IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY, LORILLARD TOBACCO COMPANY, COMMONWEALTH BRANDS, INC., LIGGETT GROUP LLC, and SANTA FE NATURAL TOBACCO COMPANY, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration, and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendants.

Civil Action No. 11-01482 (RCL)

REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

While the Government has authority to mandate that manufacturers accurately warn consumers about the dangers of their products in a plain, clear, and legible manner, the Government lacks authority to compel manufacturers to replace their product labels and logos with emotionally-charged photographs and messages demanding that adult customers stop using their lawful products. As Defendants have publicly acknowledged, the Rule seeks to "rebrand[] our cigarette packs"[1] so that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's anti-smoking message.[2] The Government's own findings, moreover, demonstrate that the Rule will have no impact on consumer understanding or smoking rates. Indeed, although similar graphic warnings have been required for years in Canada, the Government has yet to cite *any* empirical evidence that they have actually resulted in a meaningful reduction in smoking by youth or adults in that country, or anywhere else they have been used. The Rule is accordingly irreconcilable with the First Amendment and the APA.

The other preliminary injunction factors—including especially strong equitable considerations—likewise weigh heavily in favor of granting an injunction. Plaintiffs seek only to retain the compliance period that Congress itself thought appropriate—15 months after the legal requirements of the new law become clear. Without that implementation period, Plaintiffs will be required to spend millions of dollars that will not be recoverable regardless of how this Court resolves the merits of this dispute. It is well-established that such monetary losses are *per se* irreparable harm. And the Government has not even alleged any harm that would be caused by this short delay, during which time the current warnings will remain in place. Accordingly, Plaintiffs are entitled to the preliminary relief that they seek here.

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[1] Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011) ("Press Briefing"), http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser.

[2] FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010) ("Tobacco Strategy"), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm.

I. PLAINTIFFS HAVE A HIGH LIKELIHOOD OF SUCCESS ON THE MERITS

A. THE RULE VIOLATES THE FIRST AMENDMENT

On its face, the Rule is not aimed at preventing consumer deception by providing purely factual information, but at sending already-informed, adult consumers a stark message: "Don't Smoke!" The Rule is accordingly subject to strict scrutiny. However, because FDA's own analyses show that the warnings will have no meaningful impact on consumer understanding or smoking rates, the Rule cannot satisfy any level of First Amendment review. The Government's arguments to the contrary ask the Court to ignore all context, disregard FDA's own findings, and defer blindly to the Government's unsupported characterizations of a non-controlling, non-final, and factually distinguishable district court opinion. Consequently, Plaintiffs are likely to succeed on the merits of their First Amendment challenge.[3]

1. Defendants' Repeated Calls for Blind Deference to the *Commonwealth Brands* Decision Are Baseless.

The Government's lead argument, that Plaintiffs' claims in this case are identical to the facial challenge in *Commonwealth Brands* to the statute's general graphic warnings requirement, Dkt 18, Defendants' Memorandum in Opposition ("U.S. Opp.") 2, 8-10, 13-22, is incorrect. Plaintiffs continue to believe the statute is facially unconstitutional (and have thus appealed the *Commonwealth Brands* decision), but this case presents an as-applied challenge to *the Rule*, which was not even promulgated when *Commonwealth Brands* was decided, and is based on a record not before that court. That record demonstrates beyond question that the graphic warnings FDA selected will not achieve FDA's stated goal of reducing smoking. Accordingly, the decision in *Commonwealth Brands*, which is currently under review by the Sixth Circuit, has no preclusive effect here, and the Government does not even argue otherwise. Indeed, given the factual and legal distinctions between the two cases, the *Commonwealth Brands* decision is not even persuasive non-binding authority.

[3] *See* Dkt 11, Memorandum in Support of Plaintiffs' Motion for Preliminary Injunction ("PI Mem."); Dkt 10, Memorandum in Support of Plaintiffs' Motion for Summary Judgment ("SJ Mem.").

a. Unlike the statute at issue in *Commonwealth Brands*, the Rule contains numerous new features that remove all doubt as to the message conveyed by the warnings:

- It requires specific gruesome and/or non-factual images that, as one popular news media outlet observed, effectively "grab people by the lapels and … yell[]: 'Stop smoking!'"[4]
- It requires that the warnings literally urge smokers to "QUIT-NOW" through inclusion of the smoking cessation hotline, 1-800-QUIT-NOW.
- It makes explicit that FDA selected these images precisely because they were the ones most likely to make viewers feel "depressed, discouraged, and afraid," notwithstanding the fact that "recall of associated warning message statements may be *reduced* in the short term" by such warnings. 76 Fed. Reg. at 36,638. FDA took this approach, it said, because such warnings might "motivate positive behavior change" and increase "intentions to quit" through "evoked emotional responses." *Id.* at 36,652, 36,639.

Plaintiffs have consistently argued that these factors—*none of which is required by the statute*—in *combination* with the statutory factors, render the Rule unconstitutional by "cross[ing] the line" that separates purely factual and uncontroversial information from emotional and policy-laden advocacy designed to manipulate how consumers choose to live their lives. SJ Mem. 1.

b. Unlike the statute, the Rule was accompanied by FDA analyses demonstrating that the warnings selected by FDA are unlikely to affect consumer understanding or smoking behavior:

- Regulatory Impact Analysis: FDA's RIA concludes that the warnings will reduce U.S. smoking rates by less than one-tenth-of-one percent, a number it concedes is not statistically significant. SJ Mem. 7-10. Indeed, the Government does not dispute that FDA's analysis actually suggests that the graphic warnings could *increase* smoking rates. *See id.* at 10, n.9.
- FDA Study: FDA's own experimental study—which was "the largest study of consumer responses to graphic cigarette health warnings ever conducted"[5] and had the express purpose of "measur[ing] consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels," FDA Study at 1-2—concluded that the warnings would have no material impact on smoking intentions or consumer understanding when compared to providing the same textual warning in the format of the current Surgeon General's warning. SJ Mem. 11.

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

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

Moreover, these findings were reached even with FDA utilizing erroneous assumptions that artificially inflated the potential for the warnings to be found effective. SJ Mem. 8-10, 12-13.

c. None of this information, including the selection and content of the graphic warnings and the analyses of their impact (or lack thereof) was available in the *Commonwealth Brands* case, and the Government's efforts to imply that this Court is somehow bound by, or should defer to, the district court's decision in *Commonwealth Brands* is baseless.[6] The Government's argument that, because the Rule is not "inconsistent with the agency's statutory mandate," "Plaintiffs' quarrel is with Congress, not with FDA" (U.S. Opp. 23), is also irrelevant. Congress did not mandate the selection of graphics designed to frighten and shock, let alone particular images drafted to do so. And, in any event, Congress has no greater authority to mandate an unconstitutional regulation than FDA has to promulgate one. This Court therefore has an independent duty to address the merits of the Rule, and Plaintiffs submit it cannot survive that independent review.

