UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56, the defendants move for summary judgment in this action. The grounds for this motion are set forth in the memorandum filed herewith.

Respectfully submitted,

Dated: October 21, 2011

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND SUMMARY

1. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), empowers the Food and Drug Administration ("FDA") to regulate the manufacture and sale of tobacco products, including cigarettes and smokeless tobacco. As relevant here, the Act revises the content and format of the health warnings that, for decades, have been required on cigarette packaging and advertising.

The Act specifies the text of nine health warnings, which include messages such as "Cigarettes are addictive," "Cigarettes cause cancer," "Tobacco smoke can harm your children," and "Quitting smoking now greatly reduces serious risks to your health." 15 U.S.C. § 1333 Note. The Act also specifies the format of the warnings, which will comprise the top 50% of the front and rear panels of cigarette packs and 20% of cigarette advertising. *Ibid*. In addition, Congress directed the Secretary of Health and Human Services to "issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the new warning statements. *Ibid*. Congress "informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada," which had proven significantly more effective in conveying the risks of smoking than the warnings used in the United States. *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 531 (W.D. Ky. 2010), *appeals pending sub nom. Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir.).

Pursuant to Congress's directive, FDA published for public comment 36 proposed images. *See* 75 Fed. Reg. 69,524, 69,534 (Nov. 12, 2010). In selecting the final set of nine images, FDA reviewed over a thousand public comments as well as the results of an 18,000-person consumer research study, and a wealth of other relevant scientific and academic material. *See* 76 Fed. Reg.

36,628, 36,629, 36,637 (June 22, 2011); *see also* Certified Index to the Administrative Record.[1] FDA explained that the final set of images is "generally consistent with the graphic health warnings used in other countries," *id*. at 36,647, and "effectively communicates risk information to a diverse range of audiences," including the adolescent population that has been "targeted by tobacco industry marketing efforts." *Id*. at 36,636.

2. Plaintiffs acknowledge, as they must, that the warnings prescribed by Congress are accurate. Cigarettes *are* addictive, and they *do* kill smokers when used as intended, by causing cancer, fatal lung disease, strokes and heart disease. Secondhand smoke *does* kill family and friends. And it is not controversial that "[q]uitting smoking now greatly reduces serious risks to your health."

Congress does not infringe on protected First Amendment interests when it requires accurate disclosures in marketing. As the Supreme Court explained in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 650 (1985), there are "material differences between disclosure requirements and outright prohibitions on speech." Unlike restrictions on speech, warnings and other disclosure requirements do not prevent advertisers "from conveying information to the public"; they only require sellers to provide "more information than they might otherwise be inclined to present." *Ibid.* Claims that disclosure requirements are so burdensome that they "chill[] protected commercial speech," *id.* at 651, are reviewed under the framework established by *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), for restrictions on commercial speech. *See Zauderer*, 471 U.S. at 651 & n.14. The health warnings mandated by Congress easily survive scrutiny under any applicable standard.

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[1] On October 19, we served on plaintiffs' counsel the certified index to the administrative record, which is attached to this memorandum. As per Local Rule 7(n) of this Court, within 14 days of the final brief, we will file an appendix with the administrative materials which the parties have cited or on which they have relied. If the Court requires access to parts of the record not cited by the parties, we will submit them to the Court.

3. The plaintiff cigarette manufacturers can no longer directly dispute the adverse health consequences of smoking or the nature of nicotine addiction, as they did for decades in a massive scheme of fraud and deception. *See United States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010). They are, however, quite capable of ignoring those consequences, and ask this Court to do the same in considering the interests advanced by the health warnings, and the relationship between the warning format and the public health threats posed by plaintiffs' products. Plaintiffs' pleadings give no inkling "that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). They nowhere acknowledge the tenacity of nicotine addiction, even though the manufacturers have "engineered their products around creating and sustaining this addiction." *Philip Morris*, 566 F.3d at 1107. Their pleadings give no hint that the "overwhelming majority" of new victims of nicotine addiction begin using tobacco products "while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Legislative Finding 31.[2] And no reader would discern from plaintiffs' submissions that the "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products," Legislative Finding 15, and that "[t]he central purpose of the tobacco companies' image advertising is motivating adolescents to smoke." *United States v. Philip Morris USA, Inc., et al.*, 449 F. Supp. 2d 1, 572 (D.D.C. 2006).

Only by ignoring the findings of Congress, the courts, and countless public health officials, can plaintiffs discount the compelling governmental interest in communicating health risks to consumers and potential consumers of their product—including the underage and often

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

undereducated persons who constitute the bulk of their new clientele. And only by ignoring the record before Congress, and the overwhelming international consensus of public health officials, can plaintiffs attempt to claim that a text-only disclosure of the same size as the current Surgeon General warnings could communicate the health risks of smoking as effectively as the revised warnings prescribed by Congress.

Perhaps most notably, it is only by ignoring the addictive and lethal nature of their products that plaintiffs can with a straight face describe the disclosures mandated by Congress as "an ideological message" akin to the "compelled speech" involved in cases such as *Wooley v. Maynard*, 430 U.S. 705 (1977). Pl. S.J. Br. 24. Decisions such as *Wooley* reflect the core First Amendment principle that government shall not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." *Zauderer*, 471 U.S. at 651 (internal quotation marks omitted). Those decisions have no application here. That "smoking can kill you" is not an ideological message: it is a fact. There is no competing "ideology" maintaining that smoking does *not* account for more than 400,000 deaths each year.

4. Plaintiffs move seamlessly from decrying the burden of the disclosure requirements to insisting that the revised warnings would have no impact on smoking rates and thus serve no legitimate purpose. This relentlessly repeated refrain ignores two critical points. First, the purpose of the new disclosure format is to convey the health risks of smoking. Plaintiffs offer no basis whatsoever for disregarding Congress's judgment that the revised health warnings communicate those risks more effectively than warnings without accompanying graphics, even as compared to text-only warnings that are far larger than the current Surgeon General warnings. The precise extent to which the enhanced communication of risks will ultimately reduce smoking rates is not a relevant metric in assessing plaintiffs' constitutional claim. Second, plaintiffs' contention fails on its own

terms. Contrary to plaintiffs' assertion, researchers have *not* concluded that the introduction of new warnings in Canada had no bearing on the subsequent decrease in Canadian smoking rates. Instead, researchers have recognized that the decline in Canadian smoking rates was influenced by a variety of regulatory measures and that it is difficult to make statistically significant determinations about the extent to which any single factor contributed to the decline.

STATEMENT

A. Background

Congress crafted the provisions of the Tobacco Control Act on the basis of evidence gathered over decades by all three branches of government regarding the health risks posed by cigarettes and the tobacco industry's marketing of those products. This background is crucial to understanding the nature and scope of the problems addressed by the new health warnings, the reasons that Congress required the new format, and why the revised warnings do not run afoul of the First Amendment.

First, when used as intended by the manufacturers, cigarettes are deadly. "[T]obacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 161. Smoking "is responsible for at least 443,000 premature deaths per year in the United States." 76 Fed. Reg. at 36,630. It "'kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.'" *Brown & Williamson*, 529 U.S. at 134–35 (quoting 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996)); *see also* 75 Fed. Reg. at 69,526 (same). Because cigarettes are inherently dangerous when used as intended by their manufacturers, they would be banned outright if they were subject to regulation as drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), *see Brown & Williamson,* 529 U.S. at 136, and, in light of current knowledge, if cigarettes "were being introduced for the first time," they

"would not be allowed to enter the marketplace." Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation*, at 152 (2007) ("IOM Report") (discussed in H.R. Rep. No. 111-58(I) (2009)).

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

The tobacco industry has long understood the importance of nicotine addiction to their sales. An internal R.J. Reynolds memo from 1972, quoted by Congressman Ganske in 2000, acknowledged: "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiologic effects." 146 Cong. Rec. H1849 (April 5, 2000).[3] Plaintiffs' own expert in *Commonwealth Brands* emphasized the tenacity of the addiction to nicotine, which, he explained, is the "substance in tobacco that inveterate smokers crave." Rodu Decl. ¶ 40 (R. 72-2, No. 1:09-cv-117 (W.D. Ky.)). Tobacco companies "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction." Legislative Finding 49.

Third, the tobacco industry has long depended on recruiting underage users who become

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

addicted by age 18. A 2008 study found that *each day*, nearly 4,000 Americans under the age of 18 experiment with cigarettes for the first time, and approximately 1,000 children become new daily smokers. 75 Fed. Reg. at 69,526–27. Congress found that—despite laws prohibiting the sale of tobacco products to minors—the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Legislative Finding 31; *see also* 75 Fed. Reg. at 69,526 ("more than 80 percent of established adult smokers began smoking before age 18"); *Philip Morris*, 449 F. Supp. 2d at 562 ("over 80% of smokers start smoking before they turn eighteen"). According to a national survey of U.S. high-school students conducted in 2009, "almost half (46.3 percent) . . . had tried cigarette smoking, and an estimated 19.5 percent . . . were current cigarette smokers." 75 Fed. Reg. at 69,526.

