[ORAL ARGUMENT SCHEDULED FOR APRIL 10, 2012]

NO. 11-5332

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

R.J. REYNOLDS TOBACCO COMPANY et al.

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION et al.

Defendants-Appellants

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

BRIEF FOR APPELLEES

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CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

A. Parties and Amici

1. Plaintiff-Appellees are R.J. Reynolds Tobacco Company ("RJRT"); Lorillard Tobacco Company ("Lorillard"); Commonwealth Brands, Inc. ("Commonwealth Brands"); Liggett Group LLC ("Liggett"); and Santa Fe Natural Tobacco Company, Inc. ("SFNTC").

2. Defendant-Appellants are the United States Food and Drug Administration ("FDA"); FDA Commissioner Margaret Hamburg; and Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services.

3. The following groups participated as *amicus curiae* in the district court:

In support of Plaintiffs: the Association of National Advertisers, Inc., the American Advertising Federation, and the Washington Legal Foundation.

In support of Defendants: American Academy of Pediatrics, American Cancer Society, American Cancer Society Action Network, Cancer Action Network, American Heart Association, American Legacy Foundation, American Lung Association, American Medical Association, American Public Health Association, Campaign for Tobacco-Free Kids, and Public Citizen.

4. The following groups are participating as *amicus curiae* in the Court of Appeals:

In support of Plaintiffs: the Association of National Advertisers, Inc., the American Advertising Federation, the Washington Legal Foundation, the Chamber of Commerce of the United States.

In support of Defendants: American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Legacy Foundation, American Lung Association, American Medical Association, American Public Health Association, Campaign for Tobacco-Free Kids, Citizens' Commission to Protect the Truth, Public Citizen, Tobacco Control Legal Consortium, Idaho, Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Hawaii, Illinois, Iowa, Maine, Maryland, Mississippi, Montana, New Hampshire, New Mexico, Ohio, Rhode Island, South Dakota, Utah, Vermont, Virgin Islands, Washington, and West Virginia.

In support of neither party: Defending Animal Rights Today and Tomorrow.

B. Ruling Under Review

The ruling under review was issued on November 7, 2011, by the Honorable Richard J. Leon in Civ. No. 11-1482 (D.D.C.). The district court did not, as the Government repeatedly states, hold that "the cigarette health disclosures required by [Section 201 of] the Family Smoking Prevention and Tobacco Control Act of 2009 ('Tobacco Control Act')" were likely unconstitutional. U.S.Br. at 2-3, 15. Rather, the court held only that FDA's *regulation* implementing the Act—76 Fed.

Reg. 36,628 (June 22, 2011) ("the Rule")—likely violated the First Amendment based on a combination of factors, some mandated by the Act and others not. JA24-35. Having reached this conclusion, the court further concluded tfhat an injunction postponing the effective date of the Rule until 15 months after final judgment was necessary to prevent irreparable injury to Plaintiffs, and that such injunction would not harm the Government or the public interest. JA36-42.

C. Related Cases

Several tobacco product manufacturers, including some of the Plaintiffs in this action, have also challenged various speech restrictions mandated by the Act in the United States District Court for the Western District of Kentucky. The district court invalidated the Act's ban on color and imagery in tobacco advertising and one other provision, but rejected the other challenges to the Act, including the plaintiffs' challenge to the general statutory requirement that cigarette packaging and advertising display graphic warnings. *See Commonwealth Brands, Inc. v. United States,* 678 F. Supp. 2d 512 (W.D. Ky. 2010). Both sides have appealed the *Commonwealth Brands* decision to the Sixth Circuit. *See Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235. Oral argument was held on July 27, 2011.

The plaintiffs in *Commonwealth Brands* argued that the Act's general graphic warnings requirement is facially unconstitutional. Because the Rule had

not yet been promulgated when that case was filed, the *Commonwealth Brands* plaintiffs did not raise the claim brought by Plaintiffs here—that the *particular* warnings required by the Rule are unconstitutional. Accordingly, as explained by the court below, "[t]his case is … wholly separate, both factually and legally, from the *Commonwealth Brands* case." JA26.

As the Government has noted, some of the Plaintiffs in this case have argued in *United States v. Philip Morris USA, Inc., et al.*, No. 11-5145 (D.C. Cir.), that the Tobacco Control Act eliminates the basis for injunctive relief addressed in *United States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam). Although there is some overlap in the legal principles at issue, the *Philip Morris* case does not present "the same or similar issues" as this case under D.C. Circuit Rule 28(a)(1)(C). The court in *Philip Morris* will not have any occasion to address the constitutionality of the Rule; the proposed corrective statements in *Philip Morris* were based on specific fact and liability findings not at issue here; and, as the district court in *Philip Morris* recently held, the "proposed corrective statements [submitted by the Government] in th[at] case … are significantly different from the verbal and pictorial advertisements required by the FDA

Regulations," Dkt. 5950, *United States v. Philip Morris*, No. 99 Civ. 02496 (Nov. 17, 2011).[1]

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and D.C. Circuit Rule 26.1, Plaintiffs-Appellees make the following disclosures:

RJRT is a North Carolina corporation with its corporate offices and manufacturing operations located in Winston-Salem, North Carolina and is the second-largest tobacco product manufacturer in the United States. RJRT is a wholly-owned subsidiary of R.J. Reynolds Tobacco Holdings, Inc., which in turn is a wholly-owned subsidiary of Reynolds American Inc. ("RAI"), a publicly-traded corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c. indirectly

[1] In the cited Order, the district court in *Philip Morris* directed the parties to submit their views on whether the court "should defer consideration of the corrective action statements" in light of this case and "if so, for how long." *Id.* In response, Defendants argued that, because "the FDA's graphic-warnings rule raises several issues that overlap with those before this Court," "[i]n the interests of judicial economy, this Court should therefore await the resolution of that appeal before deciding the pending corrective-statement and point-of-sale issues." Dkt. 5954 at 1. The Government took the opposite position, arguing that "the legal issues raised in the ongoing challenges to the public-health warnings mandated under the [Tobacco Control Act] have very little to do with the objections to the United States' recommended statements that the Defendants have raised in this case," and, therefore, that "there is little reason to think that deferring decision on corrective statements in this case would conserve judicial resources." Dkt. 5955 at 1-2.

holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

Lorillard is the third-largest tobacco product manufacturer in the United States, with its corporate offices and manufacturing operations in Greensboro, North Carolina. Lorillard is a wholly-owned subsidiary of Lorillard, Inc. Shares of Lorillard, Inc. are publicly traded.

Commonwealth Brands, Inc. ("Commonwealth") is the fourth-largest tobacco product manufacturer in the United States with its corporate offices located in Bowling Green, Warren County, Kentucky, and its manufacturing operations in North Carolina. Commonwealth is a wholly-owned subsidiary of CBHC, Inc., which is a wholly-owned subsidiary of Imperial Tobacco Group p.l.c. Shares of Imperial Tobacco Group p.l.c. are publicly traded

Liggett Group LLC is the fifth-largest manufacturer of cigarettes in the United States in terms of unit sales and is a Delaware limited liability company with its principal place of business in Mebane, North Carolina. Liggett Group LLC is an indirect, wholly-owned subsidiary of Vector Group Ltd., which is a publicly-traded corporation. No parent corporation or publicly held company owns more than 10% of the stock of Vector Group Ltd.

SFNTC is a New Mexico corporation with its corporate offices located in Santa Fe, New Mexico, and its manufacturing operations in North Carolina, and

manufactures tobacco products sold under the Natural American Spirit brand name. SFNTC is a wholly-owned subsidiary of Reynolds American Inc. ("RAI"), a publicly-traded corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c. indirectly holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

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GLOSSARY OF ABBREVIATIONS

FDA	Food and Drug Administration
FDA Study	FDA, Experimental Study of Graphic Cigarette Warning Labels, Final Results Report (Dec. 2010).
IOM Report	Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007)
RIA	Regulatory Impact Statement
Rule	Final Regulations promulgated at 76 Fed. Reg. 36,628 (June 22, 2011)
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act of 2009

RESTATEMENT OF ISSUES

1. Whether the Rule likely violates the First Amendment.

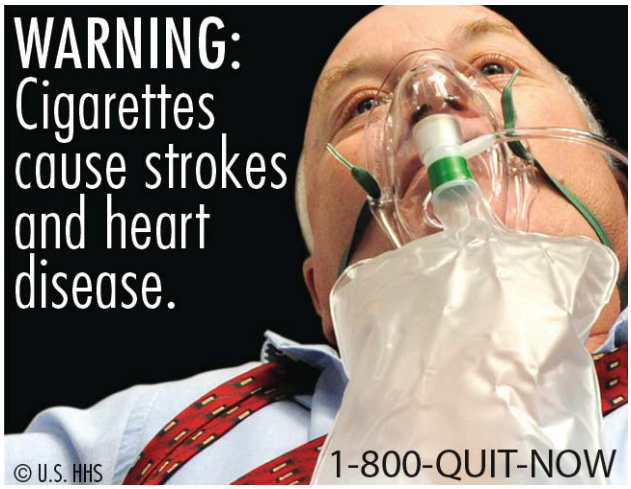
2. Whether the district court properly enjoined enforcement of the Rule for 15 months after final judgment.

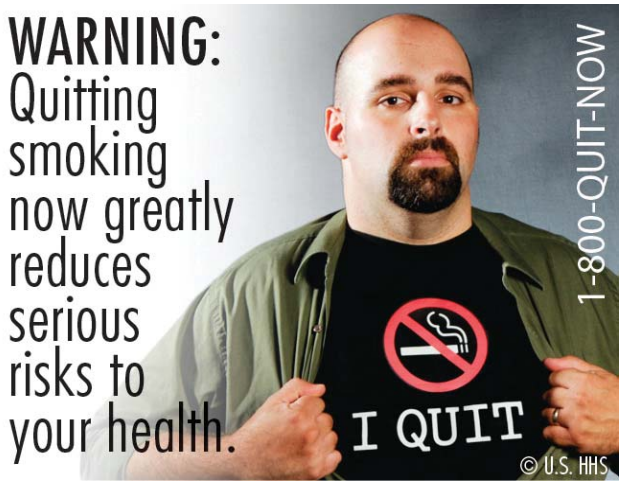
STATUTES AND REGULATIONS

All applicable statutes, etc., are contained in the Brief for Appellants.

STATEMENT OF THE FACTS

1. On June 22, 2011, FDA promulgated a rule requiring nine new graphic warnings on the top half of the front and back of cigarette packages and the top fifth of advertisements, 76 Fed. Reg. 36,628:





The warnings have three components: (1) new text, the substance of which Plaintiffs have not challenged; (2) large color graphics that include cartoon images,

photographs using actors and technological manipulation to maximize viewers' emotional response, and in one instance, an individual wearing a t-shirt depicting the universal "no smoking" symbol and declaration, "I QUIT"; and (3) a smoking cessation hotline urging consumers to "QUIT-NOW."

As the chief report relied on by the Government expressly states, the primary objective of these warnings "is not to promote informed choice but rather to discourage consumption of tobacco products."[2] Thus, as FDA candidly acknowledged, these warnings "ha[ve] a different purpose" than "disclosure requirements for other products"; they are not intended to inform consumers of how to use a product properly, but to "encourage cessation and discourage initiation." 75 Fed. Reg. 69,524, 69,540 (Nov. 12, 2010). In the words of Secretary Sebelius and Commissioner Hamburg, they will "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [tobacco use] is cool"; "encourage smokers to quit"; and, more generally, ensure that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's version of the "truth about smoking."[3] In short,

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[2] Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation*, 290-91 (2007) ("IOM Report"); *see also* U.S.S.J.Mem. vi.