2. The Rule Is Subject to and Fails Strict Scrutiny.

The applicable legal framework here is straightforward and undisputed. Regulations compelling speech, particularly content-based regulations, are presumptively subject to strict scrutiny. There is a narrow exception to this rule: the Government may require "purely factual [and] uncontroversial" commercial disclosures in order to prevent consumer deception, provided those disclosures are not "unjustified or unduly burdensome." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); *see also Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 642 (6th Cir. 2010). This narrow exception, however, does *not* apply where the compelled speech is aimed not at

[6] The Government wisely declines to advance an issue preclusion argument. *See* U.S. Opp. 14, n.7. Issue preclusion applies only where a subsequent case involves (1) the same parties or their privies, (2) an issue that was actually litigated and determined by a valid and final judgment, (3) a determination that was essential to the prior judgment, and (4) identical facts pertinent to the previously-litigated issue. *See Yamaha Corp. of Am. v. United States*, 961 F.2d 245, 254 (D.C. Cir. 1992); *Safadi v. Novak*, 574 F. Supp. 2d 52, 55-56 (D.D.C. 2008); *Montana v. United States*, 440 U.S. 147, 159 (1979). Here, the Government could not establish any of these factors: Liggett and Santa Fe were not parties or in privity with parties to *Commonwealth Brands*; the *Commonwealth Brands* court obviously never determined the validity of the Rule; and Plaintiffs' argument in this case turns heavily on FDA's RIA, the FDA Study, and the specific images chosen by FDA, none of which were implicated or available in *Commonwealth Brands*.

informing consumers, but at urging them to adopt the Government's preferred lifestyle. *See, e.g.*, *Pac. Gas & Elec. Co. v. Pub. Util. Comm'n of Cal.*, 475 U.S. 1, 8-9 (1986); *Entm't Software Ass'n v. Blagojevich,* 469 F.3d 641, 651-52 (7th Cir. 2006).

In any First Amendment challenge, "the burden is on the State" to demonstrate why the speech restriction is constitutional, *Zauderer*, 471 U.S. at 647, and the judiciary has a duty to exercise "independent judgment of the facts bearing on an issue of constitutional law," *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989). For example, in *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622 (1994), even though the plurality applied lesser scrutiny to content-neutral speech restrictions, it emphasized the judiciary's "obligation to exercise independent judgment when First Amendment rights are implicated." *Id.* at 666. It then reversed and remanded the district court's grant of summary judgment because (1) the Government had not provided "substantial elaboration … of the predictive or historical evidence upon which Congress relied, or … some additional evidence to establish" that the speech restriction at issue would solve a real harm; and (2) "the record fail[ed] to provide any judicial findings concerning the availability and efficacy of constitutionally acceptable less restrictive means of achieving the Government's asserted interests." *Id.* at 667-68.

Thus, while the Government may require Plaintiffs to *warn* consumers of the risks of their products (provided such warnings are not unjustified or unduly burdensome), it cannot force Plaintiffs effectively to "grab people by the lapels and … yell[]: 'Stop smoking!'" *Be Warned*, *supra* note 4. The Government has not even attempted to show how the Rule could satisfy strict scrutiny, but argues that it is not subject to strict scrutiny because the warnings are "purely factual [and] uncontroversial." The Government's arguments fail at every level.

a. The Government's primary argument appears to be that, while the warnings were selected for their ability to shock and repel consumers, they are nonetheless constitutional because they all depict actual effects of smoking. U.S. Opp. 26. As a threshold matter, this is simply not true. For example, with regard to the image of an actor portraying a dead body with a massive

autopsy scar, the Government does not dispute that "'autopsies' are not 'a common result of cigarette smoking.'" U.S. Opp. 26. Instead, it argues that this image *symbolizes* that "smoking kills 443,000 Americans each year." *Id*. However, an actor playing a scarred dead body is not even arguably a "purely factual [and] uncontroversial" *statement* that "smoking kills 443,000 Americans each year." Instead, it is a gratuitous, emotionally-laden image intended to shock consumers into not smoking.

The image of a man wearing a t-shirt that depicts the universal anti-smoking symbol and the message, "I QUIT," fares no better. *Id.* Unlike the textual warning, "Quitting smoking now greatly reduces serious risk to your health," this image says absolutely *nothing* about the risks of smoking or the benefits of quitting. Instead, the obvious message is: "I quit smoking and so should you!" It is thus pure advocacy to engage in conduct favored by the Government. Nor does the image of a baby enveloped in smoke even purport to describe, as a factual matter, the health consequences of exposing children to second-hand smoke. Instead, it uses the image of a mother and child as part of a naked appeal to consumers' emotions.[7]

More broadly, the Government's position ignores the practical reality that warnings including what may literally be "factual" images can—as here—convey a message that is far more than "*purely factual [and] uncontroversial*" information about the risks of products. Take, for example, the "shock and awe" tactics used by other proponents of 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 precisely the same is true of the warnings required by the Rule. These appeals are a far cry from the "purely factual and *uncontroversial*" disclosures permitted by *Zauderer*. Of course, like animal

[7] Perhaps recognizing that some of the selected images are so gruesome that they could not possibly survive First Amendment scrutiny, the Government contends these last two images are consistent with the First Amendment because they are not "'designed to shock, disgust, and frighten'" consumers. U.S. Opp. 25. The constitutional test, however, is whether the warnings are limited to "purely factual [and] uncontroversial" information about the risks of smoking. That warnings are designed to "shock, disgust, and frighten" is *one* way in which they may fail that test. But images like the foregoing also run afoul of that test by failing to communicate anything about Plaintiffs' products.

rights activists and anti-war protesters, the Government is free to forego objectivity in order to maximize emotional impact and discourage the use of products it disfavors. But it may not conscript the speech of others in that cause. As the Supreme Court recently held, "[t]he State can express [its] view through its own speech. But … [it] may not burden the speech of others in order to tilt the public debate in a preferred direction." *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2671 (2011).

The suggestion that any "true" representation of actual smoking risks necessarily conveys a "purely factual [and] uncontroversial" message also lacks any limiting principle. On this view, any labeling requirement would be given the deference owed "purely factual [and] uncontroversial" disclosures, no matter how large and intrusive the label, no matter how gruesome the graphics, and no matter how universally-known the information, so long as it describes a situation that actually occurs in the real world. The Government's position thus offers virtually no limit to the sort of graphic warnings that the Government could require for any product it wishes to discourage. Indeed, the Government does not dispute that its position would justify laws mandating images of heart attack victims on fast food packaging or cartoon drawings of sick babies on wine bottles. *See* PI Mem. 13; SJ Mem. 22.

b. The Government's argument that the warnings were not *intended* to frighten and shock consumers, but are instead aimed at "dissipat[ing] the possibility of consumer confusion or deception," U.S. Opp. 23-24, is irrelevant as well as wrong. Regardless of the Government's intent, the Rule forces Plaintiffs to disseminate a non-factual, emotionally wrought policy message about their lawful products that sweeps far beyond a "purely factual [and] uncontroversial" warning.

In any event, the Government's assertion is irreconcilable with its own admissions on the record that it chose warnings that scored high on the FDA Study for "salience," defined as an image's tendency to make viewers "depressed, discouraged, and afraid," "arouse fear," "provoke[] a highly emotional response," trigger "greater negative emotional reactions," or "confer negative feelings about smoking." 76 Fed. Reg. at 36,638-39. Indeed, even though "recall of associated

warning message statements may be *reduced* in the short term" by the shocking graphics, FDA selected such images because "these warnings [might] still increase intentions to quit *through evoked emotional responses*." *Id.* at 36,639 (emphases added). That is, FDA selected the warnings to scare consumers into "positive behavior change," *id.* at 36,652, even at the expense of informing them, and even though the FDA Study and RIA confirmed that no behavior change would likely result.

This is confirmed by the numerous outside studies that the Government relied upon in the Rule, which support, not purely factual descriptions of the risks of smoking, but rather, warnings that arouse "fear, disgust, or anger." *See* Hammond D., *Health Warnings Messages on Tobacco Products: A Review*, 20 Tobacco Control 327, 332 (March 2011) ("Hammond Review").[8] For example, after surveying the studies cited in the Rule, Dr. David Hammond, the author of many of the studies on which the Government relies, emphasized that they recommended graphic warnings precisely because of their "graphic, fear-arousing" content:

> 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.

Id. at 332. These studies urge the adoption of such fear-arousing warnings largely because of their potential "to create unfavorable emotional associations with [smoking],"[9] and "to undermine a brand's appeal and the impact of package displays at retail outlets," Hammond Review at 333. Anti-smoking researchers and advocates may have no concerns with conscripting Plaintiffs' packaging in this sort of advocacy, but the Constitution requires that such efforts be justified under strict scrutiny.

Finally, any doubt on this score is eliminated by the very language used by Congress and other government officials in describing the new warnings. As Congress found, the purpose of the

[8] *Available at* http://tobaccocontrol.bmj.com/content/early/2011/05/23/tc.2010.037630.abstract.

[9] Peters, E., 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. Mem. 19), *available at* http://www.who.int/fctc/guidelines/ArtElevenPetersSeventeen.pdf.

warnings is to negate the view that smoking is "socially acceptable." 21 U.S.C. § 387, note, Findings (17). Likewise, Secretary Sebelius and FDA Commissioner Hamburg have candidly acknowledged that the warnings "rebrand[] our cigarette packs"; convey the message that "smoking is gross"; "dispel[] the notion that somehow [tobacco use] is cool"; "help 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 anti-smoking message. *See supra* notes 1-2. Accordingly, even if the Government's intent could save the Rule's non-factual, anti-smoking warnings—and it cannot—the record conclusively demonstrates that the warnings were selected not to promote better-informed consumers, but to arouse an emotional reaction against Plaintiffs' lawful products.

c. In light of the foregoing, the Rule must clearly be reviewed under strict scrutiny, which the Government makes no effort to satisfy and which, for the reasons Plaintiffs have explained, the Rule cannot survive. PI Mem 11; SJ Mem. 25-30. For this reason alone, Plaintiffs are likely to succeed on the merits of this challenge.

3. The Warnings Are Unconstitutional Under *Any* Standard.

Even if strict scrutiny were inapplicable, the Rule could not survive any standard of First Amendment review. Even the standards invoked by the Government require a balance of the Government's interest in burdening speech against the burdens imposed on the speaker. *See Zauderer*, 471 U.S. at 651; *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980). Yet here, the record establishes the following uncontroverted facts:

- The Rule is projected to have no statistically significant impact on U.S. smoking rates. *See supra* at 3, SJ Mem. 7-10.
- The public is overwhelmingly aware of the nine specific health risks described in the new warnings. *See* SJ Mem. 14-15.
- FDA's own Study confirms that the selected warnings will not increase awareness of the risks of smoking or the likelihood that consumers will quit. *See supra* at 3, SJ Mem. 11-14. Indeed, several of the warnings studied were associated with *decreased* awareness of smoking risks or *increased* intentions to smoke. *See* Viscusi Report at 70-73.

The Government's side of the First Amendment balance is thus either zero or very close to it. In contrast, the burdens imposed on Plaintiffs by a Rule that rebrands their packaging and advertising and overwhelms Plaintiffs' commercial speech are monumental.[10]

a. The Government's primary argument, that the existing warnings are "invisible," U.S. Opp. 16-17, ignores the fact that current warnings are not noticed precisely because their content is as well known as the name of the first U.S. President. SJ Mem. 14-15. A consumer has no more reason to look at "warnings" he already understands than to look at the nameplate on his office door each morning. Likewise, placing neon lights around an employee's nameplate would make him more likely to notice his name, but it would still not tell him anything new. In the same way, the relative "salience" of the Rule's graphic warnings does not undermine Plaintiffs' undisputed showing that the risks addressed by the warnings are universally understood, and thus have no impact on smoking rates. That is precisely why the Surgeon General long ago recognized that anti-smoking strategies premised on 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 and provided them with sufficient justification not to smoke" were "*not effective*" at reducing smoking. SJ Mem. 15 (emphasis added).

b. The Government's argument that the graphic warnings are necessary to "communicat[e] with consumers with low levels of education" also fails. U.S. Opp. 16. There is no evidence that less educated consumers are unaware that "Cigarettes are addictive" and "Smoking can kill you." Indeed, the primary "study" the Government cites for this proposition, U.S. Opp. 10, is a

[10] The Government argues that the warnings are not burdensome because they leave Plaintiffs the bottom 50% of packaging and bottom 80% of ads. U.S. Opp. 17-18. But the portion of the packaging and advertising seized by the Rule is the most important part in communicating a marketing message because of how cigarettes are displayed at retail. Indeed, FDA's own website showing the before and after impact of the Rule in retail establishments, SJ Mem. 33-34, confirms that Secretary Sebelius was entirely correct when she observed that the new warnings will "rebrand[] our cigarette packs." Press Briefing, *supra* note 1. As a result, the dominant message from Plaintiffs' packaging and advertising will not be their marketing message, but the Government's anti-smoking message.

reference in the IOM Report attached to the Government's brief (which is a policy-oriented, anti-smoking report, not an empirical study) to a single, five-paragraph letter to the editor.[11] The letter states that the authors analyzed the length of sentences, average number of syllables per word, and the familiarity of the words in warnings on alcohol, cigarette, and smokeless tobacco packaging in effect in 1992. The letter does not suggest that the Government should mandate graphic warnings, but instead argues for more simplified text. Of course, the Act's new *textual* warnings do just that, and the letter to the editor provides no support for the assertion that such warnings are not understood absent emotionally-charged graphics.

c. The Government also asserts, contrary to the conclusions of the RIA and FDA Study, as well as the views of Dr. Viscusi,[12] that Canada's graphic warnings—upon which the Rule is modeled—have been shown to be effective, as have similar warnings in other countries. *See* U.S. Opp. 9, 12, 18-20. However, none of these studies contains evidence (or even addresses the issue) of whether the warnings actually cause people to stop smoking. Rather, these studies merely show people the graphic warnings and then ask them whether such warnings "'made them more likely to

[11] Malouff J, et al., *Readability of Health Warnings on Alcohol and Tobacco Products*, 82 Am. J. Pub. Health 464 (1992) (cited by 2007 IOM Report, at C-3), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1694373/.

