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.[3] 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.*, 566 F.3d 1095, 1107, 1124 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (June 28, 2010)

---

[2] The IOM Report can be found at http://www.nap.edu/catalog.php?record_id=11795. Relevant excerpts of the report are attached to this brief.

[3] The Legislative Findings are codified at 21 U.S.C. § 387, Note.

(citation and internal quotation marks omitted); Legislative Finding 49.

Third, the tobacco industry has long depended on recruiting underage users who become addicted by 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 adult smokers began smoking before age 18"). According to a national survey of high-school students conducted in 2009, "almost half (46.3 percent) ... had tried cigarette smoking, and an estimated *19.5 percent ... were current cigarette smokers*." 75 Fed. Reg. at 69,526 (emphasis added).

The adolescents who become the industry's new customers systematically underestimate the tenacity of nicotine addiction and overestimate their own ability to stop smoking. One survey showed that "fewer than 5 percent of daily smokers in high school think that they will be smoking at all in 5 years, yet more than 60 percent of high school smokers are regular daily smokers 7 to 9 years later." 76 Fed. Reg. 36,628, 36,633 (June 22, 2011).

Tobacco companies have long known that they must reach potential customers while they are underage and they have targeted their marketing accordingly. Congress 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.

Fourth, the tobacco industry has for decades misled consumers about the health risks and

addictiveness of its products. The tobacco companies' "efforts to deny and distort the scientific evidence of smoking's harms are demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *United States v. Philip Morris USA, Inc*., 449 F. Supp. 2d 1, 855 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (June 28, 2010).

2. In 1996, FDA issued regulations that aimed to cut adolescent use of tobacco products in half within seven years. 61 Fed. Reg. 44,396, 44,539 (Aug. 28, 1996). The Supreme Court concluded, however, that FDA generally lacked authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to regulate cigarettes and smokeless tobacco. *Brown & Williamson*, 529 U.S. at 126.

The Court nevertheless left no doubt as to the seriousness of the public health crisis addressed by the 1996 regulations. The Court emphasized that "[i]n its rulemaking proceeding, the FDA quite exhaustively documented that 'tobacco products are unsafe,' 'dangerous,' and 'cause great pain and suffering from illness.'" *Id*. at 134 (quoting 61 Fed. Reg. at 44,412). The Court unequivocally recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." 529 U.S. at 161. Indeed, the voluminous evidence of the severe health risks posed by use of tobacco products was key to the Supreme Court's reasoning. The Court concluded that, given their inherently dangerous nature, cigarettes would be banned outright if they were subject to regulation as drugs under the FDCA, a result not within Congress's contemplation. *Id*. at 136.

3. Congress enacted the Tobacco Control Act of 2009 to fill the regulatory void left by

Brown & Williamson, giving FDA authority to regulate tobacco products, including cigarettes and smokeless tobacco. 123 Stat. 1776. The Act contains an array of measures designed to ensure that consumers are aware of and understand the health consequences of tobacco use, and to stop the tobacco industry from continuing to market to children and adolescents.

In the health warnings provision at issue here, Congress, for the first time since 1984, updated the health warnings that must appear by federal law on all cigarette packages and advertisements. *See* 75 Fed. Reg. at 69,525, 69,529–30. The Act provides that product labels and advertisements for cigarettes must bear one of several prominent warning statements describing the adverse health effects of smoking, including statements regarding addictiveness and the impact on smokers and nonsmokers. 15 U.S.C. § 1333. The required warning statements are:

> 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.

Ibid. The Act directs the Secretary to promulgate regulations "that require color graphics depicting the negative health consequences of smoking to accompany" the text of these nine warnings. *Ibid*.

B. The *Commonwealth Brands* Litigation.

In August 2009, a group of tobacco companies—including plaintiffs in this case, R.J. Reynolds, Lorillard, and Commonwealth Brands—filed a lawsuit challenging several provisions of the Tobacco Control Act. *See Commonwealth Brands*, 678 F. Supp. 2d 512. As relevant here, the tobacco companies urged that the revised health warnings violate their First Amendment rights. The tobacco companies did not challenge the *content* of the health warnings, which, the district court

observed, "is objective and has not been controversial for many decades." *Id.* at 531.

Instead, the tobacco companies challenged the *format* of the health warnings required by Congress, including their size and the statutory requirement that the warnings be accompanied by images depicting the negative health consequences of smoking. *Id.* at 531–32.

On cross-motions for summary judgment, the district court upheld the health warnings requirement. The court rejected plaintiffs' claim that "the Act's warning requirement is unconstitutional because it '"unjustifiably and unduly burden[s] Plaintiffs' commercial speech ... [and] unconstitutionally compel[s] Plaintiffs to disseminate the Government's anti-tobacco message,'" *id.* at 528, and found that "[p]laintiffs' argument that the new warnings are too large and too prominent is unpersuasive." *Id.* at 531.

The court observed that Congress "informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada," where "[s]tudies of Canadian smokers have shown that more than half 'reported that the pictorial warnings have made them more likely to think about the health risks of smoking' and that 'approximately 95 percent of youth smokers and 75 percent of adult smokers report that pictorial warnings have been effective in providing them with important health information.'" *Id.* at 531 (quoting IOM Report, at 291–92, 294). The format mandated by Congress was also, the court observed, informed by "the international consensus reflected in the World Health Organization's Framework Convention on Tobacco Control, which calls for warnings" of the kind adopted by Congress. *Ibid.* (discussing WHO Framework Convention on Tobacco Control, art. 11.1(b)). The court declared that "[t]his is not, as Plaintiffs contend, too burdensome, for half of cigarette packs, ... and 80% of advertisements remain available for their speech." *Ibid.*

The court further noted that other congressional testimony and studies of the Institute of

Medicine underscored the importance of including graphics as part of the health warnings. As the court observed, the IOM "emphasized that graphical warnings 'may be particularly important for communicating' with consumers with low levels of education, given evidence that such smokers 'are less likely to recall health information in text-based messages than people with more education.'" *Id.* at 531 (quoting 2007 IOM Report, at 295, C-3). The court noted that studies cited in the report "showed that the current warnings 'require a college reading level' and thus 'may be inappropriate for youth and Americans with poor reading abilities.'" *Ibid.*

After reviewing a voluminous record, the court concluded that "Congress's decision to revise the content and format of the tobacco warnings [was] justified." *Id.* at 531. The court emphasized that the "government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance." *Id.* at 530 (emphasis in original).

The district court also rejected challenges to several other Tobacco Control Act provisions, but invalidated a restriction on the use of color and imagery in advertising and a provision barring claims that a tobacco product is safe or less harmful by virtue of FDA regulation. *See id.* at 521–28, 531–40. Both sides appealed the final judgment to the Sixth Circuit, where argument was held on July 27, 2011.

C. FDA's Implementing Rule.

The Tobacco Control Act directed FDA to promulgate regulations regarding the display of health warnings on cigarette packages and in cigarette advertisements to implement the new statutory requirements. To develop appropriate images to accompany the warning text, FDA drew upon the advice of "various experts in the fields of health, marketing research, graphic design and advertising," a substantial body of scientific literature analyzing the effectiveness of such warnings,

and the experience of the over thirty countries and jurisdictions that have, since 2001, implemented pictorial health warnings on cigarette labels. 75 Fed. Reg. at 69,525, 69,534. In November 2010, FDA submitted for comment a proposed rule containing several proposed health warnings for each of the nine warning statements. *See id.* at 69,534.

In selecting the final pictorial health warnings, FDA reviewed well over a thousand public comments, including joint comments submitted by plaintiffs R.J. Reynolds, Lorillard, and Commonwealth Brands. 76 Fed. Reg. at 36,629; Comment Letter of R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, and Commonwealth Brands Inc., Docket No. FDA-2010-N-0568 (Jan. 11, 2011) ("Comment Letter"). The agency also reviewed the results of a study of more than 18,000 consumers testing the relative effectiveness of the 36 proposed pictorial warnings. *See* FDA, Experimental Study of Graphic Cigarette Warning Labels, Final Results Report (Dec. 2010) (hereinafter "FDA Study Report"). 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)." 76 Fed. Reg. 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 pictorial health warnings included in the final rule are, as FDA noted, "generally consistent with the graphic health warnings used in other countries." 76 Fed. Reg. at 36,647; *see id.* at 36,636–70 (explaining selection of the images). *See* S.J. Mem. 5–6 (reproducing images). For instance, in Canada, images such as those reproduced here have appeared on cigarette packs for nearly a decade:

See Health Canada, *Graphic Health Warnings*.[4] Similar warnings have appeared on cigarette packs sold in Australia since 2006 and in the United Kingdom since 2008.[5] *See also, e.g.*, European Commission Directorate General For Health and Consumers, *Pictorial Health Warnings* (showing 42 pictorial warnings for use in EU member states).[6]

As required by section 201(b) of the Tobacco Control Act, the final rule becomes effective 15 months following its publication, on September 22, 2012. 76 Fed. Reg. at 36,702.