The adolescents who become the industry's new customers systematically "misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior." IOM Report at 93; *see also Philip Morris*, 449 F. Supp. 2d at 576–80. One survey showed that "fewer than 5 percent of daily smokers in high school think that they still will be smoking at all in 5 years, yet more than 60 percent of high school smokers are regular daily smokers 7 to 9 years later." 76 Fed. Reg. at 36,633. Indeed, scientific research has shown that "adolescents begin to show evidence of nicotine dependence within *days to weeks* of the onset of occasional use of tobacco." Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, in SMOKING: RISK, PERCEPTION, & POLICY 97, 109 (Paul Slovic ed., 2001) (emphasis added).

Tobacco companies have long known that they must reach potential customers while they are underage, and have targeted their marketing accordingly. Congress found that "[a]dvertising,

marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Legislative Finding 15; *see also, e.g.*, *Philip Morris*, 449 F. Supp. 2d at 572 (finding that "[t]he central purpose of the tobacco companies' image advertising is motivating adolescents to smoke").

Fourth, the tobacco industry has for decades misled customers and potential customers about the health risks and addictiveness of cigarettes. The tobacco companies' "efforts to deny and distort the scientific evidence of smoking's harms are demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *Philip Morris*, 449 F. Supp. 2d at 855. The D.C. Circuit expressly concluded, when it rejected the companies' First Amendment defenses to racketeering liability, that the tobacco companies' public statements were "clearly and deliberately false," and that they "knew of their falsity at the time and made the statements with the intent to deceive." *Philip Morris*, 566 F.3d at 1124. Indeed, the industry's joint public relations representative admitted internally that the industry's "'basic position in the cigarette controversy is subject to the charge, and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes.'" *Id*. at 1120 (citation omitted).

B. The Supreme Court's *Brown & Williamson* Decision

FDA issued regulations in 1996 to regulate cigarettes and smokeless tobacco. 61 Fed. Reg. 44,396 (Aug. 28, 1996). The Supreme Court ultimately concluded that FDA generally lacked authority under the FDCA to promulgate those regulations, but the Court left no doubt as to the seriousness of the public health crisis that FDA had addressed. *Brown & Williamson*, 529 U.S. at 126. The Court emphasized that, "[i]n its rulemaking proceeding, the FDA quite exhaustively

documented that 'tobacco products are unsafe,' 'dangerous,' and 'cause great pain and suffering from illness.'" *Id*. at 134 (quoting 61 Fed. Reg. at 44,412). The Court recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." 529 U.S. at 161.

Indeed, the dangers of smoking were central to the Supreme Court's reasoning. The Court concluded that *because* cigarettes are inherently dangerous when used as intended by their manufacturers, cigarettes would have to be banned outright if they were subject to regulation as drugs under the FDCA—a result that Congress had not authorized. *Id*. at 136; *see also id*. at 142 ("As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect." (emphasis in original)).

The Court also noted FDA's determination that a cigarette ban was not a practicable means to address the public health crisis caused by cigarettes, given "the high level of addiction" among smokers. *Id*. at 139. The Court did not question FDA's conclusion that, if cigarettes were banned, "current tobacco users could suffer from extreme withdrawal, the health care system and available pharmaceuticals might not be able to meet the treatment demands of those suffering from withdrawal, and a black market offering cigarettes even more dangerous than those currently sold legally would likely develop." *Ibid.* (citing 61 Fed. Reg. at 44,413). The Court concluded, however, that the FDCA did not permit FDA to take such considerations into account. *See id*. at 139-142.

C. The Tobacco Control Act

Congress enacted the Tobacco Control Act in 2009 to fill the regulatory void left by *Brown & Williamson*. As relevant here, the Act updated, for the first time since 1984, the health warnings that must appear by federal law on cigarette packaging and advertising, to ensure that cigarette manufacturers effectively inform smokers and potential smokers of the health risks and

addictiveness of cigarettes. 15 U.S.C. § 1333 Note. The Act provides that product labels and advertisements for cigarettes must bear one of several prominent warning statements describing the adverse health effects of smoking, including statements regarding addictiveness and the impact on smokers and nonsmokers. *Ibid*. The required statements are:

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

Ibid.

The Act also revised the format of the warnings, by providing that they must comprise the top 50% of the front and rear panels of cigarette packs and 20% of cigarette advertising. *Ibid*. In addition, Congress directed the Secretary to promulgate regulations "that require color graphics depicting the negative health consequences of smoking to accompany" the text of these nine warnings. *Ibid*.

D. FDA's Implementing Rule

Pursuant to that statutory directive, FDA published for comment a total of 36 proposed images to accompany the textual warnings. *See* 75 Fed. Reg. at 69,534. In developing the proposed images, FDA drew upon the advice of "various experts in the fields of health communications, marketing research, graphic design and advertising," a substantial body of scientific literature analyzing the effectiveness of such warnings, and the experience of the more than thirty countries and jurisdictions that have, since 2001, implemented pictorial health warnings on cigarette packages. *Id*. at 69,525, 69,534.

In selecting the final nine images, FDA reviewed well over a thousand public comments, including joint comments submitted by plaintiffs R.J. Reynolds ("Reynolds"), Lorillard, and Commonwealth Brands. *See* 76 Fed. Reg. at 36,629. FDA also reviewed the results of an 18,000-person consumer study that tested the relative effectiveness of the 36 proposed images in communicating the information in the text. *See* FDA, Experimental Study of Graphic Cigarette Warning Labels, Final Results Report (Dec. 2010) (hereinafter "FDA Study Report"). FDA emphasized "the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.*, photographic versus illustrative), themes, and human images (*e.g.*, race, gender, age)." 76 Fed. Reg. at 36,636. That diversity is necessary to ensure that "the final set of required warnings effectively communicates risk information to a diverse range of audiences," including audiences, like youth, that "have been targeted by tobacco industry marketing efforts." *Ibid.*

The pictorial health warnings included in the final rule are, FDA explained, "generally consistent with the graphic health warnings used in other countries." 76 Fed. Reg. at 36,647. For instance, in Canada, images similar to the ones selected by FDA have appeared on cigarette packs for more than a decade. *See* Health Canada, *Graphic Health Warnings*.[4] Similar warnings have appeared on cigarette packs in Australia since 2006 and in the United Kingdom since 2008.[5] *See also, e.g.*, European Commission Directorate General For Health and Consumers, *Pictorial Health Warnings*, at http://ec.europa.eu/health/tobacco/law/pictorial/index_en.htm.

When FDA evaluated the comments to the rulemaking, it specifically addressed contentions

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[4] http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/label-etiquette/graph/index-eng.php. The websites cited in this brief were last visited on October 10, 2011.

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

that images provoke emotions rather than convey information. The agency noted, for example, that some comments had criticized various proposed images as "'disturbing'" or "eliciting emotions," including the image "depicting a man smoking through a tracheostomy opening," the image "depicting healthy lungs juxtaposed with lungs damaged by smoking," the image "depicting a lesion consistent with that caused by oral cancer," and the image "depicting a man with an autopsy scar." 76 Fed. Reg. at 36,696. FDA explained that "[t]he comment did not assert, however, that the effects shown in the images are false, *i.e.*, that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death." *Ibid.* The agency emphasized: "The fact that the images are disturbing or evoke emotion does not mean that they are not factual representations of the effects of smoking. . . . As such, it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen." *Ibid.*

FDA explained that the emotional responses are germane because they predict the likelihood that viewers will notice and process the accompanying textual information. The agency stressed that "[t]he 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 and the extent to which the individual could personally experience a smoking-related disease." *Id*. at 36,641. The images selected "were designed to correlate with [the] warning statements," and the "available evidence base highlights the value of the text and images in graphic health warnings relating to one another in a meaningful way." *Id.* at 36,637 (citations omitted).

ARGUMENT

I. Warnings and Other Disclosure Requirements Are Subject To "Less Exacting Scrutiny" Than Restrictions On Commercial Speech.

The Supreme Court has long recognized that there are "material differences between disclosure requirements and outright prohibitions on speech." *Zauderer*, 471 U.S. at 650. Warnings and other disclosure requirements do not prevent advertisers "from conveying information to the public"; instead, they require sellers to provide "more information than they might otherwise be inclined to present." *Ibid.* Thus, the Supreme Court has explained, disclosure requirements are subject to "less exacting scrutiny" than restrictions on commercial speech. *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339–40 (2010).

In general, mandated disclosures raise First Amendment concerns only when it is claimed that "unjustified or unduly burdensome disclosure requirements . . . [are] chilling protected commercial speech." *Zauderer*, 471 U.S. at 651 & n.14. Such claims are evaluated under the framework established by *Central Hudson*, 447 U.S. 557, for review of restrictions on commercial speech. *See Zauderer,* 471 U.S. at 651. In applying those standards, a court upholds restrictions that directly advance a substantial government interest and are no more extensive than is necessary to serve that interest. *Central Hudson*, 477 U.S. at 566. That standard does not require the legislature to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient to achieve a "reasonable" fit by adopting regulations "'in proportion to the interest served.'" *Ibid*. (citation omitted).