[12] FDA's repeated references to Dr. Viscusi's report as "discredited" (Opp. 23) are inexplicable. Although the *Commonwealth Brands* court did not reach the result sought by the plaintiffs in that case, it certainly did not hold Dr. Viscusi to be unqualified as an expert or that his report could not be considered. Indeed, Dr. Viscusi's analysis and findings that that the new warnings are likely to have no statistically significant impact on smoking rates (Viscusi Report at 9-37) are consistent with FDA's own RIA, and with numerous studies cited in the IOM Report on which FDA relied. *Compare* Viscusi at 36 (graphic warnings have not altered the trend in smoking rates in Canada and warnings "that do[] not affect consumers' overall assessment of the benefits and expected costs of smoking will have no influence over their behavior.") *with* 76 Fed. Reg. at 36,776 (modeling the impact of the graphic warnings on the effect of graphic warnings in Canada and estimating that the impact of the warnings on smoking rates will be "in general not statistically distinguishable from zero."). *See also, e.g.*, Hammond, *supra* at 331 ("there is no way to attribute …declines [in smoking] to the new health warnings given that [they] are typically introduced against a backdrop of other tobacco control measures, including changes in price/taxation, mass media campaigns and smoke-free legislation."); Heather Wardle et al., E*valuating the Impact of Picture Health Warnings on Cigarette Packets*, Public Health Research Consortium 67 (2010) (finding after implementation of graphic warnings in the United Kingdom that "no increases were observed in the range or depth of awareness of the health risks associated with smoking or secondhand exposure to smoke. Cigarette smoking prevalence and cigarette consumption did not vary and there were no increases in behavioral responses such as attempting to stop smoking, forgoing a cigarette when about to smoke one or stubbing a cigarette out."). *Available at* http://www.york.ac.uk/phrc/PHRC%20A6-08%20Revised%20Final%20Report_9.8.10.pdf).

think about the health risks of smoking.'" *Id.* at 19. There are (at least) three fundamental flaws with this approach. *First*, it suffers from "social desirability bias"—that is, bias in favor of providing a socially acceptable answer. *See* SJ Mem. at 13. *Second*, and more importantly, it simply asks the wrong question: the fact that an attention-grabbing warning makes viewers think more about the subject of the warning is not surprising, but this does *not* show that the warning tells consumers anything new or will cause a smoker to quit. *Third*, it uses a (dubious) surrogate means of assessing the impact of the warnings on smoking rates (here, thinking about the hazards of smoking) when studies examining the *actual* impact of the warnings (including FDA's own RIA) uniformly conclude that the warnings will likely have *no statistically significant impact* on smoking rates.

d. The Government also argues that, even if individuals are universally aware of the main risks of smoking, there are residual information deficits that the new warnings are intended to remedy. For example, the Rule identifies studies showing that some consumers are unable to identify or estimate the likelihood of less common smoking risks such as stomach ulcers or osteoporosis, 76 Fed. Reg. at 36,632, and the Government asserts that youth "underestimate the tenacity of nicotine addiction and overestimate their own ability to stop smoking." U.S. Opp. 7; *see also* U.S. Opp. 17. Even if such information deficits exist, the warnings do not redress the problem, and the FDA Study itself, conducted for the purpose of evaluating the impact of these warnings on consumer knowledge of smoking risks, shows that the Rule will likely have *no* material impact on youth or adult understanding of the risks of smoking. SJ Mem. 11-14. Indeed, several of the graphics in the FDA Study had the *opposite* effect. *See* Viscusi Report at 70-73.[13] Again, this is why, as noted above, the

[13] Many of the same studies relied on by the Government, moreover, expressly acknowledge that consumers understand the major health risks of smoking addressed by the warnings. *See, e.g.*, Jamieson & Romer, What Do Young People Think They Know About the Risks of Smoking, in Smoking: Risk, Perception & Policy 53 (Slovic, ed. 2001) ("Consistent with Viscusi's findings, respondents in Survey 1 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.") (cited in IOM Report at 53); Arnett JJ., *Optimistic Bias in Adolescent and Adult Smokers and Nonsmokers*, 25 Addictive Behaviors Vol. 625 (2000), http://www.jeffreyarnett.com/articles/ARNETT_optimistic_bias.pdf ("Studies consistently find that both

Surgeon General concluded in 1994 that anti-smoking programs like those embodied in the warnings were "not effective." *See supra* at 10.

e. The Government fares no better when it attempts to liken the new warnings to the types of warnings used on prescription and over-the-counter drugs. U.S. Opp. 18. Such warnings are lengthy because they need to communicate detailed and complex information about how to use the product correctly. There is absolutely no evidence that the same is true of the factual information in the Rule. Moreover, drug warnings—even for products that carry a risk of dependence, addiction, or death—do not "rebrand" the packaging with prominent and emotionally-charged graphics and a "cessation resource" urging consumers to avoid the product. The drug label cited in the Government's brief is illustrative:

Entire Package

As Displayed

(continued…)

adolescents and adults agree … that smoking increases the long-term risks of a variety of health problems, such as lung cancer and heart disease. Furthermore, adolescent and adult smokers generally concede that smokers are at greater long-term risk for health problems compared to non-smokers.") (cited in IOM Report at 625). Tellingly, the Government in its opposition does not even attempt to rebut this point. Indeed, the FDA Study itself asked every participant, prior to viewing the graphic warnings or a control, whether they believed a regular smoker is likely to suffer from various smoking-related illnesses. FDA Study, App. A at 1. As a result, the FDA Study's raw data would provide the most recent and expansive set of evidence available regarding consumers' knowledge of the risks of smoking. Yet FDA has not only failed to cite this data; it has failed even to disclose it.