D. This Litigation.

The final rule was published on June 22, 2011. On August 16, plaintiffs filed this suit challenging the rule on First Amendment and APA grounds. Along with a summary judgment motion, plaintiffs filed what they styled as a motion for a preliminary injunction. The motion asks

---

[4] http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/label-etiquette/graph/index-eng.php.

[5] Australia Department of Health and Ageing, *Fact Sheet Graphic Health Warnings*, *at* http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/fact-sheet-health-warnings; United Kingdom Department of Health, *Picture Warnings on Tobacco Products*, *at* http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Tobacco/Picturewarningsontobaccoproductspressimages/index.htm.

[6] http://ec.europa.eu/health/tobacco/law/pictorial/index_en.htm.

this Court to delay the congressionally mandated September 2012 effective date for the new warnings "until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims." P.I. Mot. 5.

ARGUMENT

I. PLAINTIFFS HAVE FAILED TO DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS.

A. Plaintiffs' Position, Which Reprises Contentions Made in *Commonwealth Brands*, Is that Any Regulation that Faithfully Implements the Statutory Warning Requirements Violates the First Amendment.

The Tobacco Control Act directed FDA to issue regulations regarding new health warnings for cigarette packaging and advertising. Congress prescribed the text of the nine warnings and the details of their format, including size and placement on packaging and advertising, and mandated the use of graphic images to accompany the text. The requirements closely resemble those adopted by Canada in late 2000, of which Congress was well aware. The graphics set out in the final rule implement the statutory specifications and resemble those required by Canada and other nations such as the United Kingdom and Australia.

Plaintiffs ask the Court to declare the final rule invalid. The thrust of plaintiffs' arguments, however, attacks the constitutionality of the statutory requirements rather than any feature of the FDA rule. Plaintiffs do not and cannot argue that the graphics selected by FDA to accompany the text of the warnings are inconsistent with Congress's directive to select images that depict "the negative health consequences of smoking." 15 U.S.C. § 1333. Nor do they argue that the agency should have adopted *different* graphics. Rather, their position is that *any* rule that complied with the statute's mandate would violate the First Amendment. Similarly, in the rulemaking, plaintiffs did not support the selection of any of the 36 proposed images or propose any alternatives. They

requested instead that "FDA withdraw the proposed rule and issue a new proposed rule" that would "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." Comment Letter at 3-4. FDA plainly had no discretion to comply with plaintiffs' request and to disregard Congress's directive.

Although plaintiffs declare that "the *Commonwealth Brands* plaintiffs did not raise the claim brought by Plaintiffs here," S.J. Mem. 16, they cannot plausibly insist that they are advancing different constitutional arguments here than they raised in *Commonwealth Brands*. In *Commonwealth Brands,* as in this case, plaintiffs argued that the health warning requirement is an impermissible attempt to force them to further an anti-smoking campaign. 678 F. Supp. 2d at 530; S.J. Mem. 20–24. There, as here, plaintiffs argued that the health warnings are unnecessary because the public already overestimates the risks associated with smoking. 678 F. Supp. 2d at 529; S.J. Mem. 25. And there, as here, plaintiffs argued that the health warnings impermissibly burden their commercial speech by prohibiting plaintiffs from using the top 50% of their packages and the top 20% of their advertisements. 678 F. Supp. 2d at 528–29; S.J. Mem. 35–37. In both cases, plaintiffs' overarching claim is that the "purpose and effect of the warnings is to drown out Plaintiffs' own constitutionally protected speech about their lawful products and replace it with the Government's emotionally-charged anti-smoking message." P.I. Mot. 2; *see* 678 F. Supp. 2d at 530.[7]

As we show below, plaintiffs offer no reason for this Court, in assessing plaintiffs' likelihood of success on the merits here, to depart from the well-reasoned analysis in *Commonwealth Brands*,

[7] At this preliminary juncture, it is not necessary to determine to what extent their prior-filed suit forecloses the claims of plaintiffs R.J. Reynolds, Lorillard and Commonwealth Brands, or of plaintiff Santa Fe Tobacco, which has the same corporate parent as R.J. Reynolds.

which issued after a full opportunity to consider an extensive record.

B. The Health Warnings Mandated by Congress Are Based on Voluminous Evidence, Reflect an International Regulatory Consensus, and Readily Survive First Amendment Scrutiny.

1. In general, the government may impose restrictions on truthful commercial speech that directly advance a substantial government interest and are no more extensive than is necessary to serve that interest. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557, 566 (1980). That standard does not require the legislature to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Ibid*.

A still more relaxed standard applies when a regulation does not preclude the conveyance of a truthful message but, as in this case, mandates the inclusion of additional information. *See Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). The Supreme Court has stressed that such mandatory disclosure requirements are subject to "less exacting scrutiny" than limits on speech. *Milavetz v. United States*, 130 S. Ct. 1324, 1339–40 (2010).

2. The required health warnings readily survive scrutiny under any possible relevant First Amendment standard. Plaintiffs offer no valid reason to reject the extensive evidence before Congress and FDA supporting those warnings. Congress mandated new health warnings in the face of abundant evidence that the existing warnings, dating from 1984, "are unnoticed and stale," and that they "fail to convey relevant information in an effective way." *Commonwealth Brands,* 678 F. Supp. 2d at 530 (quoting IOM Report, at 291) (internal quotation marks omitted). Indeed, it has been clear since at least 1994 "that the Surgeon General's warnings are given little attention or

consideration by viewers." *Ibid.* (quoting Surgeon General's Report, *Preventing Tobacco Use Among Young People*, at 168 (1994)).

In testimony to Congress, the Chair of the IOM's Committee on Reducing Tobacco Use described the 1984 warnings on cigarette packs as "'invisible.'" *Id.* at 530 (quoting H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce, 110th Cong. 42 (2007) (testimony of Richard Bonnie)). Indeed, as FDA noted, "[t]he messages developed by tobacco companies in cigarette advertisements cover 96 percent of the space, are continually updated to incorporate current trends, and are targeted based on market research." 75 Fed. Reg. at 69,531. "In contrast, the current health warnings cover only 4 percent of advertising space, are solely textual, are not targeted to any population group, and consist of only four rotating messages that have not been updated for more than two and a half decades." *Ibid.* (citation omitted).

The IOM also "emphasized that graphical warnings 'may be particularly important for communicating' with consumers with low levels of education, given evidence that such smokers 'are less likely to recall health information in text-based messages than people with more education.'" 678 F. Supp. 2d at 531 (quoting 2007 IOM Report, at 295). Indeed, "one study showed that the current warnings 'require a college reading level' and thus 'may be inappropriate for youth and Americans with poor reading abilities.'" *Ibid.* (quoting 2007 IOM report, at C-3).

Plaintiffs in *Commonwealth Brands*, as in this case, nevertheless urged that larger, pictorial warnings would not advance a substantial government purpose because the public is already well informed of the risks of tobacco use. *See* S.J. Mem. 25–27. The court succinctly described the premise of their claim: "Plaintiffs' entire argument rests on the idea that, since the public already appreciates the health risks associated with using tobacco products, the government's goal must be

to browbeat potential tobacco consumers, including youths, over the head with its anti-tobacco message at the manufacturers' expense." 678 F. Supp. 2d at 530. As in this case, plaintiffs in *Commonwealth Brands* relied heavily on a declaration from Dr. W. Kip Viscusi, which declared that "'[g]iven that the new mandated warnings are conveying information that is already well known, it would appear that they are really no more than a generalized anti-tobacco message: "don't buy this product."'" 678 F. Supp. 2d at 530 (quoting Viscusi Decl. ¶ 68); c*ompare* S.J. Mem. 8, 11, 13–15, 25–27, 29, 31–33, 41–42 (citing a similar declaration by Dr. Viscusi).