[3] FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm; Press Briefing by Press Secretary Jay Carney, Health and Human Services Secretary Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011),

the new warnings effectively "grab people by the lapels and … yell[]: 'Stop smoking!'"[4]

2. FDA conducted two analyses of the effectiveness of the Rule: A Regulatory Impact Analysis ("RIA") and a massive consumer study ("FDA Study"). Both demonstrated that the Rule is unlikely to affect either smoking prevalence or consumer knowledge of smoking risks.

a. The RIA analyzed the expected benefits of the Rule by comparing the impact of similar warnings introduced in Canada in 2000. 76 Fed. Reg. at 36,709. It (1) analyzed the change in smoking trends in Canada before and after 2000; (2) assumed that any post-2000 change in Canada beyond the post-2000 change in the U.S. was attributable solely to the introduction of graphic warnings; and (3) assumed that similar warnings in the U.S. would have an identical impact on U.S. smoking rates. *Id.* at 36,755. As FDA acknowledged, apart from differences in cigarette taxes, the RIA "d[id] not account for potential confounding variables." *Id.* at 36,720. Thus, among other things, it ignored that, even after adjusting for taxes,

(continued…)

http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser.

[4] Scott Hensley, *Be Warned: FDA Unveils Graphic Cigarette Labels*, NPR.org (June 21, 2011), *available at* http://www.npr.org/blogs/health/2011/06/21/137316580/be-warned-fda-unveils-graphic-cigarette-labels?ps=sh_stcatimg.

Canadian cigarette prices were higher than U.S. prices, and that Canada had introduced more stringent smoking bans and advertising restrictions during the relevant time period.[5] The RIA therefore systematically *overestimated* the impact of graphic warnings on smoking rates.

Notwithstanding these flaws, the RIA still estimated that the new warnings would reduce U.S. smoking rates by a mere 0.088%. *Id.* at 36,721. FDA conceded, moreover, that this number was not statistically significant:

> [O]ur 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.

Id at 36,776. Indeed, an independent economist has demonstrated that data from the key years in FDA's own model actually shows that the introduction of graphic warnings in Canada correlated with an *increase* in smoking rates.[6] Thus, *at best*, "FDA's estimate of [the reduction in smoking rates] is, statistically speaking, not different from an estimate that the graphic warnings would have no effect on

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[5] These and other deficiencies are explained in greater detail in Plaintiffs' Comment Letter on the Proposed Rule, JA229-30, (Jan. 11, 2011) ("Comment Letter") and the Statement of Robert S. Maness ("Maness"), JA442-55.

[6] *See* Michael Siegel, *FDA Analysis Shows that Graphic Cigarette Warning Labels Increased Cigarette Smoking in Canada from 2001-2008* (Aug. 30, 2011), *available at* http://tobaccoanalysis.blogspot.com/2011/08/fda-analysis-shows-that-graphic.html. Plaintiffs cited this report and included their own similar analysis in the court below, P.I.Reply 3; S.J.Mem. 10 & n.9; S.J.Opp. 24-25, neither of which the Government disputed.

smoking rates." Maness, JA446. *See also, e.g.*, FDA, Food Labeling: Health Claims and Label Statements, 58 Fed. Reg. 2,537, 2,541 (Jan. 6, 1994) (rejecting "studies with statistically insignificant but generally favorable results" because "[l]ack of statistical significance indicates that such findings could have arisen by chance and thus cannot be used to support a causal relationship").

b. FDA also commissioned a consumer study that "included approximately 18,000 participants [and] was the largest study of consumer responses to graphic cigarette health warnings ever conducted."[7] It compared the responses of a control group—which was shown the new text in the format of the current warnings (on the side of the package)—to a separate group that was shown the proposed graphic warnings, to assess whether, relative to the text-only control, the graphic warnings (1) increased viewers' intention to quit or refrain from initiating smoking; (2) increased viewers' knowledge of the health risks of smoking or second-hand smoke ("environmental tobacco smoke" or "ETS"); and (3) were "salient," *i.e.,* caused viewers to feel "depressed," "discouraged," or "afraid," or describe the warnings as "informative," "meaningful," or "difficult to look at." 76 Fed. Reg. at 36,638.

[7] FDA, Frequently Asked Questions: Final Rule "Required Warnings for Cigarette Packages and Advertisements", a*vailable at* http://www.fda.gov/TobaccoProducts/Labeling/CigaretteWarningLabels/ucm259953.htm.

This is the only study Plaintiffs are aware of that asks whether the graphic warnings challenged in this case (with text and graphic pictures, taking up 50% of the front and back of the package) are more effective than textual warnings (in the format of current warnings) in either reducing smoking intentions or increasing knowledge of the health risks of smoking. Like the RIA, the FDA Study demonstrated that the new warnings were unlikely to either decrease smoking or increase knowledge of smoking risks. For example, as to the nine warnings FDA selected in the Rule, the Study showed:

1. *Hole in Throat:* No effect on any group's smoking intentions; no effect on knowledge of smoking/ETS risks among young adults or youth.

2. *Smoke Approaching Baby:* No effect on any group's awareness of smoking/ETS risks; no effect on the quit intentions of adults or young adults. Indeed, for youth, it was "*positively associated* with the likelihood of smoking 1 year from now," *i.e.*, youth who viewed it were "*more likely than controls* to report being moderately to extremely likely to be smoking 1 year from now." FDA Study 3-6 to 7 (emphases added).

3. *Healthy/Diseased Lungs:* No effect on any group's smoking intentions or knowledge of smoking/ETS risks.

4. *Cancerous Lesion on Lip:* No effect on any group's smoking intentions or knowledge of smoking/ETS risks.

5. *Oxygen Mask on Man's Face:* No effect on any group's smoking intentions or knowledge of smoking/ETS risks.

6. *Baby in Incubator:* No effect on young adult awareness of smoking risks; no effect on any group's awareness of ETS risks; no effect on reported quit intentions of adults or young adults; no effect on youth intentions to initiate smoking. Indeed, for youth, it correlated with *decreased* awareness of smoking risks.

7. *Man with Chest Staples:* No effect on any group's awareness of smoking/ETS risks; no impact on young adult quit intentions or youth intentions to initiate smoking.

8. *Woman Crying:* No effect on any group's awareness of smoking/ETS risks; no impact on adult quit intentions or youth intentions to initiate smoking.

9. *Man I Quit T-Shirt:* No effect on any group's smoking intentions or knowledge of smoking/ETS risks. *Id.*

See Statement of W. Kip Viscusi ("Viscusi"), JA304-07 (tabulating FDA Study results).

To be sure, there were a handful of findings suggesting possible positive correlations for some groups. For example, *Hole in Throat* correlated with increased awareness of smoking risks among adults when viewed on a cigarette package (but not when viewed on an advertisement). It likewise correlated with adult (but not youth or young adult) awareness of ETS risks (even though it does not address second-hand smoke). But these results are statistically meaningless. *See* S.J.Mem. 13-14; S.J.Opp. 33-35. Because the FDA Study assessed 36 warnings across 3 criteria (smoking intentions, smoking risk awareness, and ETS risk awareness) for 3 groups (youth, young adults, and adults), it gave the graphic warnings 324 opportunities to demonstrate a significant impact on at least one criterion for one group. P.I.Mem. 15 n.17. But "[i]f enough comparisons are made, random error almost guarantees that some will yield 'significant' findings, even when there is no real effect." Federal Judicial Center, Reference Manual on Scientific Evidence 127 (2d ed. 2000). Thus, as the Government conceded below,

"[b]ecause FDA considered a finding to be statistically significant if there was only a 5% chance that it was coincidence, by definition, one would expect … 5% of the total number of findings to be statistically significant if random error were the only contributing factor." U.S.S.J.Mem. 50. Yet the proposed warnings had a positive impact on smoking intentions or knowledge of smoking/ETS risks in only 4.6% (15 of 324) of the findings—*less* than "would [be] expect[ed] … if random error were the only contributing factor," U.S.Opp. 30. *See* Viscusi, JA304-307.[8] Random error also may explain why about one-third of the significant results were *negative—i.e.,* made viewers *more* likely to smoke or *less* aware of smoking/ETS risks. Viscusi, JA304-307.

Given these results, FDA did not select its graphics based on their demonstrated effectiveness in either reducing smoking intentions or informing consumers of health risks. Rather, FDA selected them based almost exclusively on the third criterion tested—their "salience." 76 Fed. Reg. at 36,639. FDA claimed that "salient" warnings would "effectively communicate the negative health consequences of smoking," because research literature "suggests that warnings that

[8] If one looks at the FDA Study's findings on salience, then, as the Government noted below, "the actual number of significant findings [is] greater by an order of magnitude," U.S.S.J.Mem. 50. But the FDA Study's results for smoking intentions and knowledge of smoking/ETS risks—whether looked at individually or combined—show that the proposed warnings had a significant positive impact only 4.6% of the time. P.I.Reply 34-35. Thus, the FDA Study's results for these two categories are consistent with random error.

generate an immediate emotional response from viewers can result in viewers attaching a negative affect to smoking (*i.e.*, feel bad about smoking), thus undermining the appeal and attractiveness of smoking." *Id.* Attaching this "negative affect to smoking" could, FDA speculated, "motivate positive behavior change." *Id.* at 36,652. Indeed, FDA relied on measures of "salience" despite evidence that "recall of associated warning message statements may be *reduced* in the short term by moderately or highly graphic pictorial warnings versus text-only controls or less graphic pictorial warnings." *Id.* at 36,639.

3. Numerous other independent studies confirm that (a) consumers are universally aware of the smoking risks addressed by the warnings; (b) graphic warnings are unlikely to have any demonstrable impact on smoking rates; and (c) the dominant academic justification for graphic warnings is *not* that they reduce smoking or increase knowledge of smoking risks, but that, in the view of some researchers, they constitute more effective anti-smoking *advocacy*.

a. According to Gallup polls taken every year for the last decade, between 96 and 99 percent of Americans are aware that smoking causes lung cancer—more than "are aware that George Washington was the first U.S. President [or] that the Earth revolves around the Sun." Viscusi, JA249-250. Similar polling shows comparable awareness regarding each of the nine subjects of the new warnings. *Id*. at JA251, 266. Indeed, the public overestimates the risks from

smoking by as much as 400%: "[T]he average perceived risk that a smoker will develop lung cancer is over 40%," whereas the "actual risk" is "about 10% of smokers." *Id*. at JA260. Likewise, public perception of overall mortality risk from smoking is "as much as three times higher" than the actual mortality risk, and "young people overestimate the dangers of smoking to an even greater degree" than adults. *Id*. at JA262-63.

Although the Government has criticized Plaintiffs' expert, Dr. Viscusi, these basic facts are largely undisputed in the academic literature, including in the studies that the Government relies on. For example, according to the IOM Report, which the Government repeatedly invoked below as the "chief[]" evidentiary basis for the Rule, U.S.S.J.Mem. vi, "most studies agree that adolescents and young adults are aware of many of the risks involved with tobacco use. In particular, they are aware that smoking involves a significant risk of lung cancer and other health outcomes." IOM Report 89. Likewise, Drs. Jamieson and Romer, upon whom the Government also relies, U.S.S.J.Reply 10, have reported that "[c]onsistent with Viscusi's findings, respondents … overestimated the extent to which smoking increases the risk of lung cancer"; moreover, "their beliefs about the likelihood of

dying from a smoking-related cause were … accurate."[9] Indeed, according to Dr. Arnett, another of the Government's researchers, U.S.S.J.Mem. 30, when asked the single most important question about smoking risks—the combined mortality rate from all smoking-related illness—the vast majority of people (including adolescents) dramatically *overestimated* this risk. *See infra* at 42-43. In short, as Dr. Arnett summarized, "studies consistently find that both adolescents and adults agree … that smoking increases the long-term risks of a variety of health problems, such as lung cancer and heart disease."[10]

b. Because telling people what they already know does not change behavior, numerous studies show that graphic warnings are unlikely to reduce smoking. As far back as 1994, the Surgeon General rejected the assumption that "young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention,'" explaining:

> In the 1960s and early 1970s, strategies to prevent … smoking were often based on the premise that adolescents who engaged in smoking behavior had failed to comprehend the Surgeon General's warnings on the health hazards of smoking. The assumption was that these

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[9] Jamieson & Romer, *What Do Young People Think They Know About the Risks of Smoking*, in Smoking: Risk, Perception & Policy 53 (Slovic, ed. 2001) ("Jamieson & Romer").