U.S. Opp. 18, n.9. As this shows, unlike the cigarette warnings, the drug warnings are printed (1) on the *back* or *side* of a package, or on an insert, (2) in black and white text, (3) with no shocking graphic content, (4) with no "cessation resource" urging consumers not to use the product, and (4) occupy no more space than is necessary to render the relevant text readable. This is a perfect example of how warnings are structured when they are truly intended to provide information, and provides a telling contrast to the warnings required by the Rule.

f. Perhaps realizing the dearth of evidence in support of the Rule, the Government next suggests that its purpose is *not* to reduce smoking, but merely to communicate to consumers solely for the sake of communication. *See* U.S. Opp. 23. This assertion is simply false. The self-evident and explicit purpose of the graphic warnings regime is "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." Act § 3(9); *see also* 76 Fed. Reg. at 36,634 (explaining that the purpose of the graphic warnings is to "discourage nonsmokers … from initiating cigarette use and to encourage current smokers to consider cessation"). As Secretary Sebelius candidly acknowledged, the warnings are intended to "chart[] a clear path to ending tobacco use in our country." Tobacco Strategy, *supra* note 2.[14] And as FDA's website states, the warnings are "part of a broader strategy to help tobacco users quit and prevent young people from starting."[15]

In any event, the Government cannot show that the Rule increases consumer knowledge of the risks of smoking either. To the contrary, FDA's own study—which was expressly commissioned to "measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette

[14] FDA has repeatedly asserted that the governmental interest supporting the Rule is to decrease the rate of smoking among adults and children in the United States, and that the warnings "will have a significant, positive impact on public health," 76 Fed. Reg. at 36,631, because they will increase the likelihood that "smokers will reduce their smoking, make an attempt to quit, or quit altogether," *id.* at 36,634. *See also id.* at 36,705 ("this regulation is expected to cause a reduction in overall smoking rates and initiation, and we estimate that this rule will reduce the number of smokers by 213,000 in 2013, with smaller additional reductions through 2031"); *id.* at 36,707 ("FDA's estimate of the benefits of the rule is determined by the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from diseases caused by smoking ….").

[15] *See* http://www.fda.gov/TobaccoProducts/Labeling/ucm259214.htm#Public_Health_Impact.

smoking in response to graphic warning labels"—demonstrates that the selected images did *not* have a significant effect on consumers' knowledge of the risks of smoking. *See supra* at 3; SJ Mem. 11-14. Indeed, FDA admits that in many cases "recall was significantly lower for the proposed required warning than for the text-only control" and 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." 76 Fed. Reg. at 36,639.[16] And for several of the graphics tested, the warnings actually *decreased* knowledge of smoking risks. *See supra* at 12.[17]

g. The Government notes the similarities between the required warnings and the warnings suggested by the World Health Organization ("WHO") and employed in other countries, such as Canada and the United Kingdom. U.S. Opp. 9, 12. But this "international consensus," *id.* at 9, is wholly irrelevant. Neither the WHO nor other countries are bound by the First Amendment, and

[16] Nor can the Government salvage this argument by suggesting the theoretical possibility that, although the warnings may *increase* emotional reactions and *decrease* recall of the actual warning statements in the short term, the effect of repeated viewings will be different over the long term. U.S. Opp. 28-29. The Government has absolutely *no evidence* that repeatedly attempting to scare people with shocking graphics will somehow improve their understanding of universally-known risks over time. Instead, the studies cited by the Government simply assert that graphic warnings are "effective" over time in "creat[ing] unfavorable emotional associations with [smoking]," Peters, *supra* note 9, and "undermin[ing] a brand's appeal and the impact of package displays at retail outlets." Hammond Review at 333. Even the Government does not contend that it has a legitimate interest in commandeering Plaintiffs' packages and advertising to scare consumers and stigmatize cigarettes absent a showing of any impact on smoking rates.

[17] The Government attempts to dispute the observation in Plaintiffs' opening brief that "[t]he general failure of the 36 proposed warnings casts doubt on even the occasional finding that a particular warning had a particular impact on a particular group." SJ Mem. 12. Specifically, the Government argues that "[b]ecause FDA considered a finding to be statistically significant if there was only a five-percent chance that the finding was coincidence, …one would expect only five percent of the total number of findings to be statistically significant if random error were the only contributing factor." U.S. Opp. 30. The Government then asserts that "the actual number of significant findings was greater by an order of magnitude." *Id.* (citing FDA Study Report, Appendix C-1). But the Government's math does not add up. The FDA Study assessed the impact of 36 warnings across 3 criteria (smoking risk awareness, ETS risk awareness, and smoking intentions) for 3 groups (youth, young adults, and adults), thereby providing the graphic warnings 324 opportunities to demonstrate a significant impact on at least one criterion for one group. SJ Mem. 12. The proposed graphic warnings had a significant impact on risk awareness or smoking intentions in only 15 instances. *See* Viscusi Report 70-73 (tabulating results of FDA Study Report, Appendix C-1). Thus, the warnings impacted consumer understanding 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. To be sure, the FDA Study also made findings regarding the warnings' "salience," *i.e.,* whether they made viewers "depressed, discouraged, and afraid." And if *these* findings are included in the tally, "the actual number of significant findings [is] greater by an order of magnitude." U.S. Opp. 30. But this reinforces rather than contradicts Plaintiffs' point: the FDA Study shows that the warnings consistently play on consumers emotions, but have no effect on their understanding of smoking risks or smoking intentions.

there is absolutely no indication that these foreign entities undertook the type of analysis required under our Constitution. In fact, the international experience only confirms that graphic warnings have no material impact on smoking rates. *See supra* note 12.

h. Finally, the Government has produced no evidence that numerous obvious alternatives to the Rule would be less effective than the new warnings—a critical element of First Amendment analysis. For example, there is no evidence that a less burdensome warning—such as putting the Act's new text on the side of the packages, where the current Surgeon General's Warning appears—would be less effective at reducing tobacco use or informing consumers of the risks of smoking than the massive new warnings mandated by the Rule. Nor could it. As noted above, FDA conducted an extensive study of the likely impact of the warnings on consumer knowledge of the risks of smoking, surveying some 18,000 individuals. FDA specifically compared the impact of (1) putting the Act's new text where the Surgeon General's warning currently appears (on the side of packages), and (2) the new warnings as implemented by the Rule. SJ Mem. 11. And FDA concluded that, in terms of increasing consumer awareness of the risks of smoking, there is no material difference between the two. SJ Mem. 11-12. It follows *a fortiori* that there is no evidence that, say, putting a larger, *text-only* warning on the *bottom third* of the front of the packaging would be less effective than the massive warnings mandated by the Rule.[18]

[18] Nor does it matter whether, as the Government suggests, FDA had no choice but to adopt the Rule. As a threshold matter, nothing in the Act mandated that FDA select emotionally-charged images the express purpose of which is to "rebrand[] our cigarette packs" so that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's anti-smoking message. FDA obviously could have employed less disturbing images; but it chose not to. In any event, both the Constitution and the Act itself provide the Executive Branch with ample authority to implement Congress's mandate in a manner consistent with the First Amendment. *See* U.S. Const. art. II, § 3, cl. 4 (the President "shall take Care that the Laws be faithfully executed"); Office of Legal Counsel, *Presidential Certification Regarding the Provision of Documents to the House of Representatives Under the Mexican Debt Disclosure Act of 1995*, 20 Op. O.L.C. 253, 278 (1996), *available at* http://www.justice.gov/olc/cdraftfin.htm.; Office of Legal Counsel, *Limitations on the Detention Authority of the Immigration and Naturalization Service*, 2003 WL 21269067 (Feb. 20, 2003), *available at* http://www.usdoj.gov/olc/INSDetention.htm; 15 U.S.C. § 1333(b)(4), (d), (e), as amended by 123 Stat. 1842-46. Consequently, the Government's claim that it is bound by a legal straightjacket is wrong. The Government is also wrong to fault Plaintiffs for not proposing alternative, less disturbing images that might satisfy the First Amendment.

Instead, the Government argues that it was not obligated to consider any alternatives that would "impose substantial new costs on state and local governments and private persons." U.S. Opp. 21 (internal quotation marks omitted). This is completely non-responsive to the alternative of imposing less burdensome warnings, which would cost the Government nothing. More fundamentally, "[c]itizens may not be compelled to forgo their [First Amendment] rights because officials … desire to save money." *Palmer v. Thompson*, 403 U.S. 217, 226 (1971). Courts thus regularly invalidate speech restrictions even where less speech-restrictive alternatives impose additional costs.[19] Were the rule otherwise, compelling speech would virtually always satisfy the First Amendment, because forcing the Government to disseminate its own message would necessarily "impose substantial new costs."

B. THE RULE VIOLATES THE APA

The Government does not even address Plaintiffs' APA arguments; accordingly, this Court may treat the invalidity of the Rule under the APA as uncontested. *See Hopkins v. Women's Div., Gen. Bd. of Global Ministries*, 284 F. Supp. 2d 15, 25 (D.D.C. 2003). In any event, as explained at length in Plaintiffs' opening briefing, Plaintiffs' APA challenge is (more than) likely to succeed because (1) the stated purpose of the Rule—to decrease smoking—is not supported by the administrative record; (2) FDA's cost-benefit analysis exaggerated the Rule's benefits while ignoring obvious costs; (3) FDA rejected comments based on the absence of empirical support even though it ignored a similar lack of empirical support in favor of the Rule; (4) FDA failed to assess numerous less burdensome alternatives to the Rule; and (5) FDA failed to disclose numerous studies and other data on which the Rule is predicated. PI Mem. 13; SJ Mem. 37-41.

(continued…)

It is the *Government's* burden to demonstrate that the warnings required by the Rule are more effective than less obstrusive alternatives, a burden the Government has not even attempted to carry.

[19] *E.g.*, *The Pitt News v. Pappert*, 379 F.3d 96, 108 (3d Cir. 2004) (Alito, J.) (more "aggressive enforcement" of alcohol laws on campus by "law enforcement officers"); *BellSouth Telecomms., Inc. v. Farris*, 542 F.3d 499, 508-09 (6th Cir. 2008); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) ("increased taxation" and "educational campaigns").

Nor can the Government avoid these arguments by suggesting that FDA had no choice here. Nothing in the Act required FDA to include gruesome and/or non-factual images that have the purpose and effect of stigmatizing cigarettes; select as a smoking cessation resource the "1-800-QUIT-NOW" hotline, which directly exhorts smokers to "QUIT-NOW"; or select and design the warnings to maximize an emotional response from viewers at the expense of informational recall.

II. PLAINTIFFS SATISFY THE OTHER REQUIREMENTS FOR INTERIM RELIEF.

The Government does not dispute that, in the absence of a preliminary injunction, Plaintiffs must spend millions of dollars and thousands of employee-hours to comply with the Rule, and that those resources will be irretrievably lost if this Court concludes that the Rule violates either the First Amendment or the APA, in whole or in part. Nor does it dispute that Congress included a 15-month compliance period because it thought Plaintiffs should not have to begin taking steps to comply with the Rule until after the Rule's requirements were clear. *See also* 76 Fed. Reg. at 36,703 ("We agree [15 months] is an appropriate amount of time for implementation of the rule."). It nevertheless argues that this Court should deny preliminary relief because (1) millions of dollars and thousands of employee-hours are not sufficiently "substantial" to invoke this Court's equitable authority, (2) smoking in general harms the public health, and (3) this Court's equitable powers do not allow this Court to prevent the irreparable harm Plaintiffs have demonstrated. These arguments are unfounded.

1. Irreparable Harm. Plaintiffs easily demonstrate irreparable harm. The Government's arguments ignore and/or distort established law.

a. Most fundamentally, none of the cases relied upon by the Government involved a violation of the movant's freedom of speech. It is, however, established law that irreparable harm exists whenever a party's "First Amendment interests are either threatened or in fact being impaired at the time relief is sought." *Wagner v. Taylor*, 836 F.2d 566, 576 n.76 (D.C. Cir. 1987). Here, as Plaintiffs explain, the Rule would force Plaintiffs to expend millions of dollars and thousands of employee-hours in furtherance of a plainly unconstitutional mandate. This itself constitutes

irreparable harm. *Id.* Thus, Plaintiffs' likelihood of success on the merits alone satisfies the irreparable harm requirement for injunctive relief. *See* PI Mem. 8-11.

b. Even beyond the First Amendment injury, however, the Government's argument that Plaintiffs' unrecoverable losses are not sufficiently "serious" is squarely foreclosed by this Court's decision in *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (Leon, J.), *aff'd*, 627 F.3d 891 (D.C. Cir. 2010), and numerous other cases holding that, "[w]here a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by the plaintiff is irreparable *per se*.'" *Id.* (quoting *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008)).

The Government can argue otherwise only by conflating two distinct lines of cases. The first, which the Government invokes, finds irreparable injury where monetary harm is so great that—*even if ultimately recoverable*—it threatens the existence of the plaintiff's business. All but one of the cases cited by FDA involve this issue and are inapposite where, as here, the monetary expenditures will *not* ultimately be recoverable because of sovereign immunity. *See* U.S. Opp. 37-38.[20] Plaintiffs' claim of irreparable injury, however, relies on a *separate* line of cases, exemplified by *Smoking Everywhere*, which holds that monetary losses are *per se* irreparable harm where, as here, they are irretrievable because of the sovereign immunity of the defendant.

In *Smoking Everywhere*, manufacturers sought a preliminary injunction to prevent FDA from blocking the importation of electronic cigarettes following an FDA determination that they were an unapproved drug-device combination. This Court concluded that the plaintiffs had demonstrated a likelihood of success on the merits and irreparable harm, noting that the economic harm resulting

[20] The only exception is *Coalition for Common Sense in Government Procurement v. United States*, 576 F. Supp. 2d 162 (D.D.C. 2008). In that case, however, the party claiming irreparable injury relied solely on three cases that involved a substantial irreparable injury, and were thus distinguishable, and failed to cite the foregoing caselaw. *See id.* at 169 n.3; Plaintiffs' Application for Preliminary Injunction at 35-36, *id.* (No. 08 Civ. 996). This doctrinal outlier is hardly sufficient to overrule the directly applicable and extensive authority holding that monetary injury that is unrecoverable due to sovereign immunity is *per se* irreparable harm, particularly where the Court was not apprised of such authority.

from FDA's challenged action posed a grave threat to the companies' existence. *Smoking Everywhere*, 680 F. Supp. 2d at 76-77. The Court further explained:

> It is also worth noting that even if the claimed economic injury did not threaten plaintiffs' viability, it is still irreparable because plaintiffs cannot recover money damages against FDA. Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, "any loss of income suffered by the plaintiff is irreparable *per se*." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D. D.C. 2008)…. There being no apparent avenue for obtaining damages against FDA, any economic loss suffered by plaintiffs due to the detention or refused admission of their products can never be recovered and is therefore irreparable.

Id. at 77 n.19.[21] Likewise, *Feinerman* squarely rejected the Government's argument here:

> The defendant argues that "monetary loss is not irreparable harm unless it threatens the very existence of the plaintiff's business." The Court agrees … as a general matter. But where, as here, the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity, any loss of income suffered by a plaintiff is irreparable *per se*.

558 F. Supp. 2d at 51 (internal citations omitted). This Court has repeatedly affirmed the rule recognized in these cases.[22]

Although the Government suggests that the expenditure of irretrievable money and employee-hours to comply with an unconstitutional law cannot constitute irreparable harm, *see* U.S. Opp. 39-42, it again ignores numerous cases that have squarely held to the contrary, including

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[21] Unable to come to grips with this holding, the Government fails even to acknowledge it and even suggests that *Smoking Everywhere* makes no such holding at all. *See* U.S. Opp. 39 (quoting *Smoking Everywhere* but omitting portion of holding discussing *per se* irreparable harm and arguing that the "Court did not suggest…that the degree of economic harm is irrelevant to the inquiry").

[22] *See Nalco Co. v. U.S. E.P.A.*, No. 11-760, 2011 WL 1882397, at *10 (D.D.C. May 18, 2011) (granting a preliminary injunction against a stop-sale order by EPA that was challenged as arbitrary and capricious, and observing that plaintiff demonstrated irreparable harm for damages for which it would have "no right of recourse against the federal government"); *Alf* v. *Donley*, 666 F. Supp. 2d 60, 70 (D.D.C. 2009) (finding irreparable harm where a debarred contractor would presumably be able to seek out government contracts if the debarment were lifted, but would be unable to recoup lost income due to the government's sovereign immunity); *Clarke v. Office of Fed. Housing Enter. Oversight*, 355 F. Supp. 2d 56, 65 (D.D.C. 2004) (Leon, J.) (noting that "courts have recognized that economic loss may constitute 'irreparable harm' where a plaintiff's alleged damages are unrecoverable"); *Hoffmann-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978) (finding economic loss to constitute irreparable injury because no "adequate compensatory or other corrective relief will be available at a later date"); *see also Armour & Co. v. Freeman,* 304 F.2d 404, 406 (D.C. Cir. 1962) (finding lost profits that cannot be recaptured to constitute irreparable harm); *Nat'l Min. Ass'n v. Jackson*, 768 F. Supp. 2d 34, 53 (D.D.C. 2011) (denying a preliminary injunction where, among other things, plaintiff failed to show losses were unrecoverable, but noting that "[i]f a plaintiff has shown that financial losses are certain, imminent, and unrecoverable, then the imposition of a preliminary injunction is appropriate, and necessary").

National Medical Care, Inc. v. Shalala, No. 95-0860, 1995 WL 465650, at *3 (D.D.C. June 6, 1995), which squarely held:

> [T]he Plaintiffs have established that this process will cost them more than 90,000 man hours of work and over $1 million. If the Court eventually decides in the Plaintiffs' favor, all of these efforts will have been rendered futile, and the Plaintiffs will have to engage in yet another costly and confusing re-billing process…. [G]iven the overwhelming likelihood that the Plaintiffs will eventually succeed on the merits of their retroactivity claim, it would be absurd to allow the Defendant to impose these costs upon the Plaintiffs at all.

See also Central Valley Chrysler-Plymouth v. California Air Res. Bd., No. 02-5017, 2002 WL 34499459, at *7 (E.D. Cal. June 11, 2002) (finding irreparable harm because "[i]n the absence of this preliminary injunction, plaintiffs will be required to expend substantial monies in order to comply with the 2001 ZEV amendments, monies they will not be able to recoup should this court ultimately rule that the 2001 ZEV amendments are unconstitutional").

Finally, even if the Court were to require some level of substantiality before recognizing unrecoverable costs as irreparable injury, the millions of dollars and thousands of employee-hours that would be wasted absent preliminary relief in this case are plainly substantial, particularly in light of Plaintiffs' likelihood of success on the merits and, as discussed below, the absence of any harm to the public interest. *See infra* at 21-22. The availability of a preliminary injunction is ultimately a question of equity. It is plainly not equitable to require Plaintiffs to expends millions of dollars and thousands of employee-hours to comply with an unconstitutional regulation when the Government cannot even claim that relief will cause any injury.

2. Public Interest. The Government's argument that the relief Plaintiffs seek is contrary to the public interest is also incorrect. Again, the Government ignores black-letter law that "there can be no public interest in enforcing an unconstitutional law." *Nat'l Black Police Ass'n v. D.C. Bd. of Elections & Ethics*, 858 F. Supp. 251, 263 (D.D.C. 1994). *See* PI Mem. 18-19. It also completely misstates the potential impact of a preliminary injunction on the public interest. The issue is not, as the Government suggests, the difference between having warnings and not having warnings. The

issue, rather, is merely whether continuing with the *existing* warnings for a few additional months would harm the public interest. The Government does not even argue that it would. Nor can it. There is no basis to conclude that a few-month delay will harm the public interest where: (1) the current warnings have been deemed adequate for decades; (2) FDA's own analyses show the new warnings will have little or no impact on smoking rates or consumer understanding even if implemented *permanently*; and (3) the legislative and administrative history demonstrate no urgency.

3. This Court's Authority. FDA also argues that, even if Plaintiffs would suffer irreparable harm absent a preliminary injunction, *and even if it were beyond doubt that Plaintiffs would succeed on the merits*, this Court lacks the power to prevent such injury. This too is wrong.

First, this Court's inherent equitable power to prevent irreparable harm—recognized in Rule 65 of the Federal Rules of Civil Procedure—provides it with ample authority to enter the relief sought here. District courts have 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) (district court may "properly employ[] its inherent equitable powers…. to prevent plaintiffs from suffering irreparable injury"); *see also Pierce v. Soc'y of Sisters*, 268 U.S. 510, 536 (1925) ("Prevention of impending injury by unlawful action is a well recognized function of courts of equity."); *Porter v. Warner Holding Co.*, 328 U.S. 395, 397-98 (1946) (district courts have inherent equitable powers to "go beyond the matters immediately underlying [their] equitable jurisdiction and decide whatever other issues and give whatever other relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justice."). It is thus established law that "[a] district court, sitting as a court of equity, unless applicable statutes provide otherwise, has all the inherent equitable power of the District Court …available for the proper and complete exercise of that jurisdiction; and has power to do equity and mould each decree to the necessities of the particular case." *United States v. Exxon Corp.*, 561 F. Supp. 816, 855 (D.D.C. 1983). The Government points to no provision expressly taking away the courts' authority to issue

the injunctive relief sought here, which plainly would be tailored to the "necessities of th[is] particular case." Thus, even apart from § 705, the Court's inherent equitable authority authorizes the relief Plaintiffs seek.

Second, the relief Plaintiffs seek is also authorized by 5 U.S.C. § 705, which authorizes this Court:

> to the extent necessary to prevent irreparable injury …[to] issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

Section 705 thus authorizes two forms of equitable relief. Where "necessary to prevent irreparable injury," this Court may either (1) "postpone the effective date of an agency action" or (2) "preserve status or rights pending conclusion of the review proceedings."

The relief Plaintiffs seek fits squarely within both forms of relief. As already explained, the irreparable injury described above can only be avoided by "postpon[ing] the effective date of an agency action." Absent such postponement, it is undisputed that Plaintiffs will be forced to spend millions of dollars and thousands of employee-hours to comply with a regulation that will likely be held unconstitutional. In addition, such postponement is *also* necessary to "maintain status quo or rights pending judicial review." The Government appears to suggest that this language allows the Court only to extend the effective date until the *conclusion* of judicial review, Opp. 36, but that is not what the text says. Moreover, such a cramped reading ignores the purpose of § 705, which is to allow courts to prevent litigants from suffering irreparable harm while the litigants' rights are being adjudicated (provided, of course, that they satisfy the equitable factors necessary for such relief). And here, the *only* way the Court can preserve the "status or rights pending judicial review" is by extending the effective date of the Rule.[23]

[23] If the Government intends to argue that the phrase "pending judicial review" limits the Court's power to "postpone the effective date of an agency action," that argument is inconsistent with well-established principles of statutory construction. Under the "last antecedent rule," "a limiting clause or phrase …should ordinarily be read as modifying only the noun or phrase that it immediately follows." *See Barnhart v. Thomas*, 540 U.S. 20, 26-28 (2003).

Indeed, federal agencies themselves regularly rely on their parallel authority under § 705 to postpone the effective date of agency action in order to allow sufficient time for implementation. For example, when the Environmental Protection Agency ("EPA") chose to review already-published air emissions standards under the Resource Conservation and Recovery Act, it invoked § 705 to postpone the effective date of those standards until several months after it planned to issue revisions to the regulations, explaining:

> Th[e review] process may result in compliance options that facilities do not now realize are available. To …ensure that all affected facilities have time to make any such alterations in their compliance plan prior to the effective date of the standards, EPA is postponing the effective date of the final rule for six months. The EPA considers a postponement of six months to be adequate time to allow for affected facilities to make any such necessary adjustments [after learning the result of the review process]. The EPA also believes that it would be inequitable not to postpone the effective date in light of the possibility of increased compliance flexibility ….

EPA, Notice of Postponed Effective Date, 60 Fed. Reg. 26,828, 26,828 (May 19, 1995) (citing 5 U.S.C. § 705).[24] The harm identified by the EPA—avoiding wasteful compliance costs—is precisely what Plaintiffs seek to avoid here.

As these examples illustrate, in many contexts, including this one, a postponement of complex regulatory requirements is the only way to avoid irreparable injury pending review. Major environmental regulations, or an industry-wide overhaul of product packaging, can of course not be completed overnight. And no responsible business would delay implementation of such regulations

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(continued…)

Here, the last antecedent before "pending conclusion of the review proceedings" is "to preserve status or rights." Thus, "to the extent necessary to prevent irreparable injury," 5 U.S.C. § 705 empowers a court either to (1) "postpone the effective date of an agency action," or (2) "preserve status or rights pending conclusion of the review proceedings."

[24] *See also* EPA, Amendment of Final Rule to Postpone Requirements, 61 Fed. Reg. 28,508, 28,508 (June 5, 1996) (postponing rule beyond agency review of final regulation "to allow facilities to avoid compliance expenditures based on the [original] final rule, expenditures which may prove unnecessary in light of the projected amendments"); Federal Trade Commission, Change In Effective Date of Portions of Final Trade Regulation Rule, 48 Fed. Reg. 45,537, 45,538 (Oct. 6, 1983) (postponing effective date of final regulation for four months to "enable petitioners to begin printing the forms necessary for compliance after the Fourth Circuit has had substantial time to consider their petition for review, thus minimizing the necessity to print forms twice should any alteration at all be ordered to the Rule by the Court").

and risk non-compliance if the regulations survive judicial review. A postponement of such requirements is therefore useless unless it includes a reasonable period for implementation *following* the conclusion of judicial review. That is, absent a reasonable implementation period, a postponement of the Rule will neither "prevent irreparable injury" nor "maintain status quo or rights pending judicial review."

Thus, it falls squarely within this Court's inherent equitable power and § 705 to postpone the effective date of the Rule to provide Plaintiffs the time allotted by Congress (15 months) to come into compliance once the final version of the rule (if any) is known. Any other result would expose Plaintiffs to irreparable harm. As neither Plaintiffs nor the Government can know the Rule's legal status until the conclusion of this litigation, Plaintiffs respectfully submit that this Court should exercise its inherent and statutory authority to issue the preliminary injunctive relief sought and postpone the effective date of the Rule to 15 months after the conclusion of review proceedings.

CONCLUSION

The Rule's warnings violate the First Amendment under any standard of review. In arguing otherwise, the Government asks this Court to blind itself to common sense as well as FDA's own findings. The Government's arguments are without limit: if the Court does not draw the line here, the Government could impose virtually any "warning" requirement on any product that it believes Americans should avoid. The First Amendment does not prevent the Government from telling consumers how to live their lives, but it does bar the Government from conscripting Plaintiffs as unwilling messengers in this paternalistic endeavor. Plaintiffs therefore respectfully request that this Court grant their Motion for Preliminary Injunction.

Respectfully Submitted,

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