IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs misapprehend several fundamental principles of First Amendment and administrative law in their challenge to the graphic warnings required by the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), as implemented by the Food and Drug Administration ("FDA"). Those legal principles, when properly applied, compel judgment in the government's favor. We discussed these principles and their application at length in our opposition to plaintiffs' summary judgment motion and cross-motion for summary judgment. Plaintiffs' Opposition adds little of substance to their previous filing, and our Reply will limit itself accordingly and will not repeat at length matters already fully treated.

ARGUMENT

I. Requirements that Sellers Disclose Serious Health Risks to Potential Consumers Are Not "Compelled Speech" or "Viewpoint Based Restrictions" Subject to Strict Scrutiny.

A. Virtually absent from plaintiffs' argument is any recognition that the statute they challenge regulates quintessential commercial speech, *i.e.*, advertisements proposing the sale of a product, and product packaging. *See, e.g.*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 97 (2d Cir. 1998) (explaining that product labels "are a form of advertising"). Regulations of commercial speech do not trigger the requirements of strict scrutiny. *See*, *e.g.*, *Bd. of Trustees v. Fox*, 492 U.S. 469, 479–80 (1989) (rejecting application of a "least-restrictive-means requirement" to restrictions on commercial speech); *Trans Union LLC v. FTC*, 295 F.3d 42, 52–53 (D.C. Cir. 2002) (declining to apply strict scrutiny to regulations restricting the disclosure of consumer credit information); *see also Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) ("To require a parity of constitutional protection for commercial and noncommercial

speech alike could invite dilution, simply by a leveling process, of the force of the Amendment's guarantee with respect to the latter kind of speech.").

Plaintiffs nonetheless argue that the requirements in the Tobacco Control Act for revised health warnings are subject to more stringent scrutiny than the review accorded to restrictions on commercial speech under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). But the Supreme Court has made clear that disclosure requirements are not subject to great scrutiny; indeed, requirements for disclosure to consumers are subject to "*less* exacting scrutiny" than restrictions on commercial speech because they are not affirmative limitations on speech. *Milavetz*, 130 S. Ct. at 1339 (emphasis added). Thus, a requirement that commercial actors disseminate factual and accurate information as part of their commercial communications must be sustained if the requirement is "reasonably related" to an identified governmental interest, and is not so "[u]njustified or unduly burdensome" as to "chill[] protected commercial speech." *Id.* at 1339–40 (citing *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651(1985)).

Plaintiffs seek to circumvent this difficulty by invoking a line of decisions addressing compelled ideological speech that have never been applied to the regulation of commercial speech. We explained in our Opposition/Cross-Motion that cases such as *Wooley v. Maynard*, 430 U.S. 705 (1977), *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974), and *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943), involved attempts by the government to "'prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein,'" *Zauderer*, 471 U.S. at 651, and are thus inapposite here. Gov't S.J. Br. 24–29.

In their Opposition, plaintiffs do not argue that the required health warnings are an effort to "prescribe what shall be orthodox in politics, nationalism, religion or other matters of opinion," and any attempt to do so would be implausible. Instead, they attempt to rely on yet other decisions that likewise did not concern regulation of commercial speech. *See* Pl. S.J. Opp. 4–5. For example, the passage plaintiffs quote from *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 641 (1994), did not address *commercial* speech, but instead addressed core protected speech. Similarly *Pacific Gas & Electric Co. v. Public Utilities Commission of California*, 475 U.S. 1, 8–9 (1986), specifically held that the speech at issue was *not* commercial speech. *See also United States v. Philip Morris*, 566 F.3d 1095, 1142 (D.C. Cir. 2009) (distinguishing *Pacific Gas & Electric* as not involving "the government's ability to dictate the content of mandatory speech" in the "commercial context."). The statement in *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573 (1995), that "a speaker has the autonomy to choose the content of his own message" likewise has no bearing on the commercial speech or product disclosure analysis here because it addressed non-commercial expressive conduct of parade marchers.

Plaintiffs' repeated references to the health warning as a "viewpoint-based restriction[]," Pl. S.J. Opp. 7, underscores the deep-seated flaws in their analysis. Plaintiffs identify no decision that has applied the rubric of viewpoint discrimination to regulation of commercial speech, let alone to any form of consumer warning or disclosure about product risks. Moreover, plaintiffs do not and cannot explain the nature of the "viewpoint discrimination." The statute mandates nine health disclosures:

> WARNING: Cigarettes are addictive.
> WARNING: Tobacco smoke can harm your children.

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

Each of these warnings is a statement of fact, not an expression of "viewpoint." Plaintiffs do not dispute the accuracy of any of these warnings, and do not challenge Congress's authority to mandate their inclusion on cigarette packaging. Pl. S.J. Br. 20.

B. Because plaintiffs do not and cannot take issue with the substance of the warnings, their argument necessarily depends on the claim that the inclusion of images fundamentally transforms the nature of the required disclosures in such a way as to require strict scrutiny. Pl. S.J. Opp. 10–12. Plaintiffs offer no doctrinal basis for this distinction, nor do they identify support for it in the record before Congress and the FDA. The images do not convey a message different than that of the accompanying text, and plaintiffs' Opposition makes no showing to the contrary. The agency explained that "the addition of graphics to warnings for cigarettes is a difference in form only and does not change the fundamental content of the messages, which convey factual information about smoking." 76 Fed. Reg. 36,628, 36,696 (Jun. 22, 2011). Plaintiffs provide no response to the FDA's clearly correct assessment. Similarly, although plaintiffs complain that some of the images include "digital enhancements," Pl. S.J. Opp. 10–11, they do not dispute FDA's explanation that the "effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease." 76 Fed. Reg. at 36,696. Indeed, the comments submitted to the agency during rulemaking "did not dispute that the images proposed

to accompany the warning statements accurately depict the negative health consequences of smoking." *Ibid.*

Plaintiffs fare no better with their claim that one of the images—that of an infant in an incubator—is a "non-factual cartoon drawing[]." Pl. S.J. Opp. 10–11. Plaintiffs do not take issue with FDA's explanation that "[t]he style of the depiction—here, a graphic illustration—does not make it less factual." 76 Fed. Reg. at 36,696. Indeed, plaintiffs concede that even more highly abstract graphics would be constitutionally permissible. Specifically, plaintiffs assert that the only acceptable images would be "charts or graphs," or abstract graphics like the following:

Pl. S.J. Opp. 10. There is no legal basis for treating the images chosen by FDA as raising different First Amendment concerns than plaintiffs' preferred style of graphic warning. Plaintiffs' graphic shows a hand about to be burned that, together with the text "HOT!", conveys the consequence of failing to heed the warning. The image of the baby in an incubator and the image of diseased lungs function in a similar fashion, by complementing and reinforcing the textual warnings that they accompany.

Moreover, if plaintiffs believed that FDA should have implemented the statutory mandate by adopting this type of image, it was incumbent on them to say so during the rulemaking. As a

result of their failure to do so, FDA had no opportunity to examine or respond to such alternatives. Plaintiffs thus should be deemed to have waived reliance on these alternatives. *See Advocates for Highway & Auto Safety v. Federal Motor Carrier Safety Admin.*, 429 F.3d 1136, 1150 (D.C. Cir. 2005).

C. We have previously discussed plaintiffs' misunderstanding of the concept of salience, Gov't S.J. Br. 34–37, a misunderstanding that plaintiffs repeat in declaring that the warnings impermissibly "evoke an emotional reaction against smoking," Pl. S.J. Opp. 10–11, and that FDA impermissibly considered the emotional reaction of viewers to the proposed warnings, *id.* at 12, 14. Plaintiffs, however, do not respond to FDA's explanation that consumers' emotional and cognitive responses to warnings are relevant *not* because they demonstrate that the warnings have "shock value," but because such responses reliably predict the likelihood that consumers will understand and appreciate the warnings' message. *See* FDA, Experimental Study of Graphic Cigarette Warning Labels, Final Results Report 4-1 (Dec. 2010) ("FDA Study Report"); *see also* 76 Fed. Reg. at 36,641 ("The overall body of scientific evidence indicates that health warnings that evoke strong emotional responses enhance an individual's ability to process the warning information, leading to increased knowledge and thoughts about the harms of cigarettes[.]"). More fundamentally, plaintiffs cite no case law suggesting that the *effect* of the warning on a viewer is relevant to the level of scrutiny owed to a commercial speech restriction.

Plaintiffs likewise reiterate their mistaken assertion that the inclusion of a telephone number for a nationally recognized smoking cessation resource—1-800-QUIT-NOW—renders the warnings subject to strict scrutiny. Pl. S.J. Opp. 12–13. Again, plaintiffs cite no case law or other doctrinal support for this assertion. Plaintiffs do not deny that their own websites contain

links to similar smoking cessation resources, and that Lorillard's website advises consumers to call the same resource that plaintiffs in this forum allege to be "ideological." *See* Gov't S.J. Br. 44–45. In any event, in context, the number at most conveys the same message as the warning statement "Quitting smoking now greatly reduces serious risks to your health."

The full anomaly of plaintiffs' invocation of strict scrutiny is demonstrated by their challenge to the size and placement of the health warnings. No principle of law suggests that a large health warning is subject to a different standard of constitutional scrutiny than a small warning. Similarly, there is no doctrinal support for the contention that warnings with images are subject to a different standard of scrutiny than warnings that do not include images.

II. The Statutory Requirement for Updated Health Warnings, and FDA's Implementation of that Requirement, Readily Survive First Amendment Scrutiny Under Any Standard of Review.

A. Plaintiffs' Request that this Court Reweigh the Scientific Evidence that Was Before Congress and the FDA Is Contrary to Controlling Precedent.

Under *Central Hudson*, regulations of commercial speech are upheld if they directly advance a substantial governmental interest. 447 U.S. at 566. Under *Zauderer* and *Milavetz*, a commercial disclosure requirement is subject to "less exacting scrutiny," and must be sustained so long as it is "'reasonably related'" to an identified governmental interest, and the disclosure is not so "[u]njustified or unduly burdensome" as to "chill[] protected commercial speech." *Milavetz*, 130 S. Ct. at 1339–40 (quoting *Zauderer*, 471 U.S. at 651). For the reasons already discussed, the statutorily required disclosures meet both of these standards. Moreover, although they are not subject to strict scrutiny, we explained in our motion for summary judgment that they would properly be upheld even if that standard were applicable. Gov't S.J. Br. 23. Plaintiffs nevertheless assert that the government has "waived" any contention that the statute

would survive strict scrutiny. Pl. S.J. Opp. 20. This assertion is incorrect and also fails to appreciate the gravity of the inquiry undertaken by a court when it considers the validity of an Act of Congress, particularly a statute that addresses the consequences of using plaintiffs' products which, "particularly among children and adolescents, pose[] perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

As our summary judgment motion explains, the revised health warnings serve public health interests of the highest order. *See* Gov't S.J. Br. 14–20. The purpose of the warnings is "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements." 76 Fed. Reg. at 36,697. Those interests are substantiated by a wealth of evidence gathered over decades by all three branches of government, public health organizations, and scientific researchers. That evidence, which is discussed at length in FDA's rule and in the government's Opposition/Cross-Motion, shows that: (1) consumers generally, and youth in particular, do not adequately appreciate the risks of smoking; (2) the current Surgeon General warnings, which occupy only four percent of the surface area of packaging and advertising, are "functionally invisible," 75 Fed. Reg. 69,524, 69,531 (Nov. 12, 2010); and (3) warnings like those mandated by the Act convey the warning message far more effectively than the current Surgeon General's warnings, particularly when paired with color graphics depicting the negative health consequences of smoking.

Plaintiffs improperly urge this Court to reweigh the costs and benefits of the rule and the scientific evidence that was before Congress and the FDA. Pl. S.J. Opp. 21–22. That approach is fundamentally inconsistent with First Amendment jurisprudence. The Supreme Court has

stressed that "[t]he Constitution gives to Congress the role of weighing conflicting evidence in the legislative process." *Turner Broadcasting System, Inc. v. FCC*, 520 U.S. 180, 199 (1997). Accordingly, in considering plaintiffs' constitutional challenges, the role of the Court is not to "reweigh the evidence *de novo*, or to replace Congress' factual predictions with [its] own." *Id.* at 211 (internal quotation marks and citation omitted). "Even in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Id.* at 196.

Thus, the "relevant inquiry" for the Court "is not whether Congress, as an objective matter, was correct" in its determinations as to the problems to be addressed or the tailoring of the remedies. *Id.* at 211. "Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress." *Ibid.* As long as that standard is satisfied, "summary judgment for [the government] is appropriate *regardless of whether the evidence is in conflict*." *Ibid.* (emphasis added).

B. Plaintiffs Offer No Valid Basis for Rejecting the Legislative Judgments Underpinning the Revised Health Warning Requirement.

Plaintiffs attack nearly all of the legislative judgments underpinning the revised health warnings. These arguments, however, share a common theme: they ignore all scientific findings that contradict plaintiffs' view of the "dispositive facts." Pl. S.J. Opp. 22. On each of these points, Congress's judgment regarding the necessity of revised warnings "was reasonable and supported by substantial evidence." *Turner Broadcasting System,* 520 U.S. at 211.

1. Plaintiffs dispute Congress's determination that the current warnings have not adequately informed consumers about the health risks of smoking. They urge that "the risks of smoking are universally known and, in fact, overestimated by the American public." Pl. S.J. Opp. 27. Plaintiffs' contention rests entirely on the declaration of their expert, Dr. W. Kip Viscusi, who posits that consumers have a sufficient understanding of the risks of smoking as long as they are aware that cigarettes commonly cause disease. *See* Viscusi Statement 14–16.

Scientific studies, however, have consistently and repeatedly shown that consumers do *not* adequately appreciate even the basic statistical risks of smoking.[1] *See generally* Gov't S.J. Br. 18–19, 29–31; 76 Fed. Reg. at 36,632. Thus, FDA noted that "[i]n a 2008 survey, more than one-quarter of current smokers did not agree that smoking increases a person's chances of getting cancer 'a lot.'" 76 Fed. Reg. at 36,632. Another study found that "only 40 percent of current smokers believed they had a higher-than-average risk of cancer and only 29 percent believed they had a higher-than-average risk of heart disease." *Ibid.* "Even among heavy smokers (those who smoke at least 40 cigarettes per day), less than half believed they were at increased risk for these diseases." *Ibid.*

Notably, the studies that plaintiffs rely upon actually support Congress's decision. For instance, plaintiffs cite one particular study because it included a finding that youth

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[1] Plaintiffs dispute the results of a 1981 review by the Federal Trade Commission finding that consumers were unaware of the health risks of smoking, by noting that the study was conducted before the revision of cigarette warnings in 1984, and that one of the researchers who provided data on which the FTC relied disputed the results of the review. Pl. S.J. Opp. 30–31; *see also id.* at 44. Plaintiffs fail to note, however, that the FTC study was cited by the Surgeon General's 1994 report, and was discussed in the government's brief only to counter plaintiffs' claim that the Surgeon General, in that report, had admitted that consumers already comprehend the risks of smoking, *see* Gov't S.J. Br. 15 n.6. In any event, the results of the FTC's 1981 review have only been reinforced by more recent studies.

"overestimated the extent to which smoking increases the risk of lung cancer," but neglect to mention the larger number of significant information gaps the same study also found. *See* Patrick Jamieson & Daniel Romer, *What Do Young People Think They Know About the Risks of Smoking?* in SMOKING: RISK, PERCEPTION & POLICY 51, 53 (Paul Slovic ed., 2001) (quoted in Pl. S.J. Opp. 28). Jamieson & Romer found that 20 percent of smokers and 19 percent of nonsmokers studied did not know whether secondhand smoke is hazardous to nonsmokers. *Id.* at 57. And, significantly, that study also concluded that "14- to 22-year-olds do not have a consistent and realistic sense of the addictive nature of smoking." *Id.* at 52.

In an effort to undermine the Jamieson & Romer study, plaintiffs mistakenly describe it as finding only that "when adolescent smokers were asked to estimate *the specific number of years* by which smoking shortens an average smoker's life, 28 percent stated they did not know." Pl. S.J. Opp. 29 (emphasis added). What that study actually showed is 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*. *See* Jamieson & Romer, *supra*, at 55–56; *see also* Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 90 (2007) ("IOM Report") (describing the Jamieson & Romer study in this way). For all of these reasons, plaintiffs cannot plausibly suggest that the government has "merely point[ed] to alleged information deficits on issues that the graphic warnings do not even purport to redress." Pl. S.J. Br. 28.

Moreover, to the extent that consumers have an accurate sense of certain statistical risks of smoking, Viscusi's belief in the adequacy of this statistical knowledge depends on a simplistic view of risk perception that has been persuasively rejected by independent experts in the field.

See, e.g., Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, in SMOKING: RISK, PERCEPTION, & POLICY 97, 107–110 (Paul Slovic ed., 2001) (detailing the "[s]hortcomings" in Viscusi's approach). Those experts have concluded that mere awareness that smoking carries negative health consequences, and even awareness of certain statistical risks, are insufficient to ensure that consumers appreciate the risks that smoking poses to them personally, in part because of the addictive power of nicotine. 76 Fed. Reg. at 36,632-33. Dr. Paul Slovic, for example, has explained that "[a]lthough most smokers acknowledge a high degree of risk associated with many years of smoking, many believe they can get away with some lesser amount of smoking before the risk takes hold." Slovic, *supra*, at 109. That prediction, as Slovic concluded, is usually proven false, because smokers start to show the effects of nicotine addiction "within *days to weeks* of the onset of occasional use of tobacco." *Ibid.* (emphasis added). Although the government cited Slovic's research in its opening brief, Gov't S.J. Br. 18–19, plaintiffs do not address it.

2. Plaintiffs' argument that "there is no evidence" that mandated health warnings "increase knowledge of smoking risks," Pl. S.J. Br. 33, likewise depends on studious avoidance of contrary scientific findings. *See generally* 76 Fed. Reg. 36,633–36 (discussing studies). As we explained at length in our Opposition/Cross-Motion, Gov't S.J. Br. 16–20, numerous studies examining pictorial warnings have concluded that such warnings *do* increase consumers' understanding of the health risks of smoking. *See, e.g.*, David Hammond, *Health Warnings Messages on Tobacco Products: A Review*, 20 Tobacco Control 327, 329–30 (2011). Plaintiffs have offered no convincing response to this body of scientific literature, which substantially supports Congress's decision to revise the health warnings.

Thus, although plaintiffs assert that the "studies relied upon in the Rule advocate the use of graphics based not on their factual content, but rather, on their ability to arouse 'fear, disgust, or anger,'" Pl. S.J. Opp. 13–14, each of the studies from which plaintiffs quote isolated sentences actually concludes that depictions of the health consequences of smoking *ensure* that consumers notice and remember the factual content of the health warning. David Hammond, whom plaintiffs repeatedly attempt to co-opt as supporting their position, *see, e.g.*, P.I. Hr'g Tr. 73, rejected their view decisively in the review article from which plaintiffs quote. Hammond's actual conclusion is that the existing studies "suggest that health warnings with pictures are significantly more likely to draw attention, result in greater information processing and improve memory for the health message." David Hammond, *Health Warnings Messages on Tobacco Products: A Review*, 20 Tobacco Control 327, 329–30 (2011). Likewise, Ellen Peters and her colleagues, from whose article plaintiffs also quote an isolated statement out of context, Pl. S.J. Opp. 14 & n.4, concluded that "considerable psychological research suggests that the mere presentation of hazard information is not sufficient to motivate perceptions of risk," and that "[r]isk is most readily communicated by information that arouses emotional associations with the activity." Ellen Peters, et al., *The Impact and Acceptability of Canadian-Style Cigarette Warning Labels Among U.S. Smokers and Nonsmokers*, 9 Nicotine & Tobacco Research 473, 479 (2007). And the review by Geoffrey T. Fong and colleagues likewise resoundingly supports Congress's and the FDA's position, rather than plaintiffs': "Taken as a whole, the research on pictorial warnings shows that they are: (i) more likely to be noticed than text-only warning labels; (ii) more effective for educating smokers about the health risks of smoking and for increasing smokers' thoughts about the health risks; and (iii) associated with increased

motivation to quit smoking." Geoffrey T. Fong, et al., *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, 87 Bulletin of the World Health Organization 640, 640 (2009).[2]

Similarly, an Australian study showed that, after Australia introduced larger pictorial warnings in 2006, "students were more likely to read, attend to, think about, and talk about health warnings." Hammond, *supra*, 20 Tobacco Control at 330 (citing Victoria White, et al., *Do Graphic Health Warning Labels Have an Impact on Adolescents' Smoking-Related Beliefs and Behaviors*?, 103 Addiction 1562 (2008)). Plaintiffs challenge the conclusions of this study—which was published in a peer-reviewed scientific journal—for failing to control for "new anti-smoking commercials [that] were aired on television" just prior to the survey. Pl. S.J. Opp. 38–39. But as the researchers undoubtedly recognized, there was no need to control for the commercials' effects, as they were created only to "promote the new warning labels," and "depict[ed] two of the new health warnings . . . used on cigarette packs." White, *supra* at 1563.

Rather than fairly address this full body of scientific evidence supporting the health warning requirement, plaintiffs make misguided attacks on a handful of selected studies. Thus, they criticize a 1995 study comparing Canadian warnings to U.S. warnings on the ground that the study "does not address graphic warnings at all." Pl. S.J. Opp. 38; *see also id.* at 44 (same).

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[2] *See also* 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 Pl. S.J. Opp. 14 n.5) ("Regarding cognitive reactions, graphic warnings are more visible . . . , easier to understand and increase awareness and knowledge of the health hazards of smoking."); European Commission, Directorate General for Health and Consumers, *A Review of The Science Base to Support the Development of Health Warnings for Tobacco Packages* (2009) (cited in Pl. S.J. Opp. 14 n.5) ("Combined pictorial + text warnings are significantly more effective than text only warnings, especially educating the public of the health risks and changing consumer behaviour. They are also more effective than text only in minimising 'wear out' over time.").

That study examined the difference between Canadian text-only warnings and U.S. warnings at a time when the Canadian warnings were prominently displayed on the fronts of cigarette packs. *See* IOM Report at C-4. The study's finding that "83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages, compared to only 7 percent of U.S. students," *ibid.*, is thus relevant to plaintiffs' challenge to the size and placement of the warning.

Plaintiffs also continue their mistaken reliance on FDA's consumer research study as proof that the updated health warnings will not "affect consumers' knowledge of smoking risk or smoking intentions." Pl. S.J. Opp. 33, 36. But plaintiffs fail entirely to address FDA's point that this study was not designed to provide an assessment of this sort, but instead only to provide one basis for assessing the *relative* impact of different pictorial warnings based on participants' exposure to one warning on one occasion. 76 Fed. Reg. at 36,639.