The court in *Commonwealth Brands* flatly rejected the premise of plaintiffs' argument. Based on a careful examination of the evidence before Congress and the evidence submitted by the plaintiffs, the court explained that "the government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance." 678 F. Supp. 2d at 530; *see also* 76 Fed. Reg. at 36,632 (discussing evidence of consumers' lack of knowledge of the health risks of smoking). The court's evaluation of Dr. Viscusi's evidence accorded with that of the district court in *Philip Morris* following a nine-month bench trial. That court explained that "the research and expert testimony demonstrate that most youth, at a time when they are deciding whether to start smoking, have a very inadequate understanding of the medical consequences, physical pain, and emotional suffering which results from smoking and the unlikelihood of their being able to quit smoking at some future time." *Philip Morris*, 449 F. Supp. 2d at 579-80. Plaintiffs offer no basis for this Court to second-guess the factual findings, made on full evidentiary records, in the *Commonwealth Brands* and *Philip Morris* cases, especially in the current preliminary posture of this case.

It is equally clear that the content, size, and location of the package health warnings do not unconstitutionally "confiscate[] the most prominent portion of Plaintiffs' packaging" or "overwhelm

and drown out Plaintiffs' own marketing messages." S.J. Mem. 33–36. As the district court in *Commonwealth Brands* explained, "half of cigarette packs, ... and 80% of advertisements remain available for their speech." 678 F. Supp. 2d at 531.

It is not novel for federal law to require extensive labeling and advertising disclosures. Drug companies must include all of a prescription drug's risk information, as well as other information about the drug in print advertisements. Although these disclosures are collectively described as the "Brief Summary," the information required is so extensive that it "would take many minutes to read or scroll down a TV screen," and "is usually presented on its own page of a print ad." FDA, *Drug Advertising: A Glossary of Terms*.[8] Even for less dangerous over-the-counter ("OTC") drugs, FDA regulations impose detailed labeling requirements. 21 C.F.R. § 201.66. The wrapper or outside container for a retail OTC package must contain a "Drug Facts" panel with information on the active ingredient, drug purpose, indications, directions, warnings, inactive ingredients, and other information. *Id*. § 201.66(c). For many products, the required disclosures comprise more than 50% of the packaging. *See, e.g.*, FDA Label Information, Omeprazole 20mg Tablet (OTC heartburn medication).[9]

Moreover, in contrast to the cases on which plaintiffs rely, "Congress has provided reasons for the particular features of the warning requirement here." 678 F. Supp. 2d at 531. For example, "Congress ... informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada." *Ibid.* (citing IOM Report, at 291–92; H.R. 1108, Family Smoking Prevention And Tobacco Control Act: Hearing Before the House Subcommittee on Health of the

---

[8] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm

[9] http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022032s003lbl.pdf

Committee on Energy and Commerce, 110th Cong. 36 (2007) (testimony of Richard Bonnie)). The Canadian warning occupies the top half of the two main panels of cigarette packs. *See, e.g.*, Health Canada, *Graphic Health Warnings* (examples of Canadian warnings).[10] "Studies of Canadian smokers have shown that more than half 'reported that the pictorial warnings have made them more likely to think about the health risks of smoking' and that 'approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information.'" 678 F. Supp. 2d at 531 (quoting IOM Report, at 294).

"Indeed, there is no more efficient method of reaching smokers than through the use of graphic and highly visible warning labels." Peters, E., *et al.*, "The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers," Nicotine & Tobacco Research, vol. 9, no. 4, pp. 473–481, at 479 (Apr. 2007) (cited as reference 45 in the final rule). "One study comparing Canadian and U.S. warnings found that while '83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,' only '7 percent of U.S. students' did the same." 678 F. Supp. 2d at 531 (quoting IOM Report, at C-3 to C-4). Another study comparing the Canadian graphic warning images to the text-only warnings that were formerly used in the United Kingdom "found that the Canadian pictorial warnings had a greater impact on smokers than the ... UK warnings." 75 Fed. Reg. at 69,533. In particular, "Canadian smokers ... were significantly more likely than those in the UK to report that the warnings made them think about the health risks of smoking." *Ibid.* Finding that "[t]he benefits flowing from the larger warnings are clear" while "[t]he detriments to the manufacturers' expressive interest in creative

[10] http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/label-etiquette/graph/index-eng.php.

packaging are small," the Canadian Supreme Court unanimously rejected a challenge analogous to the one asserted here. *Canada v. JTI-Macdonald Corp.*, [2007] 2 S.C.R. 610, 2007 SCC 30, ¶ 139.

The experience among the 30 countries that, since 2001, have joined Canada in requiring pictorial health warnings further substantiates Congress's belief that more prominent, pictorial warnings will more effectively communicate the health risks of smoking. For example, a study of Australia's pictorial health warnings, which were introduced in 2006, showed that "[a]mong students in year levels 8 to 12 in Melbourne, cognitive processing of cigarette warnings (*i.e.*, reading, attending to, thinking and talking about the warnings) increased in the year" the warnings were adopted. 75 Fed. Reg. at 69,531. In another study, middle and high school students in Greece who were asked to compare the graphic warnings prepared by the European Union with text-only warnings "consistently selected the graphic warnings as more effective in making them think about the effects of smoking on health." *Id.* at 69,532.[11]

3. Plaintiffs' contention that the government failed to consider less-speech-restrictive alternatives was also considered and rejected by the district court in *Commonwealth Brands*. Indeed, the primary support plaintiffs offer for their argument is a declaration that was filed in that case and then resubmitted to FDA during its current rulemaking. *See* S.J. Mem. 29 (citing Reynolds Decl., filed as Exhibit D to Comment Letter). There, as here, plaintiffs argued that Congress should have considered alternatives to the health warnings, such as "requiring states to use CDC-recommended levels of tobacco revenues for tobacco control programs," "increasing support for interventions that address the personal and social factors that influence tobacco use," "preventing the unlawful retail

[11] For all of these reasons, as the district court in *Commonwealth Brands* explained, plaintiffs' reliance on *Ibanez v. Florida Dept. of Business and Professional Regulation*, 512 U.S. 136 (1994), and *Entertainment Software Association v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), is misplaced. *See* 678 F. Supp. 2d at 529–30.

sale of tobacco products to youth by, e.g., increasing the compliance rate required by the Synar Amendment, Pub. L. No. 102-321, § 1926," and "increasing the price of tobacco products." 678 F. Supp. 2d at 537 (internal quotation marks and brackets omitted); *compare* S.J. Mem. 29.

But the district court in *Commonwealth Brands* correctly observed that "this is not a case where Congress went 'straight to [plaintiffs'] speech,'" but rather "a case where Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry." 678 F. Supp. 2d at 538. Rather than new measures that the government has not yet considered, plaintiffs' proposals are all "'variations on strategies already adopted'": Congress has already barred tobacco sales to persons under 18, provided civil penalties for retailer violations, directed the Secretary to implement a program to ensure compliance, and enacted a 62-cent increase in the federal excise tax on cigarettes. *Ibid.* (citing Act § 102; 21 C.F.R. § 897.14 (1997) (now codified at 21 C.F.R. § 1140.14); 21 U.S.C. §§ 331(oo), 333(f)(5), 387a-1(a)(2)(G), (a)(5); Children's Health Insurance Program Reauthorization Act of 2009, Title VII, § 701, Pub. L. No. 111-3, 123 Stat. 8, 106-07 (2009)).

Plaintiffs' proposals would also "impose substantial new costs on state and local governments and private persons." 678 F. Supp. 2d at 537. For example, as plaintiffs themselves have argued, cigarette tax increases can unfairly burden low-income users, encourage illicit purchases, and produce other adverse effects. *See, e.g.*, http://www.nocigtax.com/why-cig-taxes-hurt-you/taxpayers (Reynolds website); Campaign for Tobacco-Free Kids, Press Release (May 8, 2003) (noting that "Lorillard's ads, which are running in Delaware, New Jersey and Pennsylvania,

argue that cigarette tax increases lead to increased crime and cigarette smuggling").[12] Plaintiffs' other proposals would primarily punish states, retailers, and minors for taking inadequate measures to combat the evils of plaintiffs' products.[13]

C. The Particular Images FDA Selected to Accompany the Warning Statements Are Consistent with the Statutory Mandate, and Convey Accurate Information Regarding the Uncontested Health Consequences of Smoking in a Form that Is Readily Understandable to a Broad Cross-Section of Consumers.