When the Supreme Court described in *Zauderer* the standard of scrutiny that applies to disclosure requirements in the commercial speech context, it expressly distinguished its cases involving "compelled speech" in areas of core protected speech. The Court noted that, "to be sure,"

it has "held that in some instances compulsion to speak may be as violative of the First Amendment as prohibitions on speech." *Zauderer*, 471 U.S. at 650 (citing *Wooley*, 430 U.S. 705; *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974); and *West Virginia State Bd. of Ed. v. Barnette*, 319 U.S. 624 (1943)). The Court stressed, however, that "the interests at stake" in the commercial speech context "are not of the same order as those discussed in *Wooley*, *Tornillo*, and *Barnette*," which involved attempts by the government to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." *Id*. at 651 (quotation marks and citation omitted). "Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," an advertiser's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Ibid*.

As we explain next, the health warnings mandated by Congress and implemented by the FDA readily satisfy the standards established by *Zauderer* and *Central Hudson*, and would even survive the strict scrutiny that plaintiffs (wrongly) insist is required.

II. Congress Mandated Health Warnings for Cigarettes in a Format that Accurately Conveys the Extraordinary Risks of Smoking and Violates No First Amendment Principle.

A. The Revised Warnings Substantially Advance the Government's Overwhelming Interest in Informing Consumers About the Grave Dangers of Cigarette Smoking.

1. The Current Surgeon General Warnings Are Essentially "Invisible."

Congress has required that cigarette packaging and advertising bear health warnings since 1965. Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965). Prior to the 2009 legislation now at issue, the content and the format of the warnings had not been revised since 1984. Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474,

98 Stat. 2200 (1984). As early as 1994, however, the Surgeon General reported that empirical studies dealing "with the visibility of cigarette warnings in advertising . . . consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." Surgeon General, *Preventing Tobacco Use Among Young People* 168 (1994).[6] Evidence presented to Congress showed that the current warnings "fail to convey relevant information in an effective way," IOM Report at 291, and are essentially "invisible." 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).

In the intervening quarter century, regulators' understanding of nicotine addiction and the health risks of smoking has increased dramatically. This enhanced understanding has resulted, in significant part, from the exposure of the tobacco industry's concerted campaign to discredit public health officials and minimize consumer concerns about health risks and addiction. For decades, the industry sought to convince consumers that they might reasonably choose to smoke because sufficient doubt existed as to the risks of smoking and the nature of nicotine addiction. The D.C. Circuit explained in *Philip Morris* that "[e]vidence at trial revealed that at the same time Defendants were disseminating advertisements, publications, and public statements denying any adverse health effects of smoking and promoting their 'open question' strategy of sowing doubt, they internally

[6] Although plaintiffs cite the Surgeon General's 1994 report in support of their claim that the revised warnings are unnecessary, Pl. S.J. Br. 15, that report, in fact, concluded that studies dealing "with the visibility of cigarette warnings in advertising . . . consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." Surgeon General, *Preventing Tobacco Use*, *supra*, at 168. The report also noted that a "comprehensive review of studies on health risk awareness" conducted by the Federal Trade Commission found that "significant numbers of consumers and still higher numbers of smokers were unaware of even the most rudimentary risk information about smoking," which led the FTC to "call for a larger and more attention-demanding format." *Id.* at 169.

acknowledged as fact that smoking causes disease and other health hazards." 566 F.3d at 1106.

Based on this fuller understanding of health risks, nicotine addiction, and consumption patterns, an international consensus has developed regarding the minimum requirements for warnings that will effectively convey the health risks of smoking. These standards are reflected in the World Health Organization's Framework Convention on Tobacco Control and include "warnings that are rotating, 'large, clear, visible and legible,'" that " occupy 50 percent or more of the principal display areas," and "may be in the form of or include pictures or pictograms." 75 Fed. Reg. at 69,525 (citation omitted). "Worldwide, over 30 countries/jurisdictions have implemented pictorial warnings on tobacco packages and requirements for pictorial warnings are pending in several other countries/jurisdictions." *Ibid.*

2. Evidence Before Congress and the FDA Establishes that the Warnings Mandated by Congress Convey the Health Risks of Smoking More Effectively than Text-Only Warnings of Any Size.

In formulating the new health warnings, Congress and the FDA looked, in particular, to the Canadian disclosure requirements that went into effect in 2000. *See Commonwealth Brands*, 678 F. Supp. 2d at 531 (Congress "informed its warning requirement by looking at the use of a nearly identical warning requirement in Canada"). Like the warnings mandated by Congress, those warnings comprised the top 50% of the front and rear panels of cigarette packs and included color graphics depicting the negative health consequences of smoking. *See* Physicians for a Smoke-Free Canada, *Canada's Graphic Health Warnings*.[7]

The evidence before Congress and the FDA amply demonstrated that this size and placement attract and retain consumer attention far more effectively than the current Surgeon General warnings, particularly when the textual message is combined with accompanying pictures. One

[7] http://www.smoke-free.ca/warnings/canada-warnings.htm.

study showed that whereas "'83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,' only '7 percent of U.S. students' did the same." *Commonwealth Brands*, 678 F. Supp. 2d at 531 (citation omitted). In another study, when "U.S. college students were shown images of the Canadian cigarette warnings and the current warnings appearing on cigarette packs sold in the United States . . . the Canadian graphic warnings significantly increased aided recall of the warnings, increased depth of message processing, and increased the perceived strength of the message." 75 Fed. Reg. at 69,531. These findings are consistent with focus group research in which young adults in the United States "reported that the Canadian warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States." *Ibid.*

Recent research confirms that cigarette warnings that combine images and text are more effective than text alone in conveying the risks identified in the text. For instance, from 1995 to 2005, Australia required cigarette manufacturers to display large, text-only warnings that covered the top 25% of the front of the pack. David Hammond, *et al.*, *Effectiveness of Cigarette Warning Labels in Informing Smokers about the Risks of Smoking*, 15 Tobacco Control iii19, iii20 (2005). After Australia introduced larger pictorial warnings in 2006, a longitudinal study of youth "found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented." David Hammond, *Health Warnings Messages on Tobacco Products*: *A Review*, 20 Tobacco Control 327, 330 (2011) (discussing 2008 study); *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) (study comparing the EU's large text-only warnings to its new pictorial warnings concluded that the results "clearly demonstrate[] that visual messages, as opposed to text warnings, are more effective"). Research also "suggests that larger pictorial warnings sustain their effects longer" than text-only counterparts. *See* 20 Tobacco Control at 333.

These results should not be surprising. It is axiomatic in cognitive psychology that "pictures are easier to remember than words." S. David Leonard, *et al.*, *Comprehension and Memory*, *in* WARNINGS AND RISK COMMUNICATION 149, 158 (Michael S. Wogalter *et al.*, eds. 1999). The brain has distinct coding systems for words and for images, and information in the "image" memory system is more likely to be retained and is more easily retrieved. *Ibid.* This is particularly the case for words "representing abstract concepts." *Ibid.* Information that is coded in both systems is particularly easy to remember "because theoretically more 'paths' are created in memory, making the information more accessible (more likely to be cued) at later times." *Ibid.* Thus, even apart from tobacco-specific research, studies have "found that pictorials in combination with conspicuous print facilitated recollection of warning contents," and that "the enhanced memory was directly related to the fact that the warning was noticed in the first place." Wendy A. Rogers, *et al.*, *Warning Research: An Integrative Perspective*, 42 Human Factors 102, 114 (Spring 2000); *see also, e.g.*, Steven Young & Michael Wogalter, *Comprehension and Memory of Instruction Manual Warnings: Conspicuous Print and Pictorial Icons*, 32(6) Human Factors 637, 646 (1990) (comparing the relative effectiveness of instruction-manual warnings with and without pictorials, and finding that "warnings that have both conspicuous print and illustrative pictorial icons enhance comprehension and memory of the warnings' message content").

Conveying information in cigarette warnings poses special difficulties that make using images particularly appropriate. First, although the health consequences of smoking are severe, they generally do not become manifest for many years. Because of that time lag, smokers—and adolescents in particular—tend to disregard or discount discomforting factual information about the long-term consequences of using plaintiffs' product. Dr. Paul Slovic has explained that "[a]lthough most smokers acknowledge a high degree of risk associated with many years of smoking, many

believe they can get away with some lesser amount of smoking before the risk takes hold." Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, *supra*, at 109.

Dr. Slovic notes that "[m]any young smokers, in particular, believe that smoking for only a few years poses negligible risk," and "are more prone to belief in this safety of short-term smoking than are young non-smokers." *Ibid.* This failure to fully appreciate the risks of tobacco smoking is compounded by the powerful nature of nicotine addiction, which starts to take hold "within days to weeks of the onset of occasional use of tobacco." *Ibid.*; *see also Philip Morris*, 449 F. Supp. 2d at 577 (citing Dr. Slovic's testimony in finding that "[b]ecause the most serious harmful consequences of smoking are cumulative, and occur in the distant future, and because teenagers are focused on the present rather than the future and lack an understanding of the addictive properties of cigarettes, it is unlikely that the decisions by teenagers to initiate smoking are influenced by concerns about future harmful consequences").