Plaintiffs make a few additional points regarding the efficacy of the graphic warning requirement, none of which have merit. Plaintiffs urge that the required warnings will have no effect on smokers, because of "the common phenomenon of 'optimism bias,' *i.e.*, many people believe (irrationally) that their chances of avoiding known risks are better than average." Pl. S.J. Opp. 29. In a similar vein, plaintiffs contend that providing children and youth with "additional 'purely factual and uncontroversial'" information is pointless given the Government's view that children and adolescents are "not capable of making a fully informed decision whether or not to start or continue smoking." *Id.* at 31. These arguments, however, cut in the government's favor: the fact that consumers, by reason of their age, their naivete, or their addiction to nicotine, tend

to discount health warnings provides ample basis for Congress's decision to implement prominent warnings that cannot be easily ignored.[3]

3. Plaintiffs likewise err in claiming that the size and placement of the warnings mandated by Congress—the top half of the front and back of cigarette packages and the top twenty percent of advertisements—"exceeds anything plausibly necessary to dispassionately inform consumers of even the most serious health risks." Pl. S.J. Opp. 8–10. FDA and outside experts have reasonably concluded that the current size and location of cigarette warnings renders them "functionally invisible," 75 Fed. Reg. at 69,531; *see also* Testimony of Richard Bonnie, Chair of IOM's Committee on Reducing Tobacco Use, H.R. 1108, Family Smoking Prevention & Tobacco Control Act: Hearing Before the House Subcommittee on Health, Committee on Energy and Commerce, 110th Cong. 42 (2007). Congress's decision to increase the size of the warning and move it to a more prominent location is eminently sensible in light of the serious and undisputed harms created by use of plaintiffs' products.

Plaintiffs erroneously assert that because many over-the-counter drugs display warnings on the back or side of packaging, there is no reason for the warnings here to be displayed on the front and back of packaging. *See* Pl. S.J. Opp. 8–9 (reproducing packaging for heartburn medication). But over-the-counter drugs are wholly unlike plaintiffs' products, which are lethal

[3] Plaintiffs also dispute Congress and FDA's reasonable conclusion that, even beyond pictorial warnings' demonstrated ability to convey health risks to consumers in general, such warnings can be additionally justified on the ground that they are particularly important for communicating to consumers with low education levels. Pl. S.J. Br. 41–42. Although plaintiffs dispute the relevance of one of the scientific studies cited, *ibid.*, they do not challenge FDA's finding that "research shows that knowledge of smoking risks is lower among people with lower incomes and fewer years of education." 76 Fed. Reg. at 36,633. Congress was not required to adopt plaintiffs' solution of providing text-only warnings, particularly given evidence that graphic warnings are more effective.

and addictive when used as intended. That difference alone justifies placing warnings on cigarette packs in a more prominent location. Furthermore, unlike medical product warnings, cigarette warnings are not intended to enable consumers to safely use the product, as there is no safe method of using cigarettes. Rather, cigarette warnings promote awareness of cigarette-related health risks.

Plaintiffs are similarly incorrect in their assumption that product warning labels are commonly relegated to the backs or sides of product packaging, in a format that "occup[ies] no more space than necessary to render the relevant text readable." Pl. S.J. Opp. 9. The Consumer Product Safety Commission (CPSC) regularly requires potentially dangerous products to carry large warnings on the front of product packaging. For example, in 1996, based on evidence that then-existing warnings on packages of charcoal had been insufficient to prevent roughly 28 carbon-monoxide deaths per year caused by consumers burning charcoal in enclosed spaces, CPSC engaged in rulemaking to "make the label more noticeable and more easily read and understood." 61 Fed. Reg. 19,818, 19,818 (May 3, 1996). The revised label occupies a substantial portion of the front of charcoal bags, thus belying plaintiffs' claim that the size and placement of the warnings here represent a departure from other product warning labels.[4]

4. Plaintiffs also reiterate their argument that the warnings must be invalidated because the government provided "no evidence" that the graphic warnings will have "any statistically significant impact on smoking prevalence." Pl. S.J. Opp. 22, 25. Plaintiffs fail, however, to respond to the point that the First Amendment does not require the government to make a showing of this sort. *See* Gov't S.J. Br. 31–32.

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[4] *See* http://www.acetogo.com/photo/product/8281271.jpg (last accessed 12/7/2011).

In any event, plaintiffs are simply incorrect that the government provided "no evidence" that the revised health warnings will likely reduce smoking rates. *See id.* at 32–33. Plaintiffs seek to diminish the studies cited by the government by claiming that they only examine whether the warnings make study participants "more *motivated* to quit," and that this measure may be tainted by "social desirability bias, wherein test subjects are biased in favor of providing a socially desirably response." Pl. S.J. Opp. 25. But plaintiffs fail to address FDA's finding that "[t]he more recent scientific literature shows that statements by smokers concerning their intentions to quit smoking *are predictive* of their making subsequent quit attempts." 75 Fed. Reg. 52,352, 52,354 (Aug. 25, 2010) (emphasis added). Moreover, many of the cited studies in fact asked more than just whether smokers were motivated to quit, and assessed consumers' actual reduction in smoking. *See, e.g.*, 75 Fed. Reg. at 69,532 (noting that in one Canadian study, twenty-six percent of smokers who quit after the introduction of graphic warnings reported that the "graphic warnings on cigarette packages helped them remain abstinent"); Hammond, 20 Tobacco Control at 331 (summarizing the results of fifteen studies, and concluding that "significant proportions of adult and youth smokers report that large text and pictorial health warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit and increased the likelihood of remaining abstinent following a quit attempt"). Plaintiffs offer no response to these scientific findings.

III. Plaintiffs' Purported APA Claim Suffers from the Same Defects as Their First Amendment Argument and Reduces to the Contention that FDA Should Have Declined To Implement the Statutory Mandate.

Plaintiffs' APA arguments continue to conflate the First Amendment and APA analyses and the distinct institutional roles of Congress and the FDA. At bottom, plaintiffs' APA challenge is premised on a fundamental misunderstanding of FDA's role in implementing the warnings that Congress mandated in the statute and a mischaracterization of the agency's decision-making process.

A court will hold unlawful and set aside agency action under the APA only if the action is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2). The agency action at issue in this case is FDA's selection of the specific color images that are to accompany the textual warnings Congress selected. Congress itself mandated that such graphics accompany the textual warnings, and it further determined the size of the warnings and their placement on cigarette packaging and advertisements. *See* 15 U.S.C. § 1333 Note. Thus, as relevant, only the composition of the specific images was left to FDA's discretion.

Plaintiffs' assertion that FDA was free to disregard the statutory mandate is based on a misreading of the relevant statutory provisions. *See* Pl. S.J. Opp. 48–49. While § 201(a) of Act affords the Secretary leeway to "adjust the type, size, text and format of the label *statements*," that is, the textual portion of the warnings, that section does not authorize FDA to reduce the overall size of the warning or exclude graphics. 15 U.S.C. § 1333 Note (emphasis added) (stating that any such adjustments must ensure, among other things, that the graphic and text "appear within the specified area"). Although a separate provision of the Act gives FDA authority to engage in rulemaking to "adjust the format, type size, color graphics, and text of any

of the label requirements," that provision requires a "find[ing] that such a change would *promote greater public understanding of the risks associated with the use of tobacco products*." Act § 202(b) (emphasis added). No such finding supports plaintiffs' proposal to have "the Tobacco Control Act's new textual warnings be displayed in the same manner in which the Surgeon General's warnings have been displayed for years," Comment Letter 3–4, and accordingly § 202(b) is of no aid to plaintiffs here.

Plaintiffs' APA challenge to FDA's rule is thus inextricably intertwined with their challenge to the statutory mandate that the agency faithfully implemented. Neither in their Opposition nor at any prior point have plaintiffs identified any image chosen by the FDA that is inconsistent with the statutory mandate. Indeed, as explained at length in our summary judgment motion, the agency, in exercising its delegated authority, engaged in a detailed examination of potential images. Based on the ample evidence it collected, the agency selected nine images that, together with the warning statements, would most effectively convey the health risks of smoking to consumers. *See* Gov't S.J. Br. 34–45. Specifically, FDA initially selected thirty-six images as candidates to accompany the textual warnings. The agency then subjected those images to rigorous review in order to ascertain which mix of images would most effectively assist in conveying to a broad range of consumers the information in the text warnings. A study involving 18,000 participants compared the images' effect on several different variables, including the salience metrics discussed above.[5] *See* 76 Fed. Reg. at 36,639. As explained in the

[5] Plaintiffs' claim that the findings of the FDA study are "consistent with random sampling error," Pl. S.J. Opp. 33–34, depends on ignoring the numerous and statistically significant salience findings, which, as explained, showed that the selected warnings were likely to effectively convey the warning messages. Thus, while plaintiffs claim that the Viscusi statement "tabulat[es] results of [the] FDA Study Report," *id.* at 33, Viscusi actually excludes all

government's summary judgment brief, Gov't S.J. Br. 34–37, 49–50, these salience metrics provided an appropriate basis for distinguishing among potential images because they predict the likelihood that viewers will notice and process the information contained in the text. *See* FDA Study Report at 1-2, 4-1 (citing studies); 76 Fed. Reg at 36,639 (same). Relying in large part on the results of that study, FDA in its final rulemaking selected nine images from the initial thirty-six. FDA also looked to the experience of other countries, including Canada, and to studies documenting the efficacy of the images used in such countries to convey information about the health risks of smoking. *See, e.g.*, 76 Fed. Reg. at 36,636. Plaintiffs offer no challenge to this method of selecting pictorial warnings.

Indeed, each of plaintiffs' supposed APA challenges to the rule underscores the extent to which their quarrel is not with the agency, but with Congress. Plaintiffs first urge that the rule is arbitrary and capricious because "the Rule is not expected to advance the goal of reducing smoking in a statistically significant way." Pl. S.J. Opp. 48. They also contend that FDA erred in failing to consider less burdensome alternatives to the pictorial warnings, and that FDA's cost-benefit analysis ignores obvious costs and does not support the decision to require pictorial warnings. *Id.* at 46–48. Among other problems, each of these claims is properly leveled at the initial decision to require that images accompany the textual warnings—a decision made by Congress rather than FDA. As noted, FDA had no authority to second-guess that decision, nor was it under any obligation to amass a record supporting it. Instead, the administrative record is appropriately tailored to the task with which FDA was actually charged—*i.e.*, selecting the specific images that are to accompany the textual warnings chosen by Congress. The

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of the study findings regarding salience. *Compare* Viscusi Statement 70–73 *with* FDA Study Report appx. C, table C.1.

consideration of alternative measures and the costs and benefits of requiring pictorial warnings were likewise matters for Congress to address when it enacted the warnings requirement in the Tobacco Control Act. Accordingly, they are not properly the subject of an APA challenge.

Although these flaws suffice to dispose of plaintiffs' claims, it is worth noting some of the arguments' additional defects. Plaintiffs have largely abandoned their reliance on the rule's regulatory impact analysis (RIA), which, as explained, *see* Gov't S.J. Br. 46–47, was undertaken in compliance with Executive Orders designed to "improve the internal management of the Federal Government," Executive Order 12,866, § 10, 58 Fed. Reg. 51,735, 51,744 (1993); *see* Executive Order 13,563, § 7(d), 76 Fed. Reg. 3,821, 3,823 (2011), and *not* as a basis for justifying either the rule or Congress's decision to mandate graphic warnings. Nevertheless, plaintiffs continue to mischaracterize the RIA, which does not in fact predict that the new warnings will have little if any impact on smoking rates. *See* Pl. S.J. Opp. 48. As explained, plaintiffs' contrary argument depends on wrenching caveats in the RIA from their context. In full, the relevant sentence states: "Although both of the estimation methods . . . lead to the conclusion that graphic warning labels will reduce smoking rates, FDA has had access to very small data sets, so our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate." 76 Fed. Reg. at 36,776. That statement emphasizes that FDA's best estimates suggest a reduction in smoking rates while acknowledging the methodological challenges inherent in the analysis.

To the extent plaintiffs raise claims potentially cognizable under the APA, their arguments are entirely without merit. It is difficult to understand why FDA's rejection of certain

comments for lacking a "scientific" basis "reflects a lack of the even-handedness required by the APA." Pl. S.J. Opp. 49 & n.28. As exhaustively detailed in the government's briefs to this Court and in the rule's preamble, FDA exercised its discretion in selecting images to accompany the warning statements on the basis of an ample body of scientific evidence, and FDA's rejection of comments that were not so supported was not arbitrary or capricious. Similarly insubstantial is plaintiffs' assertion that FDA failed "to include in the record information necessary to 'provide the public with a meaningful opportunity to comment' on the Proposed Rule." *Id.* at 52. Plaintiffs fail to explain exactly how any supposedly missing information was necessary to permit them to respond fully to FDA's proposed rulemaking.

IV. Plaintiffs Provide No Proper Legal Basis for Their Request To Delay Implementation of the Warning Requirements.

Plaintiffs ask this Court to invalidate FDA's regulation and, in doing so, take the further step of ordering that any *new* regulation not be effective until 15 months after its issuance. As explained, because plaintiffs' challenge to the rule is meritless, their request for this relief is moot. *See* Gov't S.J. Br. 54. But in any event, there would be no legal basis for this relief even if plaintiffs prevail on some portion of their claim. Plaintiffs do not deny that the APA authorizes judicial review of final agency action on the basis of an administrative record compiled by the agency, and permits a court only to "set aside" those actions. *See* 5 U.S.C. § 706. Nor do plaintiffs deny that the APA does not permit a court to mandate the contours or effective date of action yet to be taken; these are matters left to the agency's discretion in the first instance. There is thus no basis at this juncture for addressing plaintiffs' contention that a hypothetical future regulation with an effective date earlier than 15 months would be contrary to the terms of the Tobacco Control Act.

Respectfully submitted,

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