1. Plaintiffs identify no respect in which the FDA rule is inconsistent with the agency's statutory mandate, and they do not dispute that Congress contemplated adoption of this type of pictorial warning. Nor do plaintiffs argue that FDA made irrational choices among the 36 images presented in its proposed rule. As underscored by their comments in the rulemaking, plaintiffs do not believe that the agency could properly adopt any of those 36 images. And, neither in their comments nor in their filings in this case, have plaintiffs proposed or described alternative images that would, in their view, satisfy both the statute's requirements and the First Amendment. Their position, instead, is that no image that comports with the statute's requirements can pass constitutional muster.

---

[12] http://www.tobaccofreekids.org/press_releases/post/id_0639

[13] Plaintiffs' suggestion that "the Government could provide an exemption from the graphic warnings requirement for 'reminder' advertising and labeling," S.J. Mem. 29, fails on every level. The exemption on which it is based applies to drug labeling that "calls attention to the name of the drug product but does not include indications or dosage recommendations for use of the drug product." 21 C.F.R. § 201.100(f). Because cigarettes have no therapeutic benefit whatsoever, tobacco advertising and labeling never includes indications or dosage recommendations—the only healthy dose is no dose at all—and therefore the proposed exception would completely swallow the rule. Moreover, the reminder-labeling exception applies only to drugs dispensed by prescription, is inapplicable to particularly hazardous prescription drugs, and may be withdrawn by FDA if there is "evidence of significant incidence of fatalities or serious injury associated with the use of a particular prescription drug." *Ibid.* There is no basis for providing such an exception to a product that consumers use without a doctor's supervision and that is lethal and addictive when used as intended.

2. Plaintiffs argue that FDA was required to prove that its selected images would reduce national smoking rates. *See, e.g.*, S.J. Mem. 20, 39. This contention fails for two independent reasons, even apart from the fact that, as we explain below, plaintiffs misunderstand FDA's conclusions about the likely effect of the rule. *See infra* 28–29, 34–35.

First, this argument merely reprises plaintiffs' claim that the statutorily mandated warnings do not advance a legitimate governmental purpose. Congress required FDA to issue warnings consistent with the statute, and FDA was obligated to comply with that mandate. Congress did not ask FDA to determine whether warnings would reduce national smoking rates and did not make issuance of the rule contingent on such a determination. In any event, plaintiffs do not argue that FDA overlooked alternative warnings that would convey the health risks more effectively or would be more likely to affect the decisions of consumers and potential consumers. Plaintiffs' quarrel is with Congress, not with FDA.

Second, this argument reflects plaintiffs' fundamental misunderstanding of the nature and purpose of the warnings. Their primary purpose is "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements." 76 Fed. Reg. at 36,697. The most relevant metric in evaluating the warnings is not their short-term impact on smoking rates, but the extent to which they more effectively convey information about health risks to consumers and potential consumers. Thus, as the court explained in *Commonwealth Brands*, "the government's goal is ... to ensure that the health risk message is actually *seen* by consumers in the first instance." 678 F. Supp. 2d at 530. *See also Zauderer*, 471 U.S. at 651 (warnings and disclosures may be required "in order to dissipate the possibility of consumer confusion or deception").

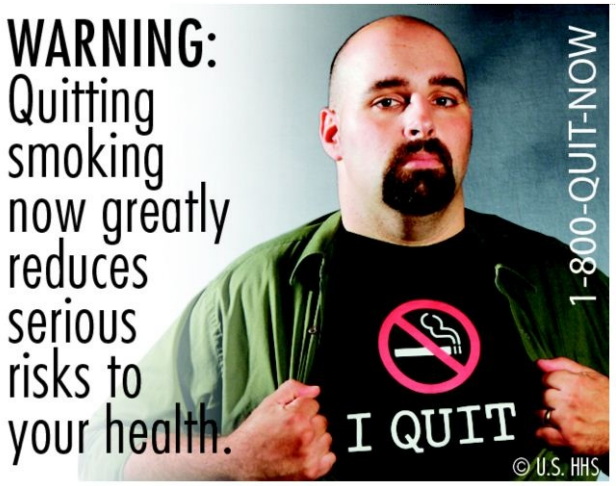
Other than the discredited theories of Dr. Viscusi, plaintiffs offer no basis for their assertion that the images "will have no material impact on consumers' understanding of smoking risks." S.J.

Mem. 25. As the previous discussion demonstrates, ample evidence supported Congress's determination that pictorial health warnings are crucial for communicating with groups of consumers who may have difficulty reading or comprehending the textual warnings, and FDA addressed the same point in its rulemaking. 75 Fed. Reg. at 69,531–32. *See also Commonwealth Brands*, 678 F. Supp. 2d at 531 (noting studies showing that "the current warnings 'require a college reading level' and thus 'may be inappropriate for youth and Americans with poor reading abilities'" (citation omitted)).

The experience of countries such as Canada, Australia, and the United Kingdom—which have, for years, required cigarette packs to display pictorial warnings using images similar to those selected by FDA—demonstrates that such images effectively communicate the message contained in the textual health warning statement. As FDA explained, the scientific literature examining this international experience "provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking." 76 Fed. Reg. at 36,639. For example, as noted above, data from Health Canada "indicate[s] 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." 75 Fed. Reg. at 69,532.

3. Plaintiffs also contend that the images selected by FDA are "nonfactual" and "designed to shock, disgust, and frighten." S.J. Mem. 1, 23. At first blush, this argument might appear to invite the Court to engage in line-drawing between permissible and impermissible images without the benefit of any constitutional standards. In fact, however, plaintiffs' position is that *all* of the images selected—or considered in the rulemaking—by FDA are impermissible and, indeed, that *no* image within the contemplation of the statute could satisfy the requirements of the First Amendment. Thus plaintiffs urge that "[*n*]*one* of the nine graphic images required by the Rule provides 'purely

factual and uncontroversial' information about the health risks of tobacco products." S.J. Mem. 21. This blanket attack on the images is untenable. For example, plaintiffs cannot plausibly contend that the following images are "designed to shock, disgust, and frighten." S.J. Mem. 1, 23.



Plaintiffs' position here echoes their comments in the rulemaking, in which they objected to *all thirty-six* warnings proposed by FDA without differentiating among them. Plaintiffs thus refused to acknowledge, for example, that an image of a woman blowing a soap bubble that accompanied the statement "WARNING: Quitting smoking now greatly reduces serious risks to your health," was not "designed to shock, disgust, and frighten." *See* Comment Letter at 2–4. Rather than suggesting any means by which FDA could comply with the statute, plaintiffs urged that color warnings of the size explicitly set out by Congress were unconstitutional, that the need for graphic warnings had not been adequately demonstrated, and that FDA should issue a new proposed rule that would "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." *Id.* at 3–4.

In any event, plaintiffs are incorrect that the warnings are "nonfactual" and "designed only to shock, disturb, and frighten." Plaintiffs "do not challenge dissemination of the purely factual information contained in the text of the new warnings," S.J. Mem. 2, 32, and they nowhere explain

why the images chosen do not convey the substance of the warning message accurately. Plaintiffs are wrong to assert that the chosen images "exaggerate the effects of sickness and disease." S.J. Mem. 20. FDA explained that, although "some of the photographs were technologically modified to depict the negative health consequences of smoking, the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking, and the comments did not dispute this fact." 76 Fed. Reg. at 36,696. Thus, each of the images is entirely "consistent with the information conveyed in the accompanying textual warning statements" and "depicts themes and subjects that provide visual context for the textual warning statements." *Id.* at 36,695–96.

The objections that plaintiffs offer ignore the means by which images convey information. For example, plaintiffs object to the image that accompanies the statement "WARNING: Smoking can kill you," on the ground that "autopsies" are not "a common result of cigarette smoking." S.J. Mem. 21. Plaintiffs do not dispute, however, that smoking kills 443,000 Americans each year, 76 Fed. Reg. at 36,629, or that, among children that become regular smokers, "*about half eventually will die from a disease caused by tobacco use*," President's Cancer Panel, "Promoting Healthy Lifestyles," at 64 (2007) (emphasis added). The autopsy image underscores this factual, non-controversial information and is a good deal less "disturbing" than photographs of the most common ravages of the diseases caused by plaintiffs' products.

Plaintiffs assail the image accompanying the statement "WARNING: Smoking during pregnancy can harm your baby" on the grounds that it is a "cartoon image." S.J. Mem. 4. Plaintiffs do not contend that a graphic illustration cannot convey accurate information. More important, they suggest no respect in which the use of the image contained in the FDA warning fails to convey the health risks described in the undisputed accompanying text. Cigarette manufacturers maintained for decades that smoking during pregnancy would have no adverse impact long after they knew the

contrary to be true. *See Philip Morris*, 449 F. Supp. 2d at 194 (noting that a 1971 press release of the Tobacco Institute, of which R.J. Reynolds, Lorillard, and Liggett were members, "challenged the claim that smoking is harmful to pregnant women"). At this point, however, plaintiffs no longer dispute that "smoking during pregnancy has negative effects, including increasing rates of preterm delivery and shortened gestation." 76 Fed. Reg. at 36,696. Nor do they offer any basis for setting aside the agency's conclusion that the image "accurately depicts the health consequences smoking during pregnancy can have for infants born to mothers who smoke." *Ibid.* FDA correctly noted that "[t]he style of the depiction—here, a graphic illustration—does not make it less factual," *id.* at 36,696, and further explained that "the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.*, photographic versus illustrative)," is demonstrated by the experience of other countries, *id.* at 36,653.

Ultimately, plaintiffs' objection to the pictorial health warnings is not that they are false, but that they are *true*. Although plaintiffs express concern that the images are "shocking," as FDA explained, "the severe, life-threatening and sometimes disfiguring health effects of smoking conveyed in the required warnings *are* disturbing and the images ... selected appropriately reflect this fact." 76 Fed. Reg. at 36,696. Plaintiffs' arguments here are of a piece with their long-standing efforts to obscure the truth about the health effects and addictiveness of their product. *See Philip Morris*, 566 F.3d at 1124 ("Cigarette smoking causes disease, suffering, and death. Despite internal recognition of this fact, Defendants [the tobacco companies] have publicly denied, distorted, and minimized the hazards of smoking for decades.") (quoting *Philip Morris*, 449 F. Supp. 2d at 146).

4. To help determine which among the 36 proposed images would be most effective, FDA commissioned a study of 18,000 consumers. 76 Fed. Reg. at 36,639–40. The study divided participants into three groups: adult smokers (age 25 or older), young adult smokers (aged 18 to 24),

and youth (aged 13 to 17) who currently smoke or who are susceptible to smoking, *id.* at 36,637, and randomly exposed study participants to a cigarette package or an advertisement containing either one of the 36 health warnings proposed by FDA, or a control set of text-only warnings. FDA Study Report at 4-1. The study then asked each participant to answer a series of questions about the warning and their general views about smoking. *Id.* at 1-3. The questions were designed to examine participants' "cognitive responses" to the warnings (*e.g.*, belief that the warnings were, for instance, informative, meaningful, or difficult to look at) as well as the "emotional" impact of the warnings. The study also attempted to measure whether the various health warnings would have longer-term influences on recall and consumers' beliefs and behaviors, by asking whether participants could recall the warnings; whether the warnings had a measurable influence on participants' self-reported beliefs about the health risks of smoking; and whether the warnings had any impact on participants' intention to quit or initiate smoking. *Id.* at 1-3; 76 Fed. Reg. at 36,638. (A report describing the study and its results was made available for public comment. *See* 75 Fed. Reg. 75,936, 75,936–37 (Dec. 7, 2010)).

Plaintiffs do not contend that FDA's evaluation of the study results caused it to choose the wrong images. In their comments, plaintiffs condemned all the images under consideration, and their position continues to be that none of the images is permissible.

Moreover, plaintiffs' argument fails even on its own terms. FDA's consideration of participants' "emotional" reactions to the warnings did not, as plaintiffs suggest, reflect an effort to choose images with maximum shock value. *See* S.J. Mem. 15–16. Instead, as FDA and the report authors explained, a well-established body of scientific literature has demonstrated that the immediate cognitive and emotional responses caused by a warning message are reliable predictors of longer-term changes in consumers' awareness of the health risks posed by tobacco use. FDA

Study Report at 1-2, 4-1 (citing studies); 76 Fed. Reg at 36,639 (same). Canadian studies confirm that the level of emotional response correlates directly to the likelihood that a consumer will "have read and thought about the warnings" as well as the likelihood that they will "reduce the amount they smoke and to quit or make an attempt to quit." 76 Fed. Reg. at 36,635. Plaintiffs do not contest the validity of any of these studies.

Plaintiffs are similarly mistaken in asserting that the research study "conclude[d] that virtually none of the warnings will have a statistically significant impact on consumers' awareness of smoking risks." S.J. Mem. 7. The study was not designed to make an assessment of the kind suggested by plaintiffs. Instead, it provided one means of assessing the *relative* impact of different warnings based on participants' exposure to one graphic warning on one occasion. And, of course, plaintiffs themselves have never suggested that some warnings have greater salience than others or that any would, in their view, be constitutionally permissible.

Moreover, the impact of warnings on consumer awareness results not from a single viewing, but from repeated exposure to multiple warnings over an extended time. FDA emphasized that a pack-a-day smoker will be exposed to a package warning "more than 7,000 times per year." 76 Fed. Reg. at 36,682. In recognition of this fact, the study specified that it was not intended to furnish conclusions about "longer-term outcomes" that will be achieved by multiple viewings of the warnings. FDA Study Report at 1-2. As explained above, studies that did examine the long-term impact of pictorial warnings concluded that such warnings increase consumers' understanding of the health effects of smoking. *See* 76 Fed. Reg. at 36,642 (discussing the "substantial research showing that graphic health warnings significantly increase consumer thoughts about and understanding of the health risks of smoking after they were introduced in other countries").

Plaintiffs are equally wide of the mark in claiming that the survey design—in which FDA

studied the reactions of three different populations to the 36 pictorial health warnings—created the likelihood that the study results were the result of "random error." S.J. Mem. 13–14. The study was designed in this manner because scientific research demonstrated that the "effectiveness of health warnings in communicating the health risks of smoking may vary according to the audience" and that "[a] variety of health warnings facilitates better targeting of specific groups whose primary concerns about smoking tend to vary." 75 Fed. Reg. at 69,534. Because FDA considered a finding to be statistically significant if there was only a five-percent chance that the finding was coincidence, 76 Fed. Reg. at 36,648, by definition, one would expect only five percent of the total number of findings to be statistically significant if random error were the only contributing factor. As the data from the study demonstrates, however, the actual number of significant findings was greater by an order of magnitude. *See generally* FDA Study Report, Appendix C-1. In addition, many of the findings were significant at the .001 confidence level, meaning that "there is less than one chance in a thousand that the finding happened by coincidence." 76 Fed. Reg. at 36,648.

Plaintiffs also argue that the study (as well as other studies in the record) was biased, because survey participants systematically over-report their intention to quit smoking. S.J. Mem. 12–13. FDA directly addressed that point during rulemaking, explaining that "[t]he more recent scientific literature shows that statements by smokers concerning their intentions to quit smoking are predictive of their making subsequent quit attempts." 75 Fed. Reg. 52,352, 52,534 (Aug. 25, 2011).

5. Plaintiffs' complaint regarding FDA's inclusion of a telephone number for a nationally recognized smoking cessation hotline—1-800-QUIT-NOW—in the health warnings is also baseless. FDA explained that studies have found that "health warnings are more effective if they are combined with cessation-related information." 76 Fed. Reg. at 36,681. Indeed, because of the powerfully addictive nature of plaintiffs' products, the overwhelming majority of smokers who try to quit fail

in their efforts in any given quit attempt. *Id.* at 36,700.

The challenged phone number is that of the preexisting "National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1-800-QUIT-NOW" provided by the National Cancer Institute. *Id.* at 36,681. Based on the caller's area code, the Network "routes calls to the appropriate State quitline." *Ibid.* These state quitlines receive "significant support and oversight" from the Centers for Disease Control and Prevention, which will now require that these quitlines comply with all the requirements set out in the final rule. *Ibid.*

Plaintiffs' sole objection is that this smoking-cessation resource uses the telephone number "1-800-QUIT-NOW." *See* S.J. Mem. 23. The use of dashes and the fact that it begins with "1-800" makes plain to any reasonable reader that it is a telephone number to call, and the fact that the number is easy to remember does not make it a "subjective policy message." *Ibid.* At most, the telephone number conveys that quitting smoking is beneficial, which is plainly permissible. One of the textual warnings, which the tobacco companies "do not challenge" because it contains "purely factual information," *id.* at 20, states: "WARNING: Quitting smoking now greatly reduces serious risks to your health." Act § 201, 123 Stat. at 1843 (amending 15 U.S.C. § 1333(a)).

In making this and related arguments, plaintiffs lose sight of the uncontroverted fact that cigarettes are addictive and deadly and that it has long since been "amply demonstrated that 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. That is not a "subjective policy message." Indeed, plaintiffs' own websites convey a similar message. Reynolds declares as one of its "Guiding Principles and Beliefs" that "[t]he best course of action for tobacco

consumers concerned about their health is to quit."[14] Lorillard advises visitors to its website that "[t]he best way to reduce the health effects of cigarette smoking is to quit, and quitting smoking greatly reduces serious risks to health."[15] Indeed, Lorillard's web site instructs consumers who follow that advice to call the same phone number that plaintiffs challenge here on constitutional grounds: "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." *Ibid.*

6. The errors besetting plaintiffs' analysis are epitomized in their discussion of the regulatory impact statement conducted pursuant to Executive Orders 12,866 and 13,563. One of plaintiffs' principal contentions in this case and *Commonwealth Brands* is that the warnings mandated by Congress are unconstitutional because it has not been adequately demonstrated that they will reduce the rate of smoking. In support of this proposition, plaintiffs repeatedly quote a single sentence fragment from the regulatory impact statement to suggest that there is no evidence that the new warnings will have any impact on smoking rates. *See, e.g.*, S.J. Mem. 7, 24, 33.

First, this argument has no bearing on the validity of the regulation as distinct from the statute that it implements. Congress did not ask FDA to determine the costs and benefits of including warnings of a particular size and format with specified text and accompanying graphics—Congress itself had made that judgment. FDA had no authority to second-guess that legislative determination, and FDA was statutorily precluded from accepting plaintiffs' recommendation that FDA "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."

---

[14] http://www.rjrt.com/prinbeliefs.aspx

[15] http://www.lorillard.com/responsibility/smoking-and-health/addiction

Comment Letter at 3-4. In contrast, the decisions on which plaintiffs rely involved statutes that specifically directed an agency to consider costs and benefits in determining *whether* to promulgate a regulation. *See, e.g.*, *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1212 (D.C. Cir. 2004) (considering rule promulgated under a statute that mandated that "[b]efore prescribing or revising any ... requirement, [the agency] shall consider the costs and benefits of the requirement" (quoting 49 U.S.C. § 31506(d)).

The Executive Orders that require an impact analysis also do not permit FDA to second-guess congressional judgments. The orders apply generally to all federal rulemaking and are designed to "improve the internal management of the Federal Government." Executive Order 12,866, § 10, 58 Fed. Reg. 51,735, 51,744 (1993). They include the requirement that agency rulemaking be accompanied by a regulatory impact statement, but they explicitly declare that they do "not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person." *Ibid.*; *see also* Executive Order 13,563, § 7(d), 76 Fed. Reg. 3821, 3823 (2011) (similar language).

Plaintiffs' misunderstanding of the purpose of the impact statement is illustrated by their assertion that FDA's statement in this instance improperly failed to account for the "the healthcare, social security, and other cost *increases* caused by increased longevity." Compl. ¶ 46. For the limited purpose of complying with the Executive Orders, FDA did consider the rule's indirect effects on such costs. *See* 76 Fed. Reg. at 36,714. But that analysis is irrelevant to the issues before the Court. Congress legislated on the premise that keeping people alive is a good thing. The Constitution does not require Congress to adopt plaintiffs' accounting standards and to treat the achievement of that goal as a "cost" rather than a "benefit."

Second, as already discussed, *supra* at 23–24, the constitutionality of the statute does not turn

on statistical predictions of the impact of warnings on national smoking rates. The warnings further an important governmental purpose by conveying information about health risks more effectively than the existing warnings, which are "invisible." 678 F. Supp. 2d at 530.

Third, the impact analysis does not, in fact, predict that the new warnings will have little if any impact on smoking rates. The impact analysis compared data from Canada for the years 2000 to 2009 with data from the United States for the same period. Between 2000 (prior to the effective date of the Canadian warnings) and 2010, the smoking rate dropped 7 percentage points, from 24 percent to 17 percent. Over the same period, the smoking rate in the United States dropped less than 3 percentage points, from 23 percent to 20.5 percent. 76 Fed. Reg. at 36,720.

The impact statement observed that it could not be assumed that "the introduction of graphic warning labels in the United States will cause the U.S. smoking rate to fall by seven, or even the three percentage points needed to reach the Canadian rate." *Id.* at 36,720. The reasons for some uncertainty are evident. The federal and state governments, as well as public health organizations, have taken a variety of measures to increase public awareness of the risks of tobacco use. Attempting to quantify the extent to which any one measure, acting alone, will contribute to a decline, or avoid an increase, in smoking rates poses major challenges. Thus, although the impact statement sought to "isolate the impact of graphic warning labels on the Canadian smoking rate," it recognized that its analysis was no more than a "rudimentary approach to estimating the smoking reduction that will be effected by the new graphic warning labels and may be producing results that are off by one or more orders of magnitude." *Id.* at 36,720.

With these major caveats, the impact statement estimated that the updated warnings will have the effect of reducing the United States' adult smoking population by more than 200,000 people, an 0.088-percentage-point drop in the smoking rate from what could be expected without

the updated warnings. *Id.* at 36,721.

Plaintiffs repeatedly quote the sentence fragment that this estimate is "not statistically distinguishable from zero," without reference to the rest of the sentence in which that statement appears. *See, e.g.*, S.J. Mem. 8, 24, 25, 33. The sentence does not declare that the likely impact on smoking rates is effectively zero. It is, instead, an acknowledgment that the parameters of the economic analysis required by Executive Orders inject enormous uncertainty into its quantitative conclusions. The sentence declares that "[a]lthough both of the estimation methods" discussed in the statement "lead to the conclusion that graphic warning labels will reduce smoking rates, FDA has had access to very small data sets, so our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate." 76 Fed. Reg. at 36,776. The agency explained that the proper approach to uncertain estimates is *not* to "set[] estimates of effects equal to zero when their estimates are statistically insignificant," but rather to present the best estimate along with an analysis of the uncertainty. *Id.* at 36,712.

II. Plaintiffs Have Not Met Their Burden of Demonstrating that the Balance of Harms and the Public Interest Warrant the Extraordinary Remedy of a Preliminary Injunction.

A. Plaintiffs Cannot Obtain, Under the Rubric of a Preliminary Injunction, a Deferral of the September 2012 Effective Date Imposed by Congress.

Congress has required that the regulation implementing the health warning requirements take effect on September 22, 2012. *See* Tobacco Control Act § 201(b). Plaintiffs ask this Court to override that statutory requirement and to issue a "preliminary" injunction that would postpone the rule's effective date "until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims." P.I. Mot. 5. The authority to issue preliminary relief does not encompass an order of that

kind.

Because the challenged regulation will not take effect for over a year, plaintiffs have no need for an injunction to protect them against imminent action against them by FDA. There will be no agency action to enjoin until September 2012. Plaintiffs' "preliminary" injunction would enjoin enforcement from September 2012 to a date 15 months *after* this Court has resolved this litigation.

Such relief is not a preliminary injunction, which, 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* 5 U.S.C. § 705 (authorizing courts to "postpone the effective date of an agency action or to preserve status or rights *pending conclusion of the review proceedings*" (emphasis added)).

Nor would such relief be available as part of a final judgment. An order sustaining the constitutionality of the health warnings could not purport to abrogate their effective date.

It is therefore unsurprising that plaintiffs offer no precedent for the injunction they seek. The decisions on which they rely enjoined imminent agency action. *See* P.I. Mot. 16–17 (citing *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D.D.C. 2010) (granting preliminary injunction to prevent FDA from detaining plaintiffs' electronic cigarettes during the pendency of the case); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20 (D.D.C. 1997) (enjoining FDA from approving drug or medical device applications for ultrasound imaging solutions pending litigation over the lack of uniformity in FDA's treatment of such devices); *Hoffmann-Laroche, Inc. v. Califano*, 453 F. Supp. 900 (D.D.C. 1978) (preliminarily enjoining Maximum Allowable Cost determinations set to go into effect three days later); *Nat'l Med. Care v. Shalala*, No. 95 Civ. 0860, 1995 U.S. Dist. LEXIS 10074 (D.D.C. June 6, 1995) (enjoining HHS from giving retroactive effect to a Medicare billing amendment during the pendency of plaintiff's challenge to the validity of the agency's retroactivity

decision)). None of these cases involved compliance dates more than a year in the future, and none awarded relief that would extend beyond a final judgment.

B. Plaintiffs' Allegations Do Not Describe the Level of Injury that Would Warrant a Preliminary Injunction.

1. Even apart from this threshold defect in their request for relief, plaintiffs have failed to demonstrate the type of irreparable injury necessary to support a preliminary injunction. The D.C. Circuit "has set a high standard for irreparable injury." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). The "injury 'must be both certain and great'" and "[t]he moving party must show '[t]he injury complained of is of such *imminence* that there is a "clear and present" need for equitable relief to prevent irreparable harm.'" *Ibid.* (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam)); *see also Bill Barrett Corp. v. U.S. Dep't of Interior*, 601 F. Supp. 2d 331, 335 (D.D.C. 2004); *St. Croix Chippewa Indians of Wis. v. Kempthorne*, 535 F. Supp. 2d 33, 36 (D.D.C. 2008). "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.'" *Coal. for Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008) (quoting *Gulf Oil Corp. v. Dep't. of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981)).

Accordingly, when a claim of irreparable harm is based solely on monetary injury, the courts have declined to issue preliminary relief absent clearly documented imminent losses that are a significant portion of a plaintiff's overall business. *See, e.g.*, *Am. Ass'n for Homecare v. Leavitt*, No. 08-0992, 2008 WL 2580217, at *5 (D.D.C. June 30, 2008) (even though plaintiff argued without contradiction that it could not be reimbursed if it later won lawsuit, no irreparable harm when plaintiff's projected losses were $75,000 over the next year, but it earned $3.7 million in revenue the previous year); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (no irreparable harm

when plaintiff's projected losses were 80–90% of $31 million in sales; this "represent[ed] less than 1 percent of Sandoz's sales from generic drugs"); *Apotex v. FDA*, No. 06-0627, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) (no irreparable injury, even though plaintiff stood to lose $9 million in sales per year, because its annual revenues were $700 million); *Lightfoot v. District of Columbia,* No. 01-1484, 2006 WL 175222, at *8 (D.D.C. Jan. 24, 2006) (no irreparable harm when governmental defendants' projected costs would be either $1.3 million or $22–27 million and budget surplus was over $1 billion); *Experience Works, Inc. v. Chao*, 267 F. Supp. 2d 93, 96 (D.D.C. 2003) ($21.1 million reduction in funding is a serious financial blow, but one frequently faced by other similar entities, and not an economic loss that threatens survival of the business); *Mylan Pharma., Inc. v. Thompson*, 139 F. Supp. 2d 1, 27 (D.D.C. 2001) (finding no irreparable harm when generic drug maker stood to lose $31 million over the next year, said to be 13% of its anticipated annual earnings), *rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 221 & n.12 (D.D.C. 1996) (alleged loss of 50-70% of $97 million in product sales not irreparable harm because it would be only a small percentage of plaintiff's total sales); *Varicon Int'l v. Office of Personnel Mgmt.*, 934 F. Supp. 440, 447–48 (D.D.C. 1996) (finding no irreparable harm due to lost contract when movant's revenue would decline by 10%); *TGS Tech., Inc. v. United States*, Civ. No. 92-0062, 1992 WL 19058, at *4 (D.D.C. Jan. 14, 1992) (finding no irreparable harm where lost contract constituted 20% of movant's business).

Plaintiffs nonetheless assert that any degree of economic injury is "irreparable harm" if it cannot later be recovered through compensatory damages. P.I. Mem. 16. Plaintiffs rely on this Court's decision in *Smoking Everywhere*, in which it was established that FDA's refusal to let the plaintiffs import their only product line, electronic cigarettes, would "threaten the continued viability of [plaintiffs'] respective enterprises." *Smoking Everywhere, Inc.*, 680 F. Supp. 2d at 76, *aff'd on*

other grounds sub nom. Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010). This Court observed in a footnote that "[i]t is also worth noting that even if the claimed economic injury did not threaten plaintiffs' viability, it is still irreparable because plaintiffs cannot recover money damages against FDA." *Id.* at 77 n.19. The Court did not suggest, however, that the degree of economic harm is irrelevant to the inquiry, and any such suggestion would contravene the principle that, to support a preliminary injunction, the harm must be "'more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.'" *Coal. for Common Sense*, 576 F. Supp. 2d at 168; *accord, e.g.*, *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 123 (D.D.C. 2007); *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008); *Mylan Pharma., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000).

A preliminary injunction is an extraordinary remedy, but it would become commonplace if the ordinary costs of complying with regulations were sufficient to prove irreparable harm. *See Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) ("ordinary compliance costs are typically insufficient to constitute irreparable harm"); *Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980) ("injury resulting from attempted compliance with government regulation ordinarily is not irreparable harm"); *A.O. Smith Corp. v. FTC*, 530 F.2d 515, 527 (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.").

2. Even accepting plaintiffs' allegations at face value, they do not describe injury that is "serious in terms of its effect" on plaintiffs' enterprises. *Coal. for Common Sense*, 576 F. Supp. 2d at 168 (citation omitted). Their asserted costs of preparing to comply with the challenged regulation —which amount to twelve one-hundredths of one percent of their annual sales—cannot justify the

extraordinary remedy of a preliminary injunction.

R.J. Reynolds enumerates some $10 million in compliance costs that might lie in the future. O'Brien Decl. ¶¶ 9-13.[16] This is between one-tenth and two-tenths of one percent of R.J. Reynolds' net sales for 2010, reported as $7.350 billion by its parent corporation. Reynolds American Inc., *Annual Report* (Form 10-K), at 32 (Feb. 23, 2011), *available at* http://www.sec.gov/Archives/edgar/data/1275283/000095012311016932/g24443e10vk.htm.[17]

Lorillard estimates that by the September 2012 effective date, it will have spent some $2.25 million to prepare compliant packaging, and another $0.8 million for compliant point-of-sale advertising materials. Klepper Decl., ¶ 19; Lindsley Decl. ¶¶ 13-15. Lorillard's estimated compliance costs are thus $3.05 million; this is less than one-tenth of 1% of its reported $5.932 billion in net sales for 2010. Lorillard Inc., *Annual Report* (Form 10-K), at 25 (Feb. 18, 2011), *available at* http://www.sec.gov/Archives/edgar/data/1424847/000095012311015424/g25358e10vk

---

[16] This $10 million figure does not include $1.5 million that R.J. Reynolds spent to buy blank metal printing cylinders on June 2, 2011—three weeks *before* FDA issued the Final Rule. *Id.* ¶ 8. R.J. Reynolds makes no claim that it could recoup this pre-Final Rule, pre-lawsuit cost if the Court granted plaintiffs' motion for a preliminary injunction, and cannot properly claim this expense will be an "irreparable harm" if preliminary relief is not granted.

Apart from the above information, R.J. Reynolds does not clearly separate out which projected costs it has already incurred, which it expects to incur before plaintiffs' requested late-October decision date for preliminary injunction, and which it expects to incur after that date and before the implementation date in September 2012. With the exception of Sante Fe Natural Tobacco, the other plaintiffs are even less clear; Lorillard and Commonwealth Brands, for example, make no effort whatsoever to explain which expenses they have already incurred, which expenses they expect to incur by the end of October, and which expenses they expect to incur after November 1.

[17] Courts may take judicial notice of parties' SEC filings. *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008); *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 390 n.10 (4th Cir. 2005). R.J. Reynolds' $7.35 billion in net sales comprised 86% of its parent Reynolds American's overall net sales of $8.551 billion. Reynolds American, *Annual Report* at 25.

.htm.

Liggett estimates that it will pay $2 million to prepare an unnecessary set of packaging and other materials in time to comply with the September 2012 effective date. Sulin Decl. ¶ 22 (estimating "costs to prepare *two* complete sets of packaging designs" as $4 million) (emphasis added).[18] This estimated $2 million in duplicative costs is approximately two-tenths of one percent of the $1.06 billion that its parent corporation reported in net sales for tobacco in 2010. Vector Group Ltd., *Annual Report* (Form 10-K), at 30 (Feb. 25, 2011), *available at* http://www.sec.gov/Archives/edgar/data/59440/000095012311018301/g25404e10vk.htm.

Commonwealth Brands itemizes $3.927 million in costs to prepare compliant packaging in advance of the rule. Melton Decl. ¶¶ 10-12.[19] This amount is between three-tenths and four-tenths of one percent of Commonwealth Brands' imputed 2010 net revenue of £762.8 million, equivalent to $1.179 billion.[20]

---

[18] Unlike the other plaintiffs, Liggett based its estimates on the cost of preparing *two* designs for each of its cigarette lines. *Id.* ¶¶ 5, 8. The second design for each of Liggett's cigarette line is meant to comply with all packaging and labeling requirements *other* than the large graphic warnings that plaintiffs are challenging in this lawsuit. *Id.* ¶ 8. It thus appears that Liggett has decided to begin now to prepare designs and packaging that it will use if it and its co-plaintiffs *win* their motion for a preliminary injunction. But the cost of preparing an additional set of designs can hardly be counted as an "irreparable harm" that Liggett would incur if it were *denied* preliminary relief. The appropriate number to use is thus $2 million, rather than $4 million.

[19] This figure of $3.927 million includes Commonwealth Brands' estimates for the same tasks itemized by the other plaintiffs (specifically, purchasing metal printing cylinders, *id.* ¶ 10, hiring a graphics-design firm, *id.* ¶ 11, and engraving new packaging designs on the metal printing cylinders, *id.* ¶ 12), plus Commonwealth Brands' estimated costs to modify case printing plates, replace offset printing plates, and purchase 14 embossing units, *id.* ¶ 12. Commonwealth Brands does assert at one point that "[i]f the Rule were invalidated after September 1, 2012, Commonwealth could suffer from unrecoverable manufacturing costs that would exceed $18.4 million," *id.* ¶ 9, but it makes no attempt to support or explain that much larger figure.

[20] This figure is calculated as follows: Commonwealth Brands is the Imperial Tobacco Group PLC subsidiary that sells cigarettes within the United States. Imperial Tobacco Group PLC, *Annual*

Santa Fe Natural Tobacco estimates that it will spend approximately $0.4 million to prepare packaging in time for the Final Rule. Depalma Decl. ¶ 12. Santa Fe is the only entity that its parent corporation, Reynolds American Inc., mentioned under a "Consolidated RAI" discussion in its annual report for 2010, which shows $482 million net sales for "All Other." Reynolds American, *Annual Report* at 7, 32. The upper limit for Santa Fe's 2010 net sales would thus be $482 million; if its net sales were as low as $400 million, then its projected $0.4 million in compliance costs would be one-tenth of one percent of its annual net sales. Even if Santa Fe's net sales were as low as $200 million (41.4% of Reynolds American's "All Other" net sales), its projected compliance costs of $0.4 million would be only two-tenths of one percent of its annual net sales.

Thus, using figures alleged by plaintiffs, their estimated costs of compliance with the regulation are twelve one-hundredths of one percent of plaintiffs' combined annual sales as reported for 2010 ($19.377 million of $15.721 billion in sales), and cannot possibly rate as being "serious in terms of its effect on" plaintiffs' operations. *Gulf Oil Corp.*, 514 F. Supp. at 1026.

Moreover, it is unclear what time-frame of compliance would result in even these costs.

Report and Accounts 2010, at 157 (Dec. 14, 2010), *available at* http://files.the-group.net/library/itg/annualreport2010/pdfs/itgar10_fullreport.pdf. Imperial Tobacco reported £780 million in tobacco net revenue for the Americas in 2010. *Id.* at 113. Some 97.8% of that net revenue is attributable to the United States, and thus to Commonwealth Brands. (Imperial Tobacco estimated that its U.S. market share in 2010 was 3.9%, based on an estimated total U.S. market size of 298.5 billion cigarette sticks. *Id.* at 37. Multiplying Commonwealth Brands' 3.9% market share by the estimated market size of 298.5 billion cigarette sticks indicates Commonwealth Brands had 2010 sales of 11.642 billion sticks. This figure is 97.8% of Imperial Tobacco's reported sales volume for the Americas as a whole, of 11.9 billion. *Id.* at 37. (11.642 / 11.9 = 97.8%.)) Multiplying £780 million in tobacco net revenue for the Americas, by the 97.8% attributable to Commonwealth Brands, yields £762.8 million in net revenue attributable to Commonwealth Brands. The 2010 average currency exchange rate to convert U.K. pounds into U.S. dollars is 0.647. IRS, *Yearly Average Exchange Rates for Converting Foreign Currencies into U.S. Dollars*, http://www.irs.gov/businesses/small/international/article/0,,id=206089,00.html (last visited Sept. 1, 2011). Dividing Commonwealth Brands' imputed 2010 net revenue of £762.8 million by the 0.647 exchange rate yields $1.179 billion.

Plaintiffs have operated under the Canadian warnings regulations for a decade, and they do not explain why they require 15 months to meet the similar requirements now imposed by the United States. Indeed, when Canada enacted its warning requirements, it provided manufacturers with only 180 days from the date on which regulations were registered in which to meet the new standards. *See* Tobacco Products Information Regulations, SOR/2000-272 (Can.).[21]

C. The Public Interest Precludes an Injunction.

The health risks documented by Congress are not in dispute. 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 adult smokers began smoking before age 18"). *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. Of those who become regular smokers, about half eventually will die from a disease caused by tobacco use. *Ibid.*

Plaintiffs argue in this case, as they have in *Commonwealth Brands* and in *Philip Morris*, that the health risks created by use of their products are so well known that the prominent disclosure statements mandated by Congress can serve no purpose. Congress and the courts have rejected that assertion, and plaintiffs ignore their own substantial contribution to the state of consumer knowledge. For decades, cigarette manufacturers systematically deceived the public and regulators regarding the health risks and addictiveness of their products. *See Philip Morris*, 566 F.3d at 1123-24. Congress, fully aware of that history, enacted the new warning requirement to inform consumers of the health

[21] http://www.canlii.org/en/ca/laws/regu/sor-2000-272/latest/sor-2000-272.html

risks of cigarettes that the manufacturers had so long been at pains to obscure.

Plaintiffs further contend that postponing the statutory effective date is of no consequence because Congress required that the final rule be preceded by notice and comment rulemaking and then allowed them 15 months in which to meet the rule's requirements. P.I. Mem. 19. Plaintiffs get matters backwards. Congress balanced the urgent need to convey accurate information against the importance of obtaining public input and allowing sufficient time for compliance. It did not thereby suggest that the warnings might be delayed without undermining the goals of the legislation. The existing warnings, in place since 1984, are now well understood to be "invisible." *Commonwealth Brands*, 678 F. Supp. 2d at 530. Plaintiffs propose to keep them that way indefinitely and seek "preliminary" relief that would keep them invisible for as long as possible. The Court should not exercise its equitable powers to grant that request.

CONCLUSION

For the foregoing reasons, plaintiffs' motion for a preliminary injunction should be denied.

Respectfully submitted,

TONY WEST
Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

MAAME EWUSI-MENSAH FRIMPONG
Acting Deputy Assistant Attorney General

/s/
DRAKE CUTINI
DANIEL K. CRANE-HIRSCH
Attorneys, Consumer Protection Branch
PO Box 386
Washington, DC 20044-0386
202-307-0044 (Cutini)
drake.cutini@usdoj.gov

/s/
MARK B STERN
ALISA B. KLEIN
SARANG V. DAMLE
DANIEL TENNY
LINDSEY POWELL
Attorneys, Appellate Staff
Civil Division, Room 7217
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, DC 20530
202-514–5735 (Damle)
FAX: 202-514-9405
Email: sarang.damle@usdoj.gov

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Acting Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

KAREN E. SCHIFTER
Senior Counsel
U.S. Department of Health & Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002