[10] Arnett JJ., *Optimistic Bias in Adolescent and Adult Smokers and Nonsmokers*, 25 Addictive Behaviors Vol. 625, 625 (2000) (emphasis omitted) ("Arnett Study"), *available at* http://www.jeffreyarnett.com/articles/ARNETT_optimistic_bias.pdf).

> young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke.
> …
> Comprehensive reviews published at that time concluded that smoking-prevention programs based on the information deficit approach were not effective.

Viscusi at JA303 (quoting *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994)); *see also id.* at JA256-59 (describing recent similar studies). Thus, in 1996, FDA rejected comments suggesting that the current Surgeon General's warnings should be larger or augmented with "graphic enhancements" to make them "more noticeable" because "the current Surgeon General's warnings [we]re sufficient" to convey the 'relevant warnings, precautions, side effects, and contraindications'" of cigarettes. 61 Fed. Reg. 44,396, 44,521 (Aug. 28, 1996) (quoting 21 U.S.C. § 352(r)).

Indeed, Dr. Hammond, one of the principal researchers on whom the Government and IOM Report rely, recently surveyed all the literature in this area and *conceded* that "[t]here is no way to attribute … declines [in smoking] to the new health warnings." Hammond Review at 331. Likewise, FDA *agrees* that it is "not possible to draw a direct causal connection between the graphic warnings and [a reduction in smoking]." 75 Fed. Reg. at 69,532. Other recent studies have reached similar conclusions. *See, e.g.*, Wardle et al., *Evaluating the Impact of Picture Health Warnings on Cigarette Packets*, Public Health Research

Consortium at 67 (2010) (U.K. graphic warnings had no impact on "[c]igarette smoking prevalence and cigarette consumption")[11]; Deloitte, *Tobacco Packaging Regulation: An International Assessment of the Intended and Unintended Consequences* at 4 (2011) ("data from 27 countries over a period of 14 years" "consistently demonstrate that … increasing the size of government health warnings and the presence of graphic images, has not had a statistically significant direct impact upon licit tobacco consumption").[12]

c. Although there is no evidence that graphic warnings reduce smoking, there is a body of academic literature—relied upon by the Government here—that advocates large graphic warnings as a means to more "effectively communicate the negative health consequences of smoking." 76 Fed. Reg. at 36,639. This literature does not assert, however, that graphic warnings are more "effective" because they convey *new information*; rather, it suggests they are more effective at grabbing consumers' attention and attaching "negative affect" to smoking, which, some researchers speculate, will produce stronger anti-smoking *advocacy*. Indeed, in discussing "effective" cigarette warnings, the IOM Report candidly argues:

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[11] http://www.natcen.ac.uk/media/673685/phrc a6-08 revised final report_9.8.10.pdf.

[12] http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Deloitte%20Report%20 -%20Tobacco%20Packaging%20Regulation%20-20May%202011.pdf.

> It is time to state unequivocally that the primary objective of tobacco regulation *is not to promote informed choice but rather to discourage consumption of tobacco products*, especially by children and youths, as a means of reducing tobacco-related death and disease. Even though tobacco products are legally available to adults, *the paramount public health aim is to reduce the number of people who use and become addicted to these products*, through a focus on children and youths. *The warnings must be designed to promote this objective*.

IOM Report at 290-91 (quoting Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youth* (1994)) (emphases added).

The literature relied upon by the Government thus embraces the view "that warnings that generate an immediate emotional response from viewers can result in viewers attaching a negative affect to smoking (*i.e.*, feel bad about smoking), thus undermining the appeal and attractiveness of smoking." 76 Fed. Reg. at 36,639. For example, according to Dr. Hammond:

> Negative emotional reactions to cigarette health warnings have been associated with increases in key outcomes… . Graphic depictions of disease appear to be the most reliable way to elicit negative emotional reactions to health warnings… . Studies of the pictorial warnings developed in the European Union also support the effectiveness of fear-arousing health warnings.

Hammond Study at 331-32. Thus, any "'[n]eutral' images that fail to elicit an emotional reaction should be avoided at all costs." David Hammond, *Tobacco Labeling and Packaging Toolkit, A Guide to FCTC, Article 11* at 64 (2009).[13] In short, the anti-smoking literature is based on the premise that "'fear appeals' are

[13] *Available at* http://tinyurl.com/68ghuc6.

effective in motivating health behavior change (*e.g.*, quitting)."[14] *See also* S.J.Opp. 13-15.

The foregoing studies, however, do *not* find that emotionally-charged graphic warnings are more successful than textual warnings (or smaller and less emotionally-charged graphic warnings) at providing new information. Nor do they conclude that graphic warnings have reduced smoking prevalence. Rather, they urge the adoption of fear-arousing warnings because of their potential to "create unfavorable emotional associations with [smoking]" and "undermine a brand's appeal and the impact of package displays at retail outlets."[15]

4. In August 2011, Plaintiffs filed a complaint challenging the Rule, accompanied by motions seeking summary judgment and a preliminary injunction postponing the effective date of the Rule until 15 months after final judgment. Plaintiffs argued that the Rule was subject to strict scrutiny, but regardless, was unconstitutional under *Central Hudson Gas & Electric Corp. v. Public Service Commission of NY*, 447 U.S. 557, 566 (1980), and *Zauderer v. Office of*

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[14] Geoffrey T. Fong, et al., *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, 87 Bulletin of the World Health Organization 565 (2009) ("Fong Study"), *available at* http://www.who.int/bulletin/volumes/87/8/09-069575/en/#.

[15] E. Peters, et al., *The Impact and Acceptability of Canadian-Style Cigarette Warning Labels Among U.S. Smokers and Nonsmokers*, 9 Nicotine & Tobacco Research 473, 473-74 (2007) (cited at U.S.S.J.Mem. 19), *available at* http://www.who.int/fctc/guidelines/ArtElevenPetersSeventeen.pdf.

Disciplinary Counsel, 471 U.S. 626, 651 (1985). Plaintiffs also challenged the Rule under the APA. In support of their preliminary injunction motion, Plaintiffs submitted uncontroverted affidavits explaining that, beginning in November 2011, they would need to expend millions of dollars to meet the Rule's September 22, 2012 effective date—funds that would be unrecoverable if the Rule were later invalidated. Dkt. 11.

On November 7, 2011, the district court granted the preliminary injunction. It held that, taken as a whole, the graphic warnings were "not the type of purely factual and uncontroversial disclosures that are reviewable under th[e] less stringent standard" applicable to normal informational warnings. JA28. Instead, they constituted anti-smoking *advocacy* and, as such, were subject to strict scrutiny, a standard the Government could not meet. *Id.* at 33-35. The Court also held that preserving the 15-month compliance period mandated by Congress was necessary to avoid the irreparable harm Plaintiffs had identified. *Id.* at 23-24.

SUMMARY OF ARGUMENT

It is axiomatic that the Government may not force private parties to utter speech against their will. The sole exception to this rule, recognized in *Zauderer*, 471 U.S. at 651, is for "purely factual and uncontroversial" commercial disclosures aimed at preventing consumer deception. This narrow exception, however, distinguishes between *advocacy* regarding policy or personal decisions, on the one

hand, and dispassionate factual recitations, on the other. As the Supreme Court held in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2671 (2011): "The State can express [its] view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction."

Here, the district court correctly held that the Rule's graphic "warnings" cross the line that separates factual and dispassionate disclosures from policy-laden and controversial advocacy. In both purpose and effect, the warnings do not "promote informed choice" by requiring Plaintiffs to inform the public of unknown facts, but instead, urge consumers to "QUIT-NOW," thus converting Plaintiffs' packaging into a "mini-billboard" for the Government's anti-smoking advocacy. Indeed, according to the chief evidentiary support cited by the Government, "the primary objective" of cigarette warnings should be "not to promote informed choice but rather to discourage consumption of tobacco products." IOM Report at 290-91. Such compelled advocacy is subject to strict scrutiny, which the Government cannot possibly satisfy. For the same reason, the warnings cannot be justified under *Central Hudson*, 447 U.S. 557, which provides no support for speech restrictions that attempt "to remove a popular but disfavored product from the marketplace." *Sorrell*, 131 S. Ct. at 2671.

In any event, the Rule cannot survive First Amendment balancing under either *Zauderer* or *Central Hudson*. FDA's own analyses of the Rule demonstrate that it is unlikely to have any impact on smoking prevalence. Nor can the Government evade this conclusion by citing studies that do not address the issue at hand. The Government's characterization of these studies is highly flawed. But even taken at face value, these studies do not demonstrate that graphic warnings will reduce smoking. Nor do they show that the warnings will increase knowledge of smoking risks. Instead, they simply show that shocking graphics are "noticeable." Such studies cannot possibly overcome the Government's admission that the estimated reduction in smoking rates from the Rule is "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. The Government's side of the First Amendment balance is therefore either zero or very close to it, while the burden on Plaintiffs—confiscating the most prominent portions of their packaging and advertising—is severe.

Finally, the district court acted well within its authority in postponing the effective date of the Rule until 15 months after summary judgment—the same compliance period provided by Congress—where that was the only way to avoid forcing Plaintiffs to expend millions of unrecoverable dollars in furtherance of an unconstitutional mandate.

ARGUMENT

I. THE RULE UNCONSTITUTIONALLY COMPELS PLAINTIFFS TO DISSEMINATE ANTI-SMOKING ADVOCACY.

The Supreme Court's jurisprudence draws a clear line between speech regulations that *advocate* the Government's point of view and those that inform consumers and protect the marketplace. Here, the Rule plainly falls on the advocacy side of this line, as it forces Plaintiffs to serve as unwilling spokesmen for the Government's anti-smoking campaign.

A. Government-Compelled Advocacy Violates The First Amendment.

The common thread running throughout the Supreme Court's First Amendment jurisprudence is that the Government may not impose speech restrictions—whether mandating speech or prohibiting it—designed to manipulate citizens' personal views on matters of policy or opinion. As the Supreme Court summarized in *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston, Inc.*:

> Although the State may at times prescribe what shall be orthodox in commercial advertising by requiring the dissemination of purely factual and uncontroversial information, outside that context it may not compel affirmance of a belief with which the speaker disagrees.… Nor is the rule's benefit restricted to the press, being enjoyed by business corporations generally and by ordinary people engaged in unsophisticated expression as well as by professional publishers.

515 U.S. 557, 573-74 (1995) (internal quotation marks omitted); *see also Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion) ("For corporations as for individuals, the choice to speak includes within it the choice of what not to say.").

In the commercial context, there are two "narrow and well-understood exceptions" to this ban on content-based speech regulations. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994) ("*Turner I*").

First, the Government may require "purely factual and uncontroversial" commercial disclosures, provided they are not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651. As the Court explained in *Zauderer*, this lesser scrutiny is appropriate because such requirements do not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion," but instead "dissipate the possibility of consumer confusion or deception." *Id.* In other words, instead of "tilt[ing] public debate in [the government's] preferred direction," *Sorrell*, 131 S. Ct. at 2671, such disclosure requirements merely ensure that consumers have full information when they "decide for [themselves] the ideas and beliefs deserving of … adherence." *Turner I*, 512 U.S. at 641. Thus, while "[t]he State, of course, has substantial leeway in determining appropriate information disclosure requirements for business corporations.… [n]othing in *Zauderer* suggests … that the State is equally free to require corporations to carry the

message of third parties, where the messages themselves are biased against or are expressly contrary to the corporation's views." *Pacific Gas*, 475 U.S. at 15 n.12 (1986).

Second, in contrast to *compelling* disclosure, the Government may *restrict* commercial speech if it can prove that (1) its asserted interest is substantial, (2) the restriction directly and materially advances that interest, and (3) the restriction is narrowly tailored. *See Central Hudson*, 447 U.S. at 566.[16] The Court has made clear, however, that whether it applies strict scrutiny or *Central Hudson*, "the fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." *Sorrell*, 131 S. Ct. at 2670-71 (internal quotation marks omitted). As the Court summarized in *Sorrell*:

> In an attempt to reverse a disfavored trend in public opinion, a State could not ban campaigning with slogans, picketing with signs, or marching during the daytime. Likewise the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.

[16] Appellees believe strict scrutiny should govern all commercial-speech restrictions. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1342-43 (2010) (Thomas, J., concurring in part and concurring in the judgment). Although Plaintiffs preserve that issue for later review (*see also* S.J.Mem. 19 n.15), this brief applies controlling precedent.

Id. at 2671. Thus, the Court has invalidated speech restrictions "whenever the government creates a regulation of speech because of disagreement with the message it conveys. . . . Commercial speech is no exception." *Id.* at 2664 (internal quotation marks omitted). Paternalistic speech regulations aimed at manipulating consumer choice are "just as unacceptable in a commercial context as in any other." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 492-93 (1995) (Stevens J., concurring); *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (plurality opinion) (there is no "vice" exception under the First Amendment).

In sum, laws that regulate speech as part of a dispassionate attempt to inform consumers and protect the commercial marketplace are subject to lesser scrutiny because they do not reflect an attempt "to tilt public debate in a preferred direction." *Sorrell*, 131 S. Ct. at 2671. But speech regulations that paternalistically urge consumers to adopt the Government's preferred behavior have been uniformly invalidated regardless of whether they are adjudged under strict scrutiny or *Central Hudson.*

B. The Rule Unconstitutionally Compels Government Advocacy.

Here, the Rule is designed "not to promote informed choice but rather to discourage consumption of tobacco products." IOM Report at 290-91. It therefore crosses the line separating dispassionate "purely factual and uncontroversial"

disclosures designed "to dissipate the possibility of consumer confusion or deception," *Zauderer*, 471 U.S. at 651, from compelled advocacy. As the district court found, this is evident from numerous factors, both individually and in combination:

1. The graphic warnings use non-factual and controversial cartoon drawings, digital enhancements, and actors to dramatize the effects of smoking-related illness. Plaintiffs have never disputed that graphics may sometimes convey purely factual and uncontroversial information. *See* JA43. Here, however, the Rule does not even arguably use graphic imagery in such an objective and evenhanded way. Instead, it uses digital enhancements, some of the most gruesome images possible, and non-factual cartoon drawings to dramatize the extremes of smoking-related illness and evoke an emotional reaction against smoking. As the district court held, it is "abundantly clear" that such graphics—including a gratuitous autopsy-scarred dead body; digitally-enhanced photographs of a mouth with discolored teeth and cancerous lesions, diseased lungs, and a man smoking through a hole in his throat; a cartoon drawing of a baby in an incubator; and actors depicting a woman crying and a man wearing an oxygen mask—were selected to "evoke emotion" in order "to provoke the viewer to quit, or never start, smoking: an objective wholly apart from dissemination purely factual and

uncontroversial information." JA14. The graphics imposed by the Rule are thus neither "purely factual" nor "uncontroversial."

2. The graphics are affirmatively misleading and/or convey no information about the risks of smoking. The photographs of the autopsy-scarred dead body and the man smoking through a hole in his throat, for example, misleadingly suggest that these are common or likely consequences of smoking. But the Government does not dispute that autopsies are not a common consequence of smoking. JA28-29 & n.18. Instead, it argues that this image is "an example of metonymy, a figure of speech" designed to *symbolize* the fact that "smoking kills 443,000 Americans each year." U.S.Br. 49 (citation omitted). Likewise, the digitally-enhanced photograph of a man smoking through a hole in his throat is designed to *symbolize* "the addictive nature of cigarettes." U.S.S.J.Mem. 37. These gruesome images are *not*, however, "purely factual and uncontroversial" *statements* of these basic facts—and that distinction matters. It is one thing to say that smoking is addictive. It is quite another to show doctored photos of extreme situations—like that of the man smoking through a tracheotomy hole—that misleadingly suggest to the public that such outcomes are likely to happen in most cases. Again, such images are neither "purely factual" nor "uncontroversial."

Other images convey *no* information about the health consequences of smoking. For example, the image of a man wearing a t-shirt depicting the universal anti-smoking symbol and the message, "I QUIT," provides no information about smoking risks (or even the benefits of quitting). Instead, the obvious message is: "I quit smoking and so should you!" The Government concedes as much when it admits that, despite providing no information about smoking risks, the image "'encourag[es] cessation, and … increase smokers' motivations and confidence about quitting.'" U.S.S.J.Mem. 43 (quoting 76 Fed. Reg. at 36,65). Likewise, images of a baby enveloped in smoke and a woman crying do not portray any health consequences of smoking. Instead, they use distressing images of women and children as part of a naked appeal to emotion.

3. The graphics were not selected for their ability to provide factual information, but rather, for their shock value. As described above, the FDA Study demonstrated that the warnings did *not* increase consumer knowledge of smoking risks. *See supra* at 6-10. Instead, FDA selected the warnings based on whether they made viewers feel "depressed," "discouraged," or "afraid." 76 Fed. Reg. at 36,638. Indeed, FDA relied on these measures even though the Study concluded that "recall of associated warning message statements may be *reduced* in the short term" by the shocking graphics, because, FDA surmised, the shocking images might "still increase intentions to quit *through evoked emotional*

responses." *Id.* (emphases added). In short, FDA selected the graphics because it speculated they were likely to scare consumers into "positive behavior change," *id.* at 36,652, even at the expense of informing them.

4. The warnings explicitly urge consumers to "QUIT-NOW." Every warning is emblazoned with a hotline number admonishing consumers to "QUIT" smoking "NOW." This number does not inform consumers of the risks of tobacco use. Instead, it urges consumers to adhere to the Government's preferred policy choice about tobacco use. Indeed, the Government concedes as much when it argues that, like the "I QUIT" warning, this number is justified because "'health warnings are more effective if they are combined with cessation-related information.'" U.S.S.J.Mem. 44 (quoting 76 Fed. Reg. at 36,681). Since the phone number provides no information about smoking risks, this statement can only mean that the number makes the warnings more "effective" *at convincing people to quit*. That may be a policy message that the Government wishes to "effectively" disseminate; but it is not a "purely factual and uncontroversial" one.

5. The sheer size and placement of the graphic warnings go far beyond anything necessary to provide consumers with purely factual and uncontroversial information. As the district court held, "the[se] dimensions *alone* strongly suggest that the Rule was designed to achieve the very objective articulated by Secretary Sebelius: to 'rebrand[] our cigarette packs,' treating (as the

FDA Commissioner announced last year) 'every single pack of cigarettes in our country' as a 'mini-billboard'" for the Government's "anti-smoking agenda." JA33-34. Such "rebranding" would be entirely unnecessary if the Government's purpose were merely to convey factual information in an uncontroversial manner. *See Entm't Software Ass'n v. Blagojevich*, 469 F. 3d 641, 652 (7th Cir. 2006) ("Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's unjustified requirement of the four square-inch '18' sticker.").

Likewise, in its preliminary injunction briefing, the Government argued that the graphic warnings were no different than the following drug label:

Entire Package

As Displayed

U.S. Opp. 18, n.9. And in its summary judgment briefing, the Government analogized the graphic warnings to the warning on charcoal bags:[17]

But these examples stand in sharp contrast to the warnings at issue here and effectively illustrate how warnings are structured when they are truly intended to

[17] U.S.S.J.Mem. 17 n.4; *see also* http://www.kingsford.com/products/details/kingsford-original-charcoal/; http://www.walmart.com/ip/Royal-Oak-All-Natural-Charcoal-10lb/17043351.

provide information—including as to risks of dependence or death. Using words, and sometimes simple, non-controversial graphics, they take up only the space necessary to inform consumers how to use a product properly. They do not rebrand the packaging such that the dominant message is the warning. They do not use shocking graphics. And they do not urge consumers to avoid the underlying product. By offering these as the *best* precedents for the Rule, the Government convincingly demonstrates how unprecedented—and unnecessary—the graphic warnings here truly are.

6. The graphic warnings were intended to be anti-smoking advocacy. The IOM Report expressly admits that "the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products." IOM Report at 290-91. *See also supra* at 14-15. Likewise, FDA, in its Proposed Rule, conceded that the graphic warnings "ha[ve] a different purpose" than normal warnings; they are intended not to inform consumers of unknown risks, but to "encourage cessation and discourage initiation." 75 Fed. Reg. at 69,540. And, as noted, Secretary Sebelius and FDA Commissioner Hamburg have candidly acknowledged that the purpose of the graphic warnings are to advocate the Government's anti-smoking policy message. *See supra* at 3.

* * *

Given the totality of these factors, it cannot reasonably be asserted that the Rule's graphic warnings simply disseminate "*purely* factual and uncontroversial information" about the risks of smoking. Rather, in both purpose and effect, they advocate the Government's policy message that consumers should "QUIT" smoking "NOW." As the Supreme Court has made clear, such attempts to regulate "what shall be orthodox in … matters of opinion"—*i.e.*, whether individuals should buy and use a lawful product—must be subject to strict scrutiny. *Zauderer*, 471 U.S. at 651 (quoting *West Virginia State Bd. of Ed. v. Barnette*, 319 U.S. 624 (1943)). Here, the Government cannot possibly meet that standard—and, indeed, has not even attempted to do so, either here or in the Court below, and so has waived any such argument. *District of Columbia v. Air Florida, Inc*., 750 F.2d 1077, 1084 (D.C. Cir. 1984). For this reason alone, the district court correctly held that Plaintiffs were likely to succeed on the merits of their First Amendment claim.

C. The Government's Argument That The Graphics Convey "Purely Factual and Uncontroversial" Information Is Incorrect.

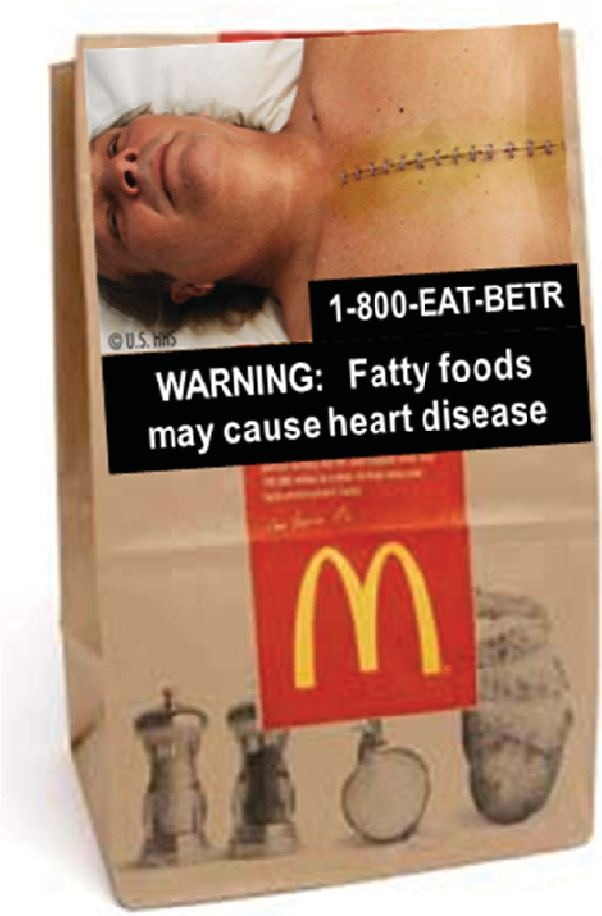
The Government's primary argument is that the graphic warnings are "purely factual and uncontroversial" because they depict "factual" and "accurate" representations of health consequences of smoking. U.S.Br. 28, 50. As explained above, the images are *not* "factual" and "accurate" descriptions of smoking risks, and they are certainly not "uncontroversial." *See supra* at 23-26.

More importantly, this argument untenably assumes that warnings are

"purely factual and uncontroversial" as long as they are not technically false. However, technically "accurate" images often advocate policy messages that are far more than "purely factual and uncontroversial." Consider the "shock and awe" tactics used by proponents of other politically controversial causes, such as animal rights advocates who depict gruesome images of brutality to animals, or anti-war advocates who display images of the ravages of war. Such imagery is intended to proselytize rather than inform, and the same is true of the graphic warnings. Likewise, there have been widespread reports about Marie-Louise Mellieur, a 117-year-old woman who was an avid smoker.[18] Cigarette advertisements depicting her image, however, would be no more "purely factual and uncontroversial" than the image of, for example, the man smoking through a tracheotomy hole. *See 95 United States v. 95 Barrels of Vinegar*, 265 U.S. 438, 443 (1924) (noting well-established principle that "[d]eception may result from the use of statements not technically false or which may be literally true").

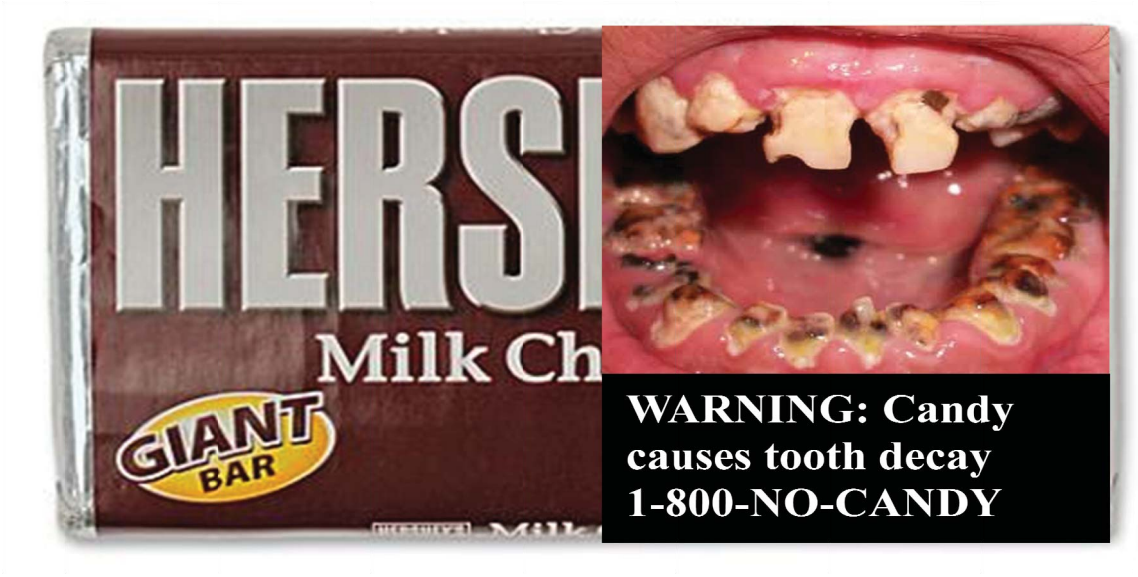
Under the Government's argument, there is no end to the "disclosures" the Government could require on any disfavored product. Indeed, the Government has never responded to Plaintiffs' assertion that, under the Government's view, it could impose identical warnings on every package of fast food, can of beer, or bottle of wine:

[18] *E.g.*, http://www.forces.org/evidence/hamilton/other/oldest.htm.

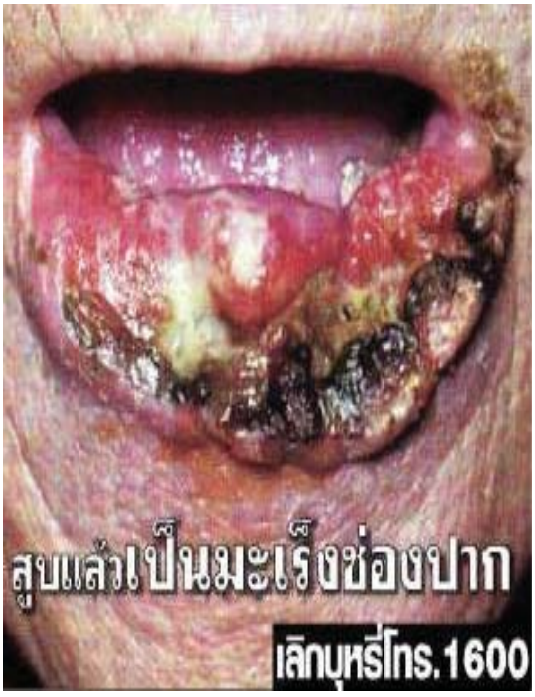


S.J.Mem. 22.[19] Nor has it responded to the district court's suggestion at the preliminary injunction hearing that the Government's theory would allow similarly gruesome warnings on every candy bar:

[19] Indeed, the World Health Organization has declared that "[a]lcohol is the world's third largest risk factor for disease," *http://www.who.int/mediacentre/factsheets/fs349/en/*, and a recent RAND Corporation study concluded that obesity "affects more people than smoking, heavy drinking, or poverty," *The Health Risks of Obesity: Worse Than Smoking, Drinking, or Poverty*, *available at* http://www.rand.org/content/dam/rand/pubs/research_briefs/2005/RB4549.pdf.



Likewise, the Government's limitless theory would permit the types of grotesque graphics used in other countries:



After all, the Government concedes that the Rule is modeled on "the graphic health warnings used in other countries." U.S. Br. at 14.

It is self-evident, however, that *none* of these warnings convey "purely factual and uncontroversial" information about risks of the underlying products. Instead, like the Rule, they convey an advocacy message: "Don't Use This Product!" The Government is free to forgo objectivity to maximize the emotional impact of its *own* advocacy messages. But "[it] may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 131 S. Ct. at 2671.

D. Compelled Advocacy Cannot Be Justified Under Central *Hudson.*

The Government also argues that even if the warnings are not "purely factual and uncontroversial," they are subject to review under *Central Hudson*, not strict scrutiny, because cigarette packaging is "quintessential commercial speech." U.S.Br. 24, 39-43. This argument is waived, since the Government did not argue anywhere in its preliminary injunction briefing that *Central Hudson* should apply to warnings that compel an advocacy message; instead, it argued only that *Central Hudson* and *Zauderer* should apply because the warnings were purely factual. U.S.Supp.Mem. 9-10. The Government cannot seek reversal based on a legal theory it did not present below. *Air Florida, Inc*., 750 F.2d at 1084. In any event, the Government's position is both wrong and irrelevant.

1. Where, as here, the Government compels commercial actors to disseminate non-factual, controversial policy statements, strict scrutiny applies,

even if the underlying speech to which that policy statement is affixed is commercial speech. *See, e.g.*, *Pac. Gas*, 475 U.S. at 17-18 (strict scrutiny applied to requirement that utility "use its property—the billing envelopes—to distribute the [policy] message of another"); *id.* at 21 (Burger, C.J., concurring) ("To compel [utility] to mail messages for others cannot be distinguished from compelling it to carry the messages of others on its trucks, its buildings, or other property used in the conduct of its business"); *Blagojevich*, 469 F.3d at 652 (7th Cir. 2006) (applying strict scrutiny to law requiring warning label for "sexually explicit" video game); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 961 (9th Cir. 2009), *aff'd*, *Brown v. Entm't Merch. Ass'n*, 131 S. Ct. 2729 (2011) (applying strict scrutiny to law requiring warning label for "violent" video games). The Government's response—that *cigarette packaging* is commercial speech—ignores the fact that the *compelled speech* here is *not*; instead, it requires Plaintiffs to disseminate the Government's policy view that consumers should not use lawful tobacco products. Indeed, under the Government's view, *Central Hudson* would apply if the Government forced Plaintiffs' packaging to "urge [their] customers to vote for a particular slate of legislative candidates," *Pacific Gas*, 475 U.S. at 15-16, simply because the packaging is "quintessential commercial speech." That is not the law. *Id.*; *see also 44 Liquormart*, 517 U.S. at 501 ("The mere fact that

messages propose commercial transactions does not in and of itself dictate [that *Central Hudson*] should apply to decisions to suppress them.").

Because the Rule attempts to "prescribe what shall be orthodox in … *matters of opinion*," *Zauderer*, 471 U.S. at 651 (emphasis added)—by compelling Plaintiffs to disseminate the Government's policy view that consumers should make a personal decision not to use lawful tobacco products—it must satisfy strict scrutiny.

2. In any event, the Rule also is irreconcilable with *Central Hudson* because paternalistic speech regulations aimed at manipulating consumer choice are "just as unacceptable in a commercial context as in any other." *Rubin,* 514 U.S. at 492-93 (Stevens J., concurring).

Indeed, just last year in *Sorrell*, the Court decisively rejected the argument that a Vermont ban on disseminating certain pharmacy records was justified by the State's goal of promoting better health policy by reducing the sale of "brand-name drugs that are more expensive and less safe than generic alternatives." 131 S. Ct. at 2670. The Court reasoned that it need not decide whether *Central Hudson* or strict scrutiny applied because, "[a]s in previous cases … , the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied." *Id*. at 2667. Vermont's ban was flatly unconstitutional under either standard because "the 'fear that people would make bad decisions if given truthful

information' cannot justify content-based burdens on speech." *Id.* at 2670-71 (citation omitted). "That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." *Id.* In short, the State was impermissibly "burden[ing] the speech of others in order to tilt public debate in a preferred direction," *i.e.*, to shape consumer choices about the purchase of lawful products. Here, as in *Sorrell*, the Rule is designed "not to promote informed choice but rather to discourage consumption of [lawful] products," IOM Report at 290-91, and accordingly cannot be reconciled with the First Amendment.

II. IN ANY EVENT, THE GRAPHIC WARNINGS FAIL *ZAUDERER* AND *CENTRAL HUDSON* BALANCING.

Even if analyzed under First Amendment balancing, the Rule is still plainly unconstitutional. In contrast to the enormous burdens it imposes on Plaintiffs' speech, the Government has adduced no evidence that the warnings will further its public health interest by reducing smoking. Recognizing as much, the Government argues that the Rule is justified solely based on an interest in increasing consumer knowledge of smoking risks. But the Government is not attempting to increase knowledge for the sake of knowledge, and, in any event, has adduced no evidence that the warnings will increase consumer knowledge of the already-universally-known risks of smoking.

A. The Rule Is Unconstitutional Because It Severely Burdens Plaintiffs' Speech And There Is No Evidence That The Warnings Will Further The Government's Public Health Interest.

Even if the Court could ignore the fact that the Rule compels government advocacy, the Rule would still be subject to the balancing tests set out in *Zauderer* and *Central Hudson*. *See Zauderer*, 471 U.S. at 651 (a "purely factual and uncontroversial" commercial disclaimer permissible only if not "unjustified or unduly burdensome"); *City of Cincinnati v. Discovery Network Inc.*, 507 U.S. 410, 417 (1993) (commercial speech restrictions must "carefully calculate[] the costs and benefits associated with the burden on speech imposed"). On one side of the balance is the Government's interest in "promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related disease." Act § 3(9). On the other side is the Rule's dramatic infringement upon Plaintiffs' free speech rights.

Here, the Government has adduced no evidence that the graphic warnings will "reduce disease risk and … social costs" by reducing smoking. *See supra* at 4-6. To the contrary, its own researcher *agrees* that "[t]here is no way to attribute … declines [in smoking] to the new health warnings." Hammond Review at 331. FDA's RIA likewise estimated that the reduction in smoking from the Rule

would be "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776.[20]

In contrast, the burdens on Plaintiffs' speech are enormous. The Rule confiscates the most prominent portion of Plaintiffs' packaging for disturbing graphic images that simultaneously encourage adult consumers *not* to purchase Plaintiffs' lawful products and drown out Plaintiffs' legitimate marketing messages. *See* Comment Letter, Exhibit D, Declaration of Robert H. Dunham ¶ 29; *id.* Exhibit D, Declaration of Timothy Jones ¶ 31. In the words of Secretary Sebelius, the graphic warnings effectively "rebrand[] our cigarette packs" such that the dominant message is not Plaintiffs' message, but the Government's "warnings." *See supra* at 3. This "rebranding" is particularly burdensome because cigarette packaging, along with print advertising, is one of the last remaining avenues through which Plaintiffs can communicate with adult consumers. S.J.Mem. 3. With no demonstration of public health benefits to justify this severe burden, the Rule fails *any* First Amendment standard.

[20] The Government has attempted to undermine the RIA by asserting that FDA "concluded only that it could not determine in a statistically significant way the extent to which the decline in Canadian smoking rates was attributable to the introduction of new warnings as opposed to other measures." U.S.S.J.Mem. 33. But "the party seeking to uphold a restriction on [even] commercial speech carries the burden of justifying it." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002) (internal quotation marks omitted). The Government thus concedes it cannot meet its burden to show that the Rule will decrease smoking.

B. The Rule Cannot Be Justified Based On An Interest In Increasing Consumer Knowledge Of Smoking Risks.

Recognizing that it cannot show the warnings will reduce smoking, the Government now argues that the warnings are justified regardless of whether they reduce smoking, because they will supposedly increase knowledge of smoking risks. U.S.Br. 28; U.S.S.J.Mem. 32. However, the studies that the Government invokes for this proposition "unequivocally" state that they are promoting strategies designed "not to promote informed choice but rather to discourage consumption of tobacco products … as a means of reducing tobacco-related death and disease." IOM Report at 290-91. Indeed, in promulgating the Rule, FDA expressly acknowledged that its purpose was to "discourage nonsmokers … from initiating use and to encourage current smokers to consider cessation." 76 Fed. Reg. at 36,633. The Government's claim that the Rule constitutes some Aristotelian pursuit of knowledge solely for the sake of knowledge is therefore absurd and provides no basis for upholding the Rule. *See Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[T]he *Central Hudson* standard does not permit us to…. turn away if it appears that the stated interests are not the actual interests served by the restriction.") (internal citation omitted); *United States v. Virginia*, 518 U.S. 515, 533 (1996) ("The justification must be genuine, not hypothesized or invented *post hoc* in response to litigation.").

In any event, there is no evidence that the Rule will increase knowledge of the risks addressed by the warnings. As discussed above, consumers are universally aware of—indeed overestimate—the risks of smoking. *See supra* at 10-12. The FDA Study thus confirms that the graphic warnings are likely to have *no impact* on knowledge of smoking risks. *Id.* at 6-9.[21] That is precisely why the graphic warnings have no impact on smoking prevalence. *Id.* at 12-14.

In the district court, the Government attempted to avoid this overwhelming evidence by engaging in myriad distortions of the academic literature. *See* S.J.Opp. 43-44. For example, the Government asserted that consumers do not understand the risks of smoking because "smokers were more than twice as likely as nonsmokers to doubt that tobacco use, even for a period of 30 to 40 years, would cause death." U.S.S.J.Mem. 30 (quoting IOM Report at 90 (citing Arnett Study at 625)). The source for this assertion, however, actually confirmed that consumers dramatically *overestimate* the risks of smoking. Specifically, it showed that 85-86

[21] The Government has attempted to undermine this devastating finding by asserting that study was designed solely to "assess[s] the relative impact of different warnings." U.S.P.I.Opp. 29. But the FDA Study was designed to compare the graphic warnings not only to each other, but also to a text-only control. Thus, the FDA Study expressly states that it was commissioned to both "evaluate the relative efficacy of various graphic images," *and also* to *"measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels."* FDA Study at 1-2 (emphasis added). The Government cannot disavow the FDA Study's findings simply because they are inconvenient.

percent of smokers and 74-82 percent of non-smokers agreed that "*[m]ost people* who smoke all their lives eventually die from an illness caused by smoking." S.J.Opp. 30. In fact, experts estimate that the risk of a lifelong smoker dying from a smoking-related illness is between 13 and 36 percent.[22] The study thus shows that smokers and non-smokers alike *overestimate* the risk of death from smoking, but that non-smokers overestimate that risk more than smokers do.[23] *See also* S.J.Opp. 43-44 (detailing the Government's numerous other distortions of academic studies).

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[22] *See* Act § 2(14) (finding that preventing 10,000,000 people from becoming regular, daily smokers would save 3,000,000 of them, *i.e.*, 30 percent, from premature death); *see also* W. Kip Viscusi & Jahn K. Hakes, *Risk Beliefs and Smoking Behavior*, 46 Economic Inquiry 45 (2008) (describing several estimates of overall mortality based on data from the U.S. Surgeon General, researchers at Johns Hopkins University, and the Office on Smoking and Health of the Centers for Disease Control), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1105984. Indeed, even assuming (wrongly) that overall mortality rate were 50%, *but see* 61 Fed. Reg. at 44,574 (noting that earlier studies produced this estimate by ignoring "potentially confounding variables, such as alcohol consumption or other lifestyle differences"), the Arnett Study *still* shows that consumers overestimate smoking mortality rates.

[23] Likewise the Government cited a study by Jamieson and Romer, *supra* n. 9, for the proposition that "nearly 26 percent of adolescent smokers and 18 percent of nonsmokers reported that they did not know whether smoking two or more packs of cigarettes a week would shorten their life span by any amount." U.S.S.J.Reply 11. In fact, this finding was based on a question asking whether it was "most likely" that smoking two or more packs a week would shorten their life, *i.e.*, whether it was more likely than not that a two-plus-pack-a-week smoker would die of a smoking-related illness. Jamieson & Romer at 55. As noted, the accurate answer to this question is "no." Accordingly, these results also show that adolescents *overestimate* smoking risks.

The Government has now abandoned many of these inapposite studies and, instead, relies on (a) different studies making similarly inapposite points, or (b) summary statements from policy reports (*i.e.*, the IOM Report and Hammond Study) that rely on the same studies that, Plaintiffs showed below, do *not* support the Government's position. This approach fares no better.

1. There Is No Evidence That Graphic Warnings Will Increase Consumer Knowledge of Smoking Risks.

The Government continues to assert that information deficits persist. But at best, the studies it cites (1) show information deficits on subjects *not addressed* by the graphic warnings, and (2) prove that consumers are fully informed of the risks that *are* addressed. *Supra* at 10-12, 14-16; S.J.Mem. 27-32.

For example, the Government emphasizes a finding in the IOM Report that youth and adolescents do not know that the risk of death from smoking exceeds the risk of death from gunshots, car accidents, and illegal drugs. U.S.S.J.Mem. 30 (citing IOM Report at 90); *see also* U.S. Br. at 5. But nothing in the graphic warnings informs consumers of these relative risks. Likewise, the Government cites a study asserting that "although most smokers acknowledge a high degree of risk associated with many years of smoking," they "tend to disregard or discount discomforting factual information about the long-term consequences" of smoking and believe they can "get away with some lesser amount of smoking before the risk takes hold." U.S.Br. 34-35 (citing Paul Slovic, *Cigarette Smokers: Rational*

Actors or Rational Fools? in SMOKING: RISK PERCEPTION & POLICY 97, 109 (Paul Slovic ed., 2001) ("*Rational Fools*"). As the IOM Report explains, these findings reflect a common phenomenon known as "optimism bias," whereby people tend to believe (irrationally) that their chances of avoiding known risks are better than average. *Id.* at 90. Thus, these studies simply show that, although consumers *do* know smoking is harmful and addictive, they discount their own chances of suffering these harms. Again, however, there is no evidence that the graphic warnings disabuse people of the notion that they can beat the odds. (Likewise, to the extent the Government is asserting that consumers underestimate the *speed* with which smoking-related illnesses can develop, the graphic warnings do nothing to address this risk.)

The Government, moreover, appears to rely on these same studies to make a different and more dangerous argument. It appears to claim that people are "not capable of making a fully informed decision whether to start or continue smoking." U.S. Mem. 19 (quoting *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d at 1, 578 (D.C. Cir. 2006) (citing Slovic testimony)). While the Government's argument focuses on youth, it appears to hold the same view with regard to the irrationality of *adult* smokers. *See* U.S.S.J.Mem. 26 (describing as "thoroughly discredited," the idea that consumers continue to smoke "after rationally weighing their immediate enjoyment against the prospect of lung and heart disease").

"[T]his failure to fully appreciate the risks of tobacco smoking," the Government adds, is "compounded by the powerful nature of nicotine addiction." U.S.Br. 36 (citing *Rational Fools*).

But the Government's view that consumers cannot rationally process information only demonstrates that the Government is not dissatisfied with consumers' *knowledge*, but with their *decisionmaking*. After all, if the Government believes people are irrational, providing them with additional "purely factual and uncontroversial" information will have no effect. Rather, the true purpose of the graphic warnings is not to inform, but to use emotionally-charged graphics to browbeat "irrational" consumers into adopting the Government's preferred course of action. Some researchers may think this approach is good policy, but it is at war with the First Amendment, which is "especially skeptical of regulations" that are based on the "offensive assumption that the public will respond 'irrationally' to the truth." *44 Liquormart, Inc.*, 517 U.S. at 503.

Finally, what the Government does *not* cite is also telling. If a meaningful number of consumers were unaware of the risks addressed by the graphic warnings, it would be simple to demonstrate simply by asking survey participants whether smoking carries those risks. The Government, however, fails to identify any such study. This failure is particularly striking because the FDA Study itself asked every participant, after viewing either the graphic warnings or a control,

whether they believed a regular smoker is likely to suffer from each of the smoking-related illnesses addressed by the graphic warnings. FDA Study, App. A at 1. As a result, the FDA Study's raw data constitutes the most recent, expansive, and direct set of evidence available on consumers' knowledge of smoking risks. If these data did anything besides corroborate the myriad other studies showing that Americans are fully informed of the risks addressed by the warnings, FDA would surely have cited them. Yet FDA has not only failed to cite these data; it has failed even to disclose them. S.J.Mem. 26 n.18; S.J.Opp. 32.

2. Studies Asserting That Graphics Are "Salient" Are Irrelevant.

The Government repeatedly argues that, because studies show that the graphic warnings are more "salien[t], *i.e.*, noticeabl[e] and readabl[e]," than the current Surgeon General's warnings, they will do a better job of informing consumers of smoking risks. U.S.Br. at 9, 13, 29, 33-34. But the unsurprising fact that shocking, gruesome images are more "noticeable," hardly demonstrates that they increase consumer knowledge. After all, a gruesome picture of a burn victim on a fire pit would certainly be "salient," but it would not tell viewers anything new about the ability of fire to cause burns.

The FDA Study demonstrates this point. As discussed *supra* at 6-9, it showed that, although the graphic warnings were quite "salient"—*i.e.,* made viewers "depressed, discouraged, and afraid" and "provoked a highly emotional

response"—they had no impact on knowledge of smoking risks.[24] In fact, FDA has conceded that "recall of associated warning message statements may be reduced in the short term" by the graphic warnings. 76 Fed. Reg. at 36,639. Nor can the Government undermine the FDA Study by speculating that the graphic warnings might perform better after "repeated exposure to multiple warnings over an extended time," U.S.S.J.Mem. 50; such assertion lacks any empirical support, *see* 76 Fed. Reg. at 36,639 (making same suggestion without citation), and is contradicted by FDA's own conclusion that "graphic images and text messages are likely to have greater impact at the time they are introduced and that meaningful impact of the warnings may decline with repeated exposure." *Id.* at 36,635-36.

Indeed, the sources cited by the Government do not even purport to find that graphics are better than text at providing consumers with new information about smoking. For example, the Government cites the IOM Report for its assertion that the current warnings are "invisible," *i.e.*, unnoticed. U.S.Br. 9, 29. But the quote from the IOM Report on which the Government relies—that the current warnings "fail to convey relevant information in an effective way," IOM Report at 291—

[24] The so-called "cognitive" salience factors confirm this point: many participants reported that the warning "Cigarettes cause fatal lung disease" was "informative," "meaningful," and/or "difficult to look at," *see* FDA Study Appendix C, even though it is undisputed that more people are aware that smoking causes lung cancer than that the earth revolves around the sun. *See supra* at 10. Thus, these "cognitive" factors do not measure whether the graphic warnings provide consumers with new information.

immediately follows the Report's admonition that "the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products." *Id*. Thus, the IOM Report asserts that the current warnings are "ineffective" not because consumers lack information, but because fully informed consumers fail to be shocked and "discourage[d]" by them.

For the same reasons, the Government's citation of a "report that the Canadian [graphic] warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States," U.S.Br. 31, does not show that they provide consumers with new information. This so-called "report" was nothing more than a summary of a researcher's subjective impressions after conducting a 1.5 hour focus-group discussion on the possible effectiveness of graphic warnings with 65 young adults from Detroit who were paid $50 to participate.[25] *See also* IOM Report at C-6 and Hammond Review at 330 (citing similar focus group "studies"). That the Government is forced to rely on the lay intuition of a handful of 18-24 year olds regarding the "effectiveness" of graphic warnings only underscores the dearth of evidence supporting the Government's position.

[25] O'Hegarty, M., Pederson, L.L., et al., *'Young Adults' Perceptions of Cigarette Warning Labels in the United States and Canada*, 4 Preventing Chronic Disease 1 (2007), *available at* http://www.cdc.gov/pcd/issues/2007/apr/pdf/06_0024.pdf.

Nor can the Government fill the evidentiary void with literature from other contexts noting that pictures may be more noticeable and "easier to remember than words." U.S.Br. 33-34 (citing studies). That literature does not even discuss graphic tobacco warnings, which address universally *known* risks, but instead addresses how to call attention to *unknown* risks or teach students *new* information. It does not remotely show that consumers are uninformed of smoking risks, or that graphic warnings will increase their knowledge. Perhaps that is why FDA never cited these sources in the Proposed Rule, the Final Rule, or its Opposition to Plaintiffs' preliminary injunction motion.

Finally, the Government cites a so-called "international consensus" regarding what warnings "will effectively convey the health risks of smoking." U.S.Br. 29. These other countries, of course, do not have a First Amendment, so provide no basis for upholding the Rule. Moreover, these countries, like the IOM Report and the other research noted above, *supra* at 14-16, find large graphic warnings to be "effective" not because they provide consumers with unknown, accurate factual information, but because "fear appeals" are effective in creating "negative associations" with cigarettes, which, researchers speculate, will "motivat[e] health behavior change (*e.g.*, quitting)." Fong, *supra* n.14. For example, Brazil's warnings are based on the theory that "stimuli that are (a) very negative, and (b) high in arousal cause an avoidance response"; "the new Brazil

warnings were [therefore] selected so that they were negative and highly arousing."[26] The international use of such graphics accordingly provides no support for the claim that the Rule provides consumers with unknown factual information.

3. Studies About Whether Graphics Cause Consumers To "Think" About Quitting Also Do Not Justify The Rule.

The Government also points to studies asserting that, after graphic warnings were introduced in Australia, adolescent smokers were more likely to report that they had *thought* about quitting. U.S.Br. 31-32. Even if taken at face value, these studies do not support the Rule. They do not show that consumers *actually* quit smoking, but only that, in a highly contrived setting, they told researchers that graphic warnings made them *think* about quitting. Thus, even Dr. Hammond conceded that these studies provide no basis for "attribut[ing] … declines [in smoking] to the new health warnings." Hammond Review at 331.

More importantly, such studies do not test whether graphics cause people to think about quitting *by providing them with new factual information*. Rather, the researchers on which the Government relies explicitly eschew such an analysis, recommending instead that graphic warnings be designed "not to promote

[26] International Tobacco Control Policy Evaluation Project 2009, *FCTC Article 11 Tobacco Warning Labels: Evidence and Recommendations from the ITC Project at 10*, *available at* www.itcproject.org/download/keyfindi/itctobaccolabelsbrov3pdf?.

informed choice but rather to discourage consumption of tobacco products." IOM Report at 291. *See also, e.g.*, U.S.Br. at 32, (citing Hammond Review at 331 (relying on researchers who urge that graphic warnings use "fear appeals" because they are "effective in motivating health behavior change")); Karine Gallopel-Morvan et al., *The Use of Visual Warnings in Social Marketing: The Case of Tobacco*, 64 J. Business Research 7, 7 (2011) (cited in Hammond Review at 332) (asserting that "loss-framed graphic warnings generating emotions of fear, disgust, or anxiety have a positive impact on quitting, attempting to quit or reducing smoking").

Moreover, the Government's description of these studies is, once again, deeply flawed. For example, the Government omits the fact that the primary study on which it relies—White, V. et al., *Do Graphic Health Warning Labels Have an Impact on Adolescents' Smoking-Related Beliefs and Behaviors?*, 103 Addiction 1562 (2008)) (cited in Hammond Review at 328)—notes that, just prior to its survey, new anti-smoking commercials were aired on television and that "adolescents have a high awareness of these types of [television] campaigns and can be influenced by them," *id.* at 1563. Yet the study made no attempt to correct its results for the independent impact of these ads. *See* SJ.Opp. at 38-39. More generally, surveys that ask individuals whether they intend to quit smoking are notoriously unreliable due to the well-known phenomenon of "social desirability

bias"—the desire to provide researchers with a "legal and/or socially desirable response" to questions. Viscusi Report, JA184-85. As one well-known anti-smoking researcher has observed:

> Given the widespread harassment of cigarette smokers and the evidence that smoking is actually dangerous to health, it is not surprising that smokers sometimes lie about their smoking. How better for a smoker to avoid the pestering of a physician or other interviewer than to say (whether believing it or not) that he wants to and has even tried to give up cigarettes? And, if the questioner asks if the attempts to stop have been serious, who would want to confess a half-hearted effort? Yet, answers to questions of 'wanting to stop' and 'trying to stop' have regularly been used uncritically—as if smokers now must be telling the truth.

Id. at 45 (quoting L. Kozlowski, *What Researchers Make of What Cigarette Smokers* Say*: Filtering Smokers' Hot Air*, Lancet, at 699 (Mar. 1980)); *see also* S. Chapman, *Smokers: Why Do They Start—And Continue?* 16 World H. Forum 1, 7 (1995) ("Plainly, social contexts in which smoking is increasingly vilified can produce a gap between what people feel obliged to say to researchers and what they genuinely feel."). Thus, quit intentions "tend to *significantly overestimate* the number of smokers who actually intend to quit as a result of the proposed warning." *Id.* at 63.[27]

[27] The Government has argued that the long-documented phenomenon of social desirability bias no longer exists because "recent scientific literature shows that statements by smokers concerning their intentions to quit smoking are predictive of their making subsequent quit attempts." U.S.S.J.Reply at 18 (quoting 75 Fed. Reg. at 52,354) (citing Zhou, X et al. *Attempts To Quit Smoking and*

Accordingly, studies purporting to show that survey participants say that graphic warnings make them *think* about quitting do not even arguably show that the graphic warnings increase consumer knowledge of smoking risks.

4. There Is No Evidence That Consumers Are Unable To Comprehend Simplified Textual Warnings.

Finally, the Government argues that graphic warnings are necessary to communicate smoking risks to less-educated people. *See, e.g.*, U.S.Br. 36 (quoting IOM Report at 295). The cited portion of the IOM Report, however, is based on a five-paragraph letter to the editor stating that the authors analyzed the length, syllables, and familiarity of text-only warnings on alcohol and tobacco packaging in 1992, and found those warnings to be written at a college reading level.[28] It then argued for more simplified *textual* warnings—such as those implemented by the

(continued…)

Relapse: Factors Associated with Success or Failure From the ATTEMPT Cohort Study, 34 Addictive Behaviors 365 (2009) ("Zhou"); Hyland A et al., Individual-Level Predictors of Cessation Behaviours Among Participants in the International Tobacco Control (ITC) Four Country Survey, 15 Tobacco Control 83 (2006) ("Hyland"))). But the underlying studies do not claim to address social desirability bias at all. Instead, they simply find that people who try to quit smoking are more likely to have intended to quit than those who do not try to quit. Zhou at 371; Hyland at 85. The Government's reliance on these studies is the equivalent of arguing that, because people who regularly exercise intend to exercise, everyone who predicts they will go to the gym will do so.

[28] J. Malouff, et al., *Readability of Health Warnings on Alcohol and Tobacco Products*, 82 Am. J. Pub. Health 464 (1992) (cited by IOM Report, at C-3 and Hammond Review at 333), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1694373/.

Act, which Plaintiffs do not challenge—not graphics. The letter does not remotely support the assertion that simplified textual warnings such as "Smoking can kill you" cannot be understood absent a college degree.

The Government similarly asserted below that "there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels." U.S.S.J.Mem. 20. But the lone study underlying this assertion actually showed the opposite: It analyzed educational disparities in Australia, Canada, England, and the U.S. in 2002, when only Canada had graphic warnings. And it found that a country *without* graphic warnings had the *smallest disparity* in risk awareness for *every* risk measured. S.J.Opp. 41-42.

The Government understandably omits this study from its brief to this Court. But this underscores a fundamental point: the academic literature that the Government relies on and consistently distorts shows that there is *no credible evidence* that graphic warnings will either reduce smoking or increase consumer knowledge of smoking risks. Instead, the most it shows is that shocking, attention-grabbing imagery is effective at shocking and grabbing attention—that it is "salien[t], *i.e.*, noticeabl[e] and readabl[e]," U.S. Br. at 13. But the Government obviously has no valid interest in shocking people solely for the sake of shocking them.

C. *Turner* Deference Is Inapplicable.

The Government now argues that, under *Turner Broadcasting Systems, Inc. v. FCC*, 520 U.S. 180 (1997) ("*Turner II*"), the district court should have deferred to "Congress's reasoned determination" regarding "effective[]"warnings. U.S.Br. 45. However, the Government never even cited *Turner* in its preliminary injunction briefing. Instead, it cited *Turner* only in its summary judgment reply brief, filed *after* it took this appeal. *See* S.J.Reply 9. This argument is therefore waived. *Air Florida, Inc*., 750 F.2d at 1084. In any event, *Turner* deference is plainly inapplicable.

First, the Supreme Court has held that *Turner* deference applies *only* to "content-neutral regulation[s]," *Brown v. Entm't. Merch. Ass'n*, 131 S. Ct. 2729, 2738, (2011).[29] Here, the graphic warnings obviously are not content-neutral. Rather, they compel Plaintiffs—through oversized "warnings," including shocking and emotionally-charged graphics and a 1-800-QUIT-NOW hotline—to urge adult consumers not to buy their lawful products.

Second, although the Government repeatedly invokes Congress's "reasoned determination" in support of the graphic warnings, no such determination exists.

[29] *See also, e.g.*, *Turner*, 520 U.S. at 225 (Stevens, J., concurring) (emphasizing that deference would be inappropriate "[i]f th[e] statute regulated the content of speech"); *44 Liquormart*, 517 U.S. at 493, 508-509 (refusing to defer to legislature regarding content-discriminatory law notwithstanding "conflicting expert testimony").

See Act § 2 (findings). Indeed, the Government does not even cite a snippet from a House or Senate report, or stray comment by a legislator, addressing the relative efficacy of graphic versus text-only warnings. Rather, the graphic warnings requirement was added to the Act on the day before its passage, and was accompanied by no factual findings. P.I.Supp.Mem. 1. Thus, there is no basis for concluding that Congress made a "reasoned determination," U.S.Br. 45, that the Rule's shocking graphic warnings were justified, not unduly burdensome, or otherwise tailored to a governmental interest in informing consumers.

Third, even when "Congress' predictive judgments are entitled to substantial deference[,] [that] does not mean … they are insulated from meaningful judicial review." *Turner I*, 512 U.S. at 666 (plurality opinion). Otherwise, the Government's burden of proof in all First Amendment cases would be meaningless. Here, the Government has introduced no credible evidence that the Rule will reduce smoking *or* increase consumer knowledge of smoking risks.

D. The Government Ignored Numerous Alternatives To The Rule

Finally, even in the commercial context, the Supreme Court has held that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson v. W. States Med. Ctr.*, 535 U.S. at 357, 371 (2002); *see also Trans Union LLC v. FTC*, 295 F.3d 42, 53 (D.C. Cir. 2002) (same, quoting *Thompson*); *BellSouth Telecomm., Inc.*

v. Farris, 542 F.3d 499, 508-09 (6th Cir. 2008) (invalidating state-law speech restriction designed to prevent consumer confusion because state had ignored a "full arsenal of options short of restricting speech"); JA224-25 (collecting cases); *Philip Morris*, 566 F.3d at 1143 ("Although the standard for assessing burdens on commercial speech has varied . . . the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are 'narrowly tailored' to achieve a substantial government goal."). Consequently, even if the Government could demonstrate that the Rule would advance a substantial interest—which it cannot—the Government would still bear the burden of proving that it could not advance its public health interests at least as well through obvious and available less restrictive alternatives.

Here, even assuming that current warnings are "ineffective" (notwithstanding the near-universal awareness of smoking risks), there is a world of less-speech-restrictive options between the current warnings and the ones adopted in the Rule, *e.g.*:

- Putting the Act's new text on the side of packages;
- Putting the Act's new text on the bottom front of packages and advertisements;
- Using less shocking graphics, like those on the charcoal bags, *supra* at 29;

- Disseminating its anti-smoking message on its own, *e.g.,* using the *$600 million* that FDA recently announced it will spend on a new anti-smoking multimedia campaign, S.J.Opp. 47

See JA221-224 (discussing these and other alternatives). The Government has offered no evidence that the Rule would provide even an incremental benefit beyond "these possibilities, alone or in combination." *Thompson*, 535 U.S. at 373. But that is the least it is required to do before trampling the speech rights of private parties. For this separate reason, the Rule violates the First Amendment under *any* standard of review.[30]

III. THE DISTRICT COURT PROPERLY GRANTED INJUNCTIVE RELIEF

The district court's preliminary injunction was well within its equitable and statutory authority.

1. Federal courts have broad "inherent equitable powers … to prevent plaintiffs from suffering irreparable injury." *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 834 (D.C. Cir. 1984). Such powers "go beyond the matters immediately underlying [their] equitable jurisdiction," authorizing courts to "decide whatever other issues and give whatever other relief may be necessary … [to] do complete rather than truncated justice." *Porter v.*

[30] As this Court held in *Sherley v. Sebelius*, 644 F.3d 388, 396-97 (D.C. Cir. 2011), if the Court rejects Plaintiffs' First Amendment arguments for preliminary relief, it should remand for consideration of Plaintiffs' APA claims.

Warner Holding Co., 328 U.S. 395, 398 (1946). Thus, courts allow operation even of *unconstitutional* statutes to allow a compliance period after judgment. *See Bowsher v. Synar*, 478 U.S. 714, 736 (1986); *N. Pipeline Constr. Co. v. Marathon Pipeline Co.*, 458 U.S. 50, 88-89 (1982); *Comcast Corp. v. FCC*, 579 F.3d 1, 11 (D.C. Cir. 2009) (Randolph, J., concurring) (discussing stays permitting unlawful agency action during agency reconsideration). Likewise, courts allow equitable relief to extend beyond the conclusion of their review. *See Consol. Gas Co.of NY v. Newton,* 274 F. 986, 988-89 (S.D.N.Y. 1921) (Hand, J.) (ordering that rates be impounded as collected until three months after "the appeal from this decree is determined"), *aff'd,* 258 U.S. 165, 173, 177-78 (1922). Courts also enjoin statutes *years* before their effective dates to prevent irreparable harm in the interim. *See Society of the Sisters of the Holy Names of Jesus & Mary v. Pierce*, 296 F. 928, 933 (D. Or. 1924), *aff'd*, 268 U.S. 510, 536 (1925) (enjoining compulsory education law over two-and-one-half years before effective date).

Here, the district court correctly found that the Rule threatens Plaintiffs with two irreparable injuries. Preparing the new graphic warnings would infringe Plaintiffs' First Amendment rights, which "unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373-74 (1976). In addition, the Rule forces Plaintiffs to spend millions of dollars that sovereign immunity renders unrecoverable. The relief ordered by the district court was the *only* way to prevent

these harms, and, therefore, fell within its broad power to "do complete rather than truncated justice." *Porter*, 328 U.S. at 398.

The Government contends that the district court lacked equitable power to prevent Plaintiffs' injury, citing cases where irreparable harm could be prevented simply by enjoining challenged regulations for the duration of judicial review.[31] That is not the situation here. As Congress recognized, and as described in Plaintiffs' uncontested affidavits, Plaintiffs would have had to begin the change-over almost immediately after the date the final rule was promulgated to comply with the statutory deadline (15 months after promulgation by FDA of a final Rule). Thus, the Rule effectively required instant compliance. Had the Government specified dates for all of the interim compliance steps, the district court could have granted preliminary injunctive relief as to each date. The fact that the Act specifies only the final compliance date eliminates neither the need for relief now, nor the equitable authority of the judiciary to fashion appropriate relief to prevent irreparable harm.

2. The district court's preliminary injunction is separately authorized by 5 U.S.C. § 705:

[31] *See* U.S.Br. 52-53, *citing*, *e.g.*, *Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 314 (1999) (noting that "a preliminary injunction *ordinarily* merges into the final judgment") (emphasis added).

> On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal[,] may issue all necessary and appropriate process [1] to postpone the effective date of an agency action *or* [2] to preserve status or rights pending conclusion of the review proceedings.

(Emphasis added.) Both prongs authorize the district court's injunction.

a. The Government does not dispute that the preliminary injunction constituted "necessary and appropriate process to postpone the effective date of an agency action." 5 U.S.C. § 705. Instead, it appears to argue that the district court had such authority only if that relief is "pending conclusion of the review proceedings." *See* U.S.Br. 53. But § 705 on its face provides that the reviewing court may act to *either* "postpone the effective date of agency action" *or* "preserve status or rights pending conclusion of the review proceedings." Any ambiguity on this point is resolved by the last antecedent rule, which provides that "a limiting clause or phrase … should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Barnhart v. Thomas*, 540 U.S. 20, 26-28 (2003). Because the district court's injunction was plainly "necessary and appropriate" to "prevent irreparable injury," it was authorized by § 705.

b. The preliminary injunction also was necessary "to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. The Government suggests that the injunction does not preserve status or rights "pending the conclusion of the review proceedings." *See* U.S.Br. 53. But even the

Government concedes that if the preliminary injunction were vacated, Plaintiffs would have to undertake "current preparations." U.S.Br. 54. Those "preparations" would occur "pending"—that is, "throughout the continuance of," "during," "while awaiting," or "until," *Black's Law Dictionary* (9th ed. 2009)—"conclusion of the review proceedings." 5 U.S.C. § 705. Thus, the district court's preliminary injunction "preserve[s] status or rights *pending* conclusion of the review proceedings."

3. The Government raises several other unpersuasive criticisms of the district court's injunction. It first asserts that a financial injury of over $20 million is insufficiently "serious" to justify relief. U.S.Br. 55-56. But "where, as here, the plaintiff … cannot recover damages … due to the defendant's sovereign immunity, any loss of income suffered by a plaintiff is irreparable *per se*." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D. D.C. 2008); *see also Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010); *Cal. Pharmacists Ass'n v. Maxwell–Jolly*, 563 F.3d 847, 849, 852 (9th Cir. 2009); *Temple Univ. v. White*, 941 F.2d 201, 215 (3d Cir. 1991). Moreover, given Plaintiffs' strong likelihood of success on the merits, they need only demonstrate "some injury" to sustain a preliminary injunction, *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006), which they plainly have done.

The Government next argues that the preliminary injunction is not tailored to protect Plaintiffs' First Amendment rights. U.S.Br. 54-55. But the injunction is carefully crafted to protect Plaintiffs' interest in avoiding compelled speech. If the Government ordered members of a political party to manufacture signs endorsing opposition candidates, the political party would "unquestionably" face irreparable injury justifying an injunction, *Elrod*, 427 U.S. at 373, even before the signs were displayed in public. Just so here.

Finally, the Government's assertion that "[n]othing distinguishes plaintiffs' claims of injury from the type of allegations that can be made by any regulated entity facing new regulatory obligations," U.S.Br. 56, is plainly false. Congress's own recognition that the Rule would require 15 months of implementation, Plaintiffs' strong likelihood of success on the merits, the threat to Plaintiffs' speech rights, the unrecoverable cost to Plaintiffs, and the district court's finding that the public interest favors preliminary relief, all set this case apart.

4. Even assuming *arguendo* that the district court lacked authority to enjoin the Rule for 15 months after final judgment, this Court should still affirm insofar as the injunction bars enforcement of the Rule *before* final judgment (or use its own authority to do the same, *see* 5 U.S.C. § 705). Plaintiffs' impending irreparable injury upon the Rule's final implementation in just a few months independently warrants preliminary relief. *See, e.g.*, *Pierce*, 296 F. at 933

(preliminary injunction entered two-and-one-half years before effective date); *Am. Fed'n of Labor v. Chao*, 297 F. Supp. 2d 155 (D.D.C. 2003) (similar); *Am. Med. Ass'n v. Weinberger*, 395 F. Supp. 515 (N.D. Ill. 1975), *aff'd*, 522 F.2d 921 (7th Cir. 1975) (rejecting ripeness challenge to preliminary injunction issued months before effective date).

CONCLUSION

For the foregoing reasons, the district court's grant of a preliminary injunction should be affirmed.

Respectfully Submitted,

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

I hereby certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times New Roman font, and the word count is 13,984.

/s/ Noel J. Francisco
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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of January, 2012, I caused the foregoing brief to be filed with the Court in hard copy and electronically and served through the Court's CM/ECF system.

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