Second, new consumers, who are not already addicted, are primarily children and adolescents who "are particularly vulnerable to cigarette marketing because they are not capable of making a fully informed decision whether to start or continue smoking for a variety of reasons, including the fact that they underestimate personal risks and lack the judgment which can only be developed through experience." *Philip Morris*, 449 F. Supp. 2d at 578. Including pictorial content is particularly important in conveying information to underage consumers and potential consumers. Summarizing the results of more than 50 youth studies, one review explained that "[i]llustrations can help learners understand what they read, can help learners remember what they read, and can perform a variety of other instructional functions." *See* W. Howard Levie & Richard Lentz, *Effects of Text Illustrations: A Review of Research*, 30 Educ. Comm. & Tech. J. 195, 226 (1982).

Smoking rates are also closely correlated with education levels. FDA noted that "49.1

percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree," and "that graphic health warnings may be particularly important communication tools for these smokers, as there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels." 76 Fed. Reg. at 36,630 (citations omitted); *see also Commonwealth Brands,* 678 F. Supp. 2d at 531 ("[G]raphical warnings 'may be particularly important for communicating' with consumers with low levels of education, given evidence that such smokers 'are less likely to recall health information in text-based messages than people with more education.'") (citation omitted).

Plaintiffs' only response is to contend that images, by their nature, do not help to convey the content of the warnings. Accordingly, at the preliminary injunction hearing, plaintiffs' counsel made clear that, in plaintiffs' view, the only type of image that could constitutionally be included with the warning "Smoking is addictive" would be "some kind of graphic chart that shows how many people smoke [and] how many people are able to quit." P.I. Hr'g Tr. 16 (9/21/2011). (Given that plaintiffs also maintain that the warnings cannot exceed the size of the current Surgeon General warnings, *see id.* 21, the proposed graph would convey as much information as a hieroglyph.)

This, of course, is not the type of warning required by Congress, and plaintiffs offer no basis for accepting their overarching position that all images considered by the FDA and, indeed, any remotely similar image, somehow violate the First Amendment.

3. The Required Health Warnings Do Not Impermissibly Burden Protected Commercial Speech.

Plaintiffs fail to demonstrate that the format required by Congress transforms the health warnings into "unjustified or unduly burdensome disclosure requirements [that] might offend the

First Amendment by chilling protected commercial speech." *Zauderer*, 471 U.S. at 651. The warnings do not in any sense burden such speech because "[h]alf of cigarette packs" and "80% of advertisements remain available for their speech." *Commonwealth Brands*, 678 F. Supp. 2d at 531.

Plaintiffs' affiliated companies have operated under comparable warning requirements in Canada for more than a decade. Nevertheless, neither in this case, nor in *Commonwealth Brands*, where they presented the same claim, have plaintiffs offered any evidence that the format chilled their protected commercial speech. Indeed, the Canadian Supreme Court unanimously rejected a challenge analogous to the one asserted here, finding that "[t]he benefits flowing from the larger warnings are clear" while "[t]he detriments to the manufacturers' expressive interest in creative packaging are small." *Canada v. JTI-Macdonald Corp.*, [2007] 2 S.C.R. 610, 2007 SCC 30, ¶ 139 (rejecting freedom-of-expression claim under the Canadian Charter of Rights and Freedoms).

Plaintiffs' contention that the government failed to consider less-speech-restrictive alternatives was considered and rejected by the district court in *Commonwealth Brands*. Notably, the primary support plaintiffs offer for their argument is a declaration that was filed in that case and then resubmitted to FDA during its current rulemaking. *See* Pl. S.J. Br. 29 (citing Reynolds Decl., filed as Exhibit D to Comment Letter). There, as here, plaintiffs argued that Congress should have considered alternatives to the health warnings, such as "requiring states to use CDC-recommended levels of tobacco revenues for tobacco control programs," "increasing support for interventions that address the personal and social factors that influence tobacco use," "preventing the unlawful retail sale of tobacco products to youth by, e.g., increasing the compliance rate required by the Synar Amendment, Pub. L. No. 102-321, § 1926," and "increasing the price of tobacco products." *Commonwealth Brands*, 678 F. Supp. 2d at 537 (internal quotation marks and brackets omitted); *compare* Pl. S.J. Br. 29.

But the district court in *Commonwealth Brands* correctly observed that "this is not a case where Congress went 'straight to [plaintiffs'] speech,'" and emphasized that, rather, it is "a case where Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry." 678 F. Supp. 2d at 538. Indeed, the alternatives that plaintiffs offer are not new measures that the government has not not yet considered, but instead are all "'variations on strategies already adopted'": Congress has already barred tobacco sales to persons under 18, provided civil penalties for retailer violations, directed the Secretary to implement a program to ensure compliance, and enacted a 62-cent increase in the federal excise tax on cigarettes. *Id.* at 537–38 (citations omitted).

Plaintiffs' proposals would also "impose substantial new costs on state and local governments and private persons." *Id.* at 537. Plaintiffs themselves have argued that cigarette tax increases can unfairly burden low-income users, encourage illicit purchases, and produce other adverse effects. *See, e.g.*, http://www.nocigtax.com/why-cig-taxes-hurt-you/taxpayers (Reynolds-sponsored website); Campaign for Tobacco-Free Kids, Press Release (May 8, 2003) (noting that "Lorillard's ads, which are running in Delaware, New Jersey and Pennsylvania, argue that cigarette tax increases lead to increased crime and cigarette smuggling").[8] Plaintiffs' other proposals would primarily punish states and retailers for taking inadequate measures to combat the evils of plaintiffs' products, and minors for becoming addicted to plaintiffs' product. *See id.* exh. D, Declaration of Cecil Reynolds ¶ 51 (recommending, among other things, measures to "[e]nhance the penalties for underage tobacco use and identify penalties that will be motivational and meaningful to the adolescents involved (*e.g.*, loss of driver's license)").

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

In short, the congressionally mandated health warnings directly advance a substantial—indeed, compelling—interest in conveying to consumers generally, and adolescents in particular, the devastating consequences of smoking and nicotine addiction. The means chosen by Congress do not chill speech and are narrowly tailored to achieve effective communication. Indeed, "there is no more efficient method of reaching smokers than through the use of graphic and highly visible warning labels." 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 (Apr. 2007). Thus, plaintiffs' claim fails under any standard of review given the government interest at stake and the means adopted.

B. Plaintiffs' First Amendment Contentions Are Without Merit.

Plaintiffs advance three principal contentions, all of which lack merit.[9] First, they claim that the health warnings constitute impermissible "compelled speech" on the theory that they constitute an "ideological" message. Second, they argue that the warnings serve no purpose because all consumers are already fully aware of the consequences of smoking. Third, they argue that the warnings are impermissible in the absence of empirical proof demonstrating the extent to which larger pictorial warnings have caused the declines in smoking rates in Canada and other countries.

1. The Warnings Do Not Constitute an "Ideological Message."

Plaintiffs seek to persuade the Court that the required health warnings are an impermissible attempt to require plaintiffs to espouse governmental "ideology." In plaintiffs' view, any expansion of the existing format converts the concededly accurate health warning into an ideological

[9] Because the *Commonwealth Brands* litigation is still pending in the Sixth Circuit, we do not address the extent to which issue or claim preclusion would bar claims brought by Commonwealth Brands, Lorillard, and Reynolds, who are plaintiffs in that litigation, and Reynolds' corporate affiliate Santa Fe. After the Sixth Circuit rules, we will address the issue as appropriate.

"Government[] anti-smoking message." Pl. S.J. Br. 2. Thus, in their joint comments to FDA, plaintiffs Reynolds, Lorillard, and Commonwealth Brands argued that the agency should "order that the Tobacco Control Act's new textual warnings be displayed in the same manner in which the Surgeon General's warnings have been displayed for years"—that is, without Congress's changes to the size and placement of the warnings, and without the congressionally required images that depict the negative health consequences of smoking. *See* Comment Letter 3–4.

In their comments, as in their pleadings, plaintiffs laid particular stress on the requirement that the warnings contain "color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333 Note. They urged that images do not "simply convey information intended to enable smokers to make informed decisions about whether to smoke cigarettes" but instead convey "the Government's viewpoint that the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them and, therefore, that no one should use these lawful products." Comment Letter 2. Plaintiffs thus declared that "the proposed warnings convey to smokers the Government's view that they should change in a significant way how they lead their lives," and argued that "[t]he viewpoint the Government proposes to be conveyed on the manufacturers' packaging and advertising is thus every bit as ideological as the message at issue in *Wooley v. Maynard*, 430 U.S. 705 (1977): 'Live Free or Die.'" *Ibid*. They asserted that, "[i]n effect, the message and viewpoint of FDA's proposed graphic warnings is: 'Live Smoke-Free or Die.'" *Ibid*.

Plaintiffs' attempts to portray the warnings as an ideological message are particularly remarkable because this tactic parallels so closely the tobacco industry's traditional strategy of characterizing the Surgeon General's reports on health risks as government propaganda that

appealed to fear rather than to reason.[10] Plaintiffs can no longer overtly question the accuracy of the crippling health consequences of smoking. Instead, they refer to the health warnings as an "ideology" as if they constituted statements of political viewpoint to be weighed against the competing claims of other "ideologies."

There are no clashing ideologies at work here. The disclosures seek to effectively convey to individual consumers the undisputed facts that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States," and that smoking "kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *Brown & Williamson*, 529 U.S. at 134–35, 161 (internal quotation marks omitted). As discussed in detail below, each of the images chosen by FDA accurately enhances the communication of an entirely noncontroversial disclosure about the risks of smoking.

Plaintiffs' mistaken attempt to transform accurate warnings into an ideological message is epitomized by their repeated assertion that the FDA Commissioner acknowledged that "the warnings are intended to ensure that 'every single pack of cigarettes in our country will in effect become a mini-billboard' for the Government's anti-smoking message." Pl. S.J. Br. 2. What the Commissioner actually said is that the warnings are intended to ensure that "every single pack of cigarettes in our country will in effect become a mini-billboard that *will tell the truth about*

[10] Thus the tobacco industry once proclaimed that "opponents of cigarettes are endeavoring to scare pregnant women with such statements as that of the Surgeon General that 'we are losing babies because of mothers' smoking.'" *Philip Morris*, 449 F. Supp. 2d at 194. And it responded to the 1988 Surgeon General report by declaring that "CLAIMS THAT CIGARETTES ARE ADDICTIVE IRRESPONSIBLE AND SCARE TACTICS." *Id.* at 283.

smoking."[11] (Emphasis added.) Plaintiffs have identified no respect in which the warnings do *not* "tell the truth about smoking."

Indeed, plaintiffs have recognized in a variety of other forums that an "anti-smoking message" has long ceased to be controversial, and it cannot plausibly be characterized as an "ideology." Plaintiffs not only publicly recognize the risks associated with their own product but further declare that, in light of those undisputed risks, consumers should not begin to smoke or should cease smoking. Santa Fe Natural Tobacco Company offers this message to nonsmokers: "[W]e cannot stress this enough: If you don't smoke, don't start." http://www.sfntc.com. Elsewhere on their web site the company asserts: "[W]e never encourage non-smokers to start, or existing smokers to smoke more." http://www.sfntc.com/Quit-Smoking/Overview.aspx. The website provides links to twenty cessation resources and wishes smokers "the best of luck" in trying to quit. *Ibid.* Lorillard's website states that "[t]he only way to avoid the health effects of cigarette smoking is to not smoke. The best way to reduce the health effects of cigarette smoking is to quit, and quitting smoking greatly reduces serious risks to health." http://www.lorillard.com/?s=quit+smoking. And, in a recent submission to FDA, Reynolds acknowledged that "it is indisputable that quitting is the only safe alternative to using any tobacco product." R.J. Reynolds, Citizen Petition 4, Docket No. FDA-2011-P-0573 (Jul. 8, 2011); *see also* R.J. Reynolds, *Guiding Principles and Beliefs*, *available at* www.rjrt.com/prinbeliefs.aspx ("The best course of action for tobacco consumers concerned about their health is to quit."). Plaintiffs' expert in *Commonwealth Brands* explained that it is uncontested that persons seeking to avoid the deadly consequences of smoking should not consume cigarettes. Rodu Decl. ¶ 30 (R. 72-2, No. 1:09-cv-117 (W.D. Ky.)); *see also*

[11] http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm (audio, minute 21:24) (quoted at Pl. S.J. Br. 2, 16).

Nat'l Citizens Comm. for Broad. v. FCC, 567 F.2d 1095, 1100 n.13 (D.C. Cir. 1977) (citing with approval *Larus & Brother Co. v. FCC*, 447 F.2d 876, 880 (4th Cir. 1971), for upholding the FCC's determination that the broadcast of "anti-smoking messages" did not trigger an obligation under the fairness doctrine to broadcast views advocating smoking "because the issue is no longer a matter of public controversy").

Plaintiffs also assert that the health warnings convey "the Government's viewpoint that the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them." Comment Letter 2. In doing so, they resurrect the thoroughly discredited claim that consumers continue to smoke for pleasure after rationally weighing their immediate enjoyment against the prospect of lung and heart disease. But plaintiffs have understood for decades that they retain their customers *not* because of their pleasure in smoking, but because smokers must satisfy their need for nicotine, which, plaintiffs' expert explained in *Commonwealth Brands*, is the "substance in tobacco that inveterate smokers crave." Rodu Decl. ¶ 40 (R. 72-2, No. 1:09-cv-117 (W.D. Ky.)). Thus, in the single year of 2004, "approximately 40.5 percent of adult smokers attempted to quit, [but] only between 3 and 5 percent were successful." 75 Fed. Reg. at 69,529. Indeed, as long ago as 1985, Philip Morris's top management was informed that research showed that "the majority of smokers wished they did not smoke." *Philip Morris*, 566 F.3d at 1128 (quotation marks omitted).

Even if an "anti-smoking message" were not so clearly noncontroversial, cases such as *Wooley* would have no bearing on the analysis here. As the Supreme Court in *Zauderer* explained, *Wooley* stands for the proposition that the government may not "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 (citation and internal quotation marks omitted). In contrast, "[b]ecause the extension of First Amendment protection to commercial speech is

justified principally by the value to consumers of the information such speech provides, [the seller's] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Ibid.*

Appellate decisions cited by plaintiffs distinguish between factual disclosures (which are reviewed under the relaxed standard of *Zauderer*) and "subjective" or "opinion-based" disclosures. In *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), for example, the Seventh Circuit invalidated a law that required video game manufacturers to place a warning label on games deemed to be "sexually explicit." *Id*. at 651–52. The label was to be applied only to games "'that the average person, applying contemporary community standards would find, with respect to minors, is designed to appeal or pander to the prurient interest.'" *Id.* at 643. That definition incorporated "widely divergent local standards" of offensiveness, *id.* at 650, making it "subjective and highly controversial" and therefore subject to strict scrutiny, *id.* at 652.

The Seventh Circuit, *id.* at 651–52, distinguished these subjective warnings from the Vermont statute upheld by the Second Circuit in *National Electrical Manufacturers Ass'n v. Sorrell*, 272 F.3d 104, 107 (2d Cir. 2001), which required manufacturers to label products containing mercury and to inform consumers that these products should be recycled or disposed of as hazardous waste. The Second Circuit applied the *Zauderer* standard, noting that "the compelled disclosure at issue . . . was not intended to prevent 'consumer confusion or deception' per se, but rather to better inform consumers about the products they purchase." *Id.* at 115 (citations omitted). The court stressed that requiring "commercial actors [to] disclose commercial information ordinarily does not offend the important utilitarian and individual liberty interests that lie at the heart of the First Amendment," and that such requirements will withstand judicial scrutiny as long as there is "a rational connection between the purpose of a commercial disclosure requirement and the means

employed to realize that purpose." *Id.* at 114–15 (citing *Zauderer*, 471 U.S. at 651).[12]

2. The Health Warnings Convey Risks of Addiction and Smoking that Are Not Adequately Appreciated by Consumers Generally and Adolescents in Particular.

The second prong of plaintiffs' argument is their insistence that no valid purpose can by served by changing the format of the current warnings because "Americans, young and old alike, are well aware of the health risks of smoking." Pl. S.J. Br. 14. In this vein they assert that "the health risks of smoking have already been 'disseminated to and absorbed by an overwhelmingly high percentage of the population' through the familiar Surgeon General's warnings and numerous other means." *Ibid*. (citation omitted).

Such claims are particularly ironic in light of the tobacco industry's fifty-year enterprise to deceive the American public about the dangers and addictiveness of smoking and to discredit the Surgeon General's reports of health risks. *Philip Morris*, 566 F.3d 1095. Their arguments about the dissemination of the message of the adverse health consequences of smoking and the consequent lack of need for any further warnings were decisively rejected by the district court in *Philip Morris* and are no more convincing here.

Plaintiffs' arguments ignore judicial findings and the vast literature regarding perception of the health risks associated with smoking, and rely, instead, on the declaration of their expert, Dr. W.

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[12] Plaintiffs' reliance on *Brown v. Entertainment Merchants Ass'n*, 131 S. Ct. 2729 (2011), is likewise misplaced. *See* Pl. S.J. Br. 28. The Court in that case considered the validity of a law that prohibited the sale or rental of violent video games to minors. As a content-based restriction on protected speech, the Court subjected the law to strict scrutiny, and concluded that it was not narrowly tailored. 131 S. Ct. at 2738. As already explained, the disclosure requirements here at issue are not subject to strict scrutiny. Just as they have nothing in common with the compelled ideological speech at issue in *Wooley*, they are readily distinguishable from the restrictions on access to video games addressed in *Brown*. Nor do plaintiffs advance their argument by relying on *Pacific Gas & Electric Co. v. Public Utilities Commission*, 475 U.S. 1, 8–9 (1986), where the Supreme Court specifically held that the speech at issue was *not* commercial speech.

Kip Viscusi, who admitted at trial in *Philip Morris* that his research was commissioned by tobacco industry law firms for use in litigation. Trial Tr. vol. 88, 17930 (Apr. 6, 2005) (filed as R. 98-1 at A16, *Commonwealth Brands*, No. 1:09-cv-117 (W.D. Ky.)). Myriad independent studies contradict Dr. Viscusi's position. The Institute of Medicine explained in 2007 that "adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior." IOM Report at 93. Although adolescents overestimate certain risks, such as the statistical risk of lung cancer, they underestimate the degree to which smoking can shorten life and the likelihood that they will suffer tobacco-related disease. *Id*. at 89-90. Both adolescent and adult smokers were more than twice as likely as nonsmokers to doubt that tobacco use, even for a period of 30 to 40 years, would cause death. *Id*. at 90. Adolescents fail to recognize that smoking causes more deaths than gunshots, car accidents, alcohol, and the use of other drugs. *Ibid*. And they "typically underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose." President's Cancer Panel, *Promoting Healthy Lifestyles*, at 64 (2007).

Dr. Viscusi disregards this body of investigation, and his limited discussion of scientific studies is inaccurate. For example, Dr. Viscusi invokes the research of Drs. Weinstein and Slovic to support his claim that "young people overestimate the dangers of smoking to an even greater degree [than adult smokers]." Comment Letter exh. A, Statement of W. Kip Viscusi ("Viscusi Statement"), at 28. Drs. Weinstein and Slovic were experts for the government in *United States v. Philip Morris*, and what they actually found is that "most people have only a superficial awareness that smoking is dangerous," 449 F. Supp. 2d at 578 (citing Slovic); "individuals have little knowledge of the reality of the pain, suffering, and despair of those with lung cancer, emphysema, congestive heart failure, and other smoking related diseases," *ibid*. (citing Weinstein & Slovic);

"[m]ore than 70% of adults and 80% of adolescents overestimated the likelihood that lung cancer is curable," *ibid*. (citing Weinstein & Slovic); "adolescents not only underestimate the harm that results from smoking cigarettes, but are overly optimistic about their ability to quit smoking," *ibid*. (citing Weinstein); and "[m]ost smokers only begin to think of risk after they have started to smoke regularly and have already become addicted," *id*. at 576 (citing Slovic). Summarizing, the *Philip Morris* court explained that "the research and expert testimony demonstrate that most youth, at a time when they are deciding whether to start smoking, have a very inadequate understanding of the medical consequences, physical pain, and emotional suffering which results from smoking and the unlikelihood of their being able to quit smoking at some future time." *Id*. at 579–80. Plaintiffs would have the Court ignore these well-established facts.

3. The Constitutionality of the Required Warnings Does Not Require a Statistical Determination Regarding the Extent to Which the Decline in Smoking Rates in Canada Should Be Attributed to the Introduction of New Health Warnings There.

To bolster their contention that the revised health warnings do not advance the government's public health interests, plaintiffs argue that the warnings will "have no material impact" on smoking rates. *See* Pl. S.J. Br. 7; *see also id.* at 39 (urging that the administrative record is "devoid of evidence" that the rule will "convinc[e] smokers [to] reduce their smoking, make an attempt to quit, or quit altogether" (internal quotation marks and citation omitted)).

This argument reflects plaintiffs fundamental misunderstanding of the nature and purpose of the warnings. As mandated by Congress, 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; *see also Commonwealth Brands*, 678 F. Supp. 2d at 530 ("[T]he government's goal is . . . to ensure that the health risk message is actually *seen* by consumers in the first instance."). Congress concluded, and the FDA affirmed, that the revised warning format *does* more effectively

convey information about health risks to consumers and potential consumers than text-only warnings. Plaintiffs' focus on smoking rates, rather than the conveyance of information, misapprehends relevant constitutional concerns. *See generally Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 115 (upholding requirement that products containing mercury be labeled with a recommendation that they be recycled or disposed of as hazardous waste, without requiring any showing by the state that the disclosure actually caused consumers to recycle or dispose of the labeled products in the suggested manner, because it is sufficient for First Amendment purposes that the compelled disclosure "better inform[s] consumers about the products they purchase").

In any event, the evidence does *not* indicate that the format required by Congress will have no material impact on smoking rates. Both the World Health Organization and the Institute of Medicine, after examining the full body of scientific research on graphic warnings, concluded that such warnings would reduce smoking rates. 75 Fed. Reg. at 69,531 (discussing Institute of Medicine report concluding that "larger, graphic health warnings would promote greater public knowledge of the health risks of using tobacco and would help reduce consumption"); *ibid.* (discussing WHO report finding that "taken as a whole, the research on graphic health warnings show that they are . . . associated with increased motivation to quit"). Other studies reinforce that conclusion. For example, 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." *Id.* at 69,532.

A survey of Australian youth found that "adolescents who were experimenting with smoking or were established smokers indicated that they thought more about forgoing cigarettes after graphic warnings appeared on cigarette packages in 2006." *Ibid*. Summarizing the results of fifteen studies, a more recent review concluded that "significant proportions of adult and youth smokers report that

large text and pictorial health warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit and increased the likelihood of remaining abstinent following a quit attempt." David Hammond, *Health Warnings Messages On Tobacco Products: A Review*, 20 Tobacco Control 327, 331 (2011).

Several studies also demonstrated that the introduction of graphic warnings prevented smokers from smoking as much as they normally would, and made smokers abstain from exposing others to secondhand smoke. 75 Fed. Reg. at 69,534. A survey of Canadian smokers indicated that "21 percent of smokers reported that on one or more occasions they chose not to smoke a cigarette due to the warnings on cigarette packages," and that "27 percent of participants reported that the then-new graphic warnings motivated them to smoke less inside their homes." *Id*. at 69,532. Another study of young Canadian smokers found that "22.6 percent of current male smokers and 26.6 percent of current female smokers reported that in the past month, noticing the warning on cigarette packages led them to decide not to have a cigarette." *Ibid*.

As discussed in greater detail below, the FDA did not, as plaintiffs claim, conclude that the new format would have no impact on smoking rates. *See infra* 46–49. FDA noted, after the introduction of graphic warnings in Canada, that smoking rates in that country dropped steeply. 76 Fed. Reg. at 36,710 (explaining that "Canada's smoking rate has decreased by around seven percentage points . . . since the implementation of graphic warning labels"). FDA's regulatory impact analysis concluded only that it could not determine in a statistically significant way the extent to which the decline in Canadian smoking rates was attributable to the introduction of new warnings as opposed to other measures. FDA's lack of certainty as to the causes of the drop in Canadian smoking rates cannot properly be understood as an admission that the warnings here will not reduce smoking rates.

Similarly, Dr. David Hammond recently concluded that, as compared to text-only warnings, "pictorial warnings are more likely to be noticed and read by smokers, [and] are associated with stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking." Hammond, 20 Tobacco Control at 330. Plaintiffs nevertheless cite the same publication to insist that Dr. Hammond believes that pictorial warnings are ineffective. *See* P.I. Reply 11 n.12; P.I. Hr'g Tr. 73, 76–77. In the passage quoted by plaintiffs, Dr. Hammond notes the difficulties inherent in determining the extent to which pictorial warnings accounted for the documented decline in Canadian smoking rates following their introduction, noting that the decline may also have been influenced by other public health measures. *See* 20 Tobacco Control at 331.

III. FDA Adopted Images to Accompany the Text of the Health Warnings that Accurately Convey the Extraordinary Risks of Smoking Consistent with the First Amendment and the APA.

A. The Images Selected By FDA Raise No First Amendment Concerns.

1. FDA Properly Considered the "Salience" of the Proposed Warnings, *i.e.*, the Extent to Which Consumers Will Notice and Process the Warnings Over Time.

As discussed in Part II, plaintiffs assert that Congress could not, consistent with the First Amendment, require inclusion of images depicting the negative consequences of smoking of the kind already mandated in Canada, Australia, Great Britain and approximately 30 other countries. Thus, in plaintiffs' view, *none* of the 36 images considered by the FDA in its rulemaking would pass constitutional muster. The only acceptable form of image in plaintiffs' view is a graph. P.I. Hr'g Tr. 16. As we have demonstrated, no principle of First Amendment law precludes Congress from requiring images to accompanying the text of the health warnings.

Plaintiffs' challenge to the images selected by FDA to accompany the text of the nine warnings is likewise flawed. In selecting the nine images, FDA reviewed extensive scientific

literature, the experience of other countries, and over a thousand comments. *See* 76 Fed. Reg. at 36,629. FDA also conducted a study to measure consumer responses to the 36 warnings submitted for comment in the proposed rulemaking. That study divided 18,000 participants into three study groups: adult smokers (age 25 or older), young adult smokers (aged 18 to 24), and youth (aged 13 to 17) who currently smoke or who are susceptible to smoking. *Id.* at 36,637. The study randomly exposed study participants to a cigarette package or an advertisement containing one of the prospective warnings proposed by FDA or a control set of text-only warnings. FDA Study Report at 1-3; 4-1. The study then asked each participant to answer a series of questions about the warning. *Id.* at 1-3. These questions were designed to elicit participants' immediate reactions to the warnings. These "salience" measures include cognitive responses (*e.g.*, belief that the warnings were, for instance, informative, meaningful, or difficult to look at) and emotional responses (*e.g.*, worry, disgust, etc.). *Id.* app. A, at A-3.

FDA recognized, based on the substantial body of scientific literature discussed above, that such cognitive and emotional responses reliably predict the likelihood that consumers would understand and appreciate the warnings' messages. *Id.* at 4-1. The study also attempted to assess whether the warnings would enhance recall of the warning statement, change the self-reported beliefs about the health risks of smoking, or impact the participants' intentions to quit or initiate smoking. *Id.* at 1-3; 76 Fed. Reg. at 36,638; *see infra* 37–44 (discussing study results).

Plaintiffs fundamentally misunderstand "salience," which they characterize as "a euphemism for shock value." P.I. Hr'g Tr. 12. FDA repeatedly explained that the "emotional" reactions of consumers are germane 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). The agency explained that "[t]he 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 and the extent to which the individual could personally experience a smoking-related disease." *Id*. at 36,641. The images selected "were designed to correlate with [the] warning statements," and the "available evidence base highlights the value of the text and images in graphic health warnings relating to one another in a meaningful way." *Id.* at 36,637 (citations omitted).

FDA noted that some comments criticized specific images as "disturbing" or "eliciting emotions." *Id.* at 36,696. These included the image "depicting a man smoking through a tracheostomy opening," the image "depicting healthy lungs juxtaposed with lungs damaged by smoking," the image "depicting a lesion consistent with that caused by oral cancer," and the image "depicting a man with an autopsy scar." *Ibid.* The comments "did *not* assert, however, that the effects shown in the images are false, *i.e.*, that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death." *Ibid.* (emphasis added). The agency emphasized: "The fact that the images are disturbing or evoke emotion does not mean that they are not factual representations of the effects of smoking. . . . As such, it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen." *Ibid.* The images do not, as plaintiffs claim, "exaggerate the effects of sickness and disease." Pl. S.J. Br. 21. FDA explained that, although "some of the photographs were technologically modified to depict the negative health consequences of smoking, the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking, and the comments did not dispute this fact." 76 Fed. Reg. at 36,696.

Ultimately, plaintiffs' objection is not that these images are false but that they are *true*: they

accurately communicate that smoking causes disease and death. As we have already discussed, *see supra* 23–29*,* plaintiffs' attempt to characterize these warnings a controversial, ideological "anti-smoking message" is without basis.

2. Plaintiffs Have Waived Any Challenge to the Specific Warnings Selected by FDA, Which Accurately Convey Consequences of Smoking.

As noted, plaintiffs' argument does not differentiate among the images considered or selected. Their pleadings offer scattered observations about some of the images chosen by the agency; but they do not contend that these warnings are any more or less constitutionally suspect than the other images reviewed or adopted in the rulemaking. Plaintiffs have thus waived any argument that the Court should hold specific images invalid if it does not accept their contention that *all* the images offend First Amendment constraints.

FDA did respond, at length, to other commenters whose comments with respect to specific images, explained why, in their view, some of the proposed graphics were more effective or less appropriate than others. We therefore address each of the images selected by FDA to accompany the text of the health warnings as well as the general objections advanced by plaintiffs. This section elaborates the previous discussion at 17–20 regarding the interaction of pictorial and text content in conveying the warnings' messages.

"WARNING: Cigarettes are addictive." FDA selected the image of a man smoking through a tracheostomy hole in his throat. 76 Fed. Reg. at 36,649. Plaintiffs do not deny that this image is a factual and accurate depiction of a health consequence of smoking. As FDA explained, "[t]he image effectively and concretely communicates the negative health consequences of smoking," and "clearly portrays the addictive nature of cigarettes, depicting a man who is still smoking despite prior evidence (a stoma in his neck) of surgery for cancer." *Ibid.* Indeed, smoking rates are "particularly high" even among those who have already been diagnosed with and are being

treated for head and neck cancer; for example, two studies found that "55–69% of head and neck cancer patients are current smokers." Robert A. Schnoll & Caryn Lerman, *Smoking Behavior and Smoking Cessation among Head and Neck Cancer Patients*, *in* HEAD AND NECK CANCER: EMERGING PERSPECTIVES 185, 187 (John F. Ensley ed. 2003) (citing studies).

The image also performed particularly well in FDA's consumer study: the image "had a significant effect ($p<0.001$)[13] on all salience measures" across "all three study populations." 76 Fed. Reg. at 36,649. The image also "had a significant impact ($p<0.05$) on adult beliefs about the health risks of smoking for smokers and a significant impact ($p<0.05$) on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, relative to the text-only control." *Ibid.* Although the image was associated with "lower statement recall at one week follow-up," FDA explained that "recall of the statement was generally high for the image," and concluded that "repetitive viewing of the required warning is likely to increase recall." *Ibid.* Furthermore, many comments—including those from "public health advocacy groups, academics, State and local public health agencies, and health care professionals"—supported use of this image. *Ibid.* FDA was amply warranted in rejecting a comment that "the image would only have a one-time shock value," explaining that "the research literature suggests that more vivid warnings are more likely to retain their salience over time." *Ibid.*

"WARNING: Tobacco Smoke Can Harm Your Children." FDA selected the image of smoke approaching a baby for this warning statement. *Ibid*. Plaintiffs urge that this image does not "even purport to describe, as a factual matter, the health consequences of exposing children to

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[13] The consumer study reported the "p-values"—the significance levels—of each of its findings. For findings that were significant at the 0.001 confidence level ($p<0.001$), "there is less than one chance in a thousand that the finding happened by coincidence." 76 Fed. Reg. at 36,648. And for findings that were significant at the 0.05 confidence level ($p<0.05$), there is less than a 5% chance that the finding was a coincidence. *Ibid.*

second-hand smoke," P.I. Reply 6, echoing comments that "the child does not appear to be suffering harms to his health" and "looks too healthy," *id.* at 36,650. But as FDA explained, "[g]raphic depictions of the visible effects of disease are not the only way of communicating the health risks of second hand smoke for children, some of which (such as impaired lung growth), are not necessarily visible in a photograph of a child exposed to secondhand smoke." *Id.* at 36,650. The chosen image also performed well in the consumer study, showing a significant effect on all the salience measures in all three study populations. *Id.* at 36,649–50. Moreover, the image "had a statistically significant effect ($p<0.05$) on youth intentions to not smoke in the next year, with 71.6 percent of youth viewing the image reporting that they would not be likely to smoke in the next year, compared to 56.9 percent in the text only control." *Id.* at 36,650. Thus, as FDA concluded, the warning "depicts the health consequences of secondhand smoke exposure in a manner that has an impact on both smokers and potential smokers." *Id.* at 36,650–51.

"WARNING: Cigarettes Cause Fatal Lung Disease." FDA selected the image comparing healthy and diseased lungs to accompany this warning statement. *Id.* at 36,651. Plaintiffs do not deny that this image is a factual and accurate depiction of a health consequence of smoking. In FDA's consumer study, the image "had a significant effect ($p<0.001$) on all the salience measures . . . in all three study populations" as compared to the text-only control, and "showed some of the largest effect sizes for image recall (at baseline and at 1 week follow-up) in adults and youth across the images proposed for use with this warning statement." *Ibid.*

"WARNING: Cigarettes Cause Cancer." FDA selected the image showing a cancerous lesion on a lip. *Ibid.* Plaintiffs do not deny that this image is a factual and accurate depiction of a health consequence of smoking. FDA received "a large number of comments supporting the use of [this] image" including comments from "public health advocacy groups, a medical organization,

academics, State and local public health agencies, and health care professionals." *Id.* at 36,652. Several of those comments noted that the image "has a very high potential to reach consumers and positively influence their behavior." *Ibid.* Other comments "addressed the benefits of using an image that shows the public that cigarettes cause oral cancers, noting that public awareness of this negative health consequence is low, and that many smokers and nonsmokers only relate cigarettes to lung cancer." *Ibid.*

FDA also found that "the selected image . . . is likely to have particular relevance for youth," because "the research literature suggests that youth are likely to relate to and be susceptible to cigarette warnings depicting the negative short-term impacts of smoking on their personal appearance, including their lips and teeth." *Ibid.* FDA's consumer study indicated that the image had "a significant effect ($p<0.001$) on all the salience measures . . . in all three study populations," and the "numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and had the numerically largest effects on the cognitive reaction scale in young adults and youth." *Id.* at 36,651.

"WARNING: Cigarettes Cause Strokes and Heart Disease." FDA selected the image depicting a man with an oxygen mask on his face. *Id.* at 36,652. Plaintiffs do not deny that this image is a factual and accurate depiction of a health consequence of smoking. FDA selected this image in part because "the person shown in this image is an older man," while other images "show younger people." *Id.* at 36,653. FDA explained that this image thus helped fulfill the goal of "selecting a set of required warnings that includes a diversity of . . . human images (*e.g.*, race, gender, age)," such that "the nine selected required warnings will effectively communicate to a wide range of consumers, including both young and older smokers." *Ibid.* Moreover, in FDA's consumer study the image "had a significant effect ($p<0.001$) on all the salience measures . . . in all three study

populations (adults, young adults, and youth)." *Id.* at 36,652. The image "also showed some of the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement." *Id.* at 36,653. The image was identified by public health groups as "the best image for use with this warning statement." *Ibid.*

"WARNING: Smoking During Pregnancy Can Harm Your Baby." FDA selected a graphic illustration of a baby in an incubator. Plaintiffs criticize this image as a "non-factual cartoon drawing[]," Pl. S.J. Br. 21, but do not contend that a graphic illustration cannot convey factual and accurate information. FDA correctly noted that "[t]he style of the depiction—here, a graphic illustration—does not make it less factual," *id.* at 36,696, and further explained that "the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.*, photographic versus illustrative)," is demonstrated by the experience of other countries, *id.* at 36,653.

More important, plaintiffs suggest no respect in which the use of the image contained in the FDA warning fails to convey the health risks described in the undisputed accompanying text. Cigarette manufacturers maintained for decades that smoking during pregnancy would have no adverse impact long after they knew the contrary to be true. *See Philip Morris*, 449 F. Supp. 2d at 194. At this point, however, plaintiffs no longer dispute that "smoking during pregnancy has negative effects, including increasing rates of preterm delivery and shortened gestation." 76 Fed. Reg. at 36,696. Nor do they offer any basis for setting aside the agency's conclusion that the image "accurately depicts the health consequences smoking during pregnancy can have for infants born to mothers who smoke." *Ibid.*

FDA's consumer research study showed that this image "had a significant effect ($p<0.001$) on all the salience measures . . . in all three study populations (adults, young adults, and youth)." *Id.* at 36,653. Those effects were the "numerically largest" among of the "images proposed for use

with this warning statement." *Ibid.* The image also had significant effects on recall of the warning statement as compared to the text-only baseline in all three study populations. *Ibid.* Although the image also had a significant effect on the beliefs about the risks of smoking among adults, it was associated with a decreased awareness of health risks for youth smokers. *Ibid.* But, "given the strength of the effects observed for this image on the salience measures," which FDA found to be the most relevant metric, FDA found that the warning is "is likely to increase awareness of the health risks of smoking and increase the likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether." *Ibid.*

"WARNING: Smoking Can Kill You." FDA selected the image depicting a man on an autopsy table with an autopsy scar. *Id.* at 36,654. Plaintiffs claim that this image is inaccurate because "autopsies [are not] a common result of cigarette smoking." Pl. S.J. Br. 21. Plaintiffs do not dispute, however, that smoking kills 443,000 Americans each year, *id.* at 36,629, or that, among children that become regular smokers, "about half eventually will die from a disease caused by tobacco use," *Promoting Healthy Lifestyles*, *supra*, at 64 (emphasis added). As FDA explained, "[v]iewers will understand that the image shows someone who has died from a smoking-related cause," particularly because "the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown." 76 Fed. Reg. at 36,655. The autopsy image thus underscores the factual, non-controversial information contained in the warning statement, and is a good deal less "disturbing" than photographs of the most common ravages of the diseases caused by plaintiffs' products.

FDA's consumer study indicated "that viewers from all age groups understood and reacted to this image in desirable ways." *Ibid.* The image had "a significant effect ($p<0.001$) on all the salience measures . . . in all three study populations (adults, young adults, and youth)." *Id.* at

36,654. The image was also "associated with higher intentions to quit smoking compared to the text-only control ($p<0.05$) in adults." *Ibid.*

"WARNING: Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers." FDA selected the image of a woman crying to accompany this warning statement. *Id.* at 36,655. Plaintiffs do not dispute FDA's conclusion that "the image is a realistic portrayal of how the negative health consequences caused by exposure to secondhand smoke can affect people." *Id.* at 36,656. FDA explained that "the negative health consequences caused by secondhand smoke exposure, including fatal lung disease, have many dimensions, including emotional suffering," and that the selected image "highlights that dimension." *Ibid.* Moreover, as FDA explained "the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown." *Ibid.* The image performed well in FDA's consumer study: it had significant effects across the salience metrics in all three study populations, and "a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in young adults." *Id.* at 36,655.

"WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health." FDA selected the image of a man wearing a t-shirt that says "I Quit" to accompany the warning statement. *Id.* at 36,656. Plaintiffs urge that this image "says absolutely nothing about the risks of smoking or the benefits of quitting." P.I. Reply 6. FDA explained that research indicates "that warnings that focus on the benefits of quitting are effective at encouraging cessation, and suggests that positive, self-efficacy messages can be used effectively as one component of graphic health warnings to increase smokers' motivations and confidence about quitting." 76 Fed. Reg. at 36,656. The agency observed that "[t]he research literature also highlights the importance of including one or more warnings that provide solutions, such as the 'man I Quit t-shirt' required warning, in a set of warnings conveying the negative health consequences of smoking." *Ibid.* Thus, "the literature

recommends that, in addition to communicating the health risks of smoking, some warnings should also provide information on how to avoid these risks (*i.e.*, by quitting), in order to optimize the effectiveness of the overall set of warning messages." *Ibid.* The image showed significant effects in FDA's consumer study: it had a significant impact in the cognitive reaction scale in all three study populations, and "showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults, young adults, and youth across the images proposed for this warning statement." *Ibid.*

In sum, individually and as a group, the warnings combine text and image to convey accurate information of the consequences of smoking.

3. The Inclusion of a Phone Number for a Smoking Cessation Resource Raises No First Amendment Concerns.

Plaintiffs do not advance their argument by insisting that inclusion of a telephone number for a nationally recognized smoking cessation resource—1-800-QUIT-NOW—in the health warnings violates the First Amendment. FDA explained (and it is not disputed) that studies have found that "health warnings are more effective if they are combined with cessation-related information." 76 Fed. Reg. at 36,681. Indeed, because of the powerfully addictive nature of plaintiffs' products, the overwhelming majority of smokers who try to quit fail in their efforts in any given quit attempt. *Id.* at 36,700.

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

Plaintiffs' sole objection is that this smoking-cessation resource uses the telephone number

"1-800-QUIT-NOW." *See* Pl. S.J. Br. 23. The use of dashes and the fact that it begins with "1-800" makes plain to any reasonable reader that it is a telephone number to call, and the fact that the number is in an easy-to-remember form does not make it a "subjective policy message." *Ibid.* At most, the telephone number conveys that quitting smoking is beneficial, which is plainly permissible. One of the textual warnings, which the tobacco companies "do not challenge" because it contains "purely factual information," *id.* at 20, states: "WARNING: Quitting smoking now greatly reduces serious risks to your health." 15 U.S.C. § 1333 Note.

Plaintiffs' arguments recapitulate their contention that the warnings reflect a government "ideology," a contention wholly without merit. *See supra* 23–29. As discussed, plaintiffs' own websites convey the same warnings and, indeed, Lorillard's web site instructs consumers who follow that advice to call the same phone number that plaintiffs challenge here on constitutional grounds: "For help in quitting smoking call 1-800-QUITNOW (TTY 1-800-322-8615), which is a 24-hour toll-free number to the National Network of Tobacco Cessation Quitlines."[14]

B. Plaintiffs' APA Challenge Reduces to the Contention that the Agency Should Have Declined to Implement the Statutory Mandate.

Plaintiffs' quarrel is not with the FDA but with Congress. They asserted in the rulemaking, and continue to maintain, that the only constitutionally acceptable course for the agency would be to require warnings that include the new text mandated by Congress but that appear in precisely "the same manner in which the Surgeon General's warnings have successfully been displayed for decades." Comment Letter 24. Plaintiffs' comments necessarily acknowledged that the statute precluded this course of action, but made the extraordinary suggestion that the agency should assert the Executive Branch's constitutional duty to take care that the law shall be faithfully executed "to

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

eliminate constitutional and other infirmities." *Ibid.*

It is thus unsurprising that plaintiffs' APA arguments challenging the rulemaking add nothing to their constitutional claim that the size and placement of the health warnings, as well as the inclusion of images, violate the First Amendment. Plaintiffs' objections to the rulemaking generally condemn the agency for faithfully implementing the statute or for not amassing additional evidence in support of the judgment already made by Congress.

1. The Regulatory Impact Statement

The errors besetting plaintiffs' analysis are epitomized in their discussion of the regulatory impact statement conducted pursuant to Executive Orders 12,866 and 13,563. They urge that FDA should not have implemented the statutorily mandated warnings because the regulatory impact statement did not demonstrate to a statistical certainty that the new warnings will reduce the rate of smoking. Pl. S.J. Br. 7–10, 25.

This argument has no bearing on the validity of the regulation. Congress did not ask FDA to determine the costs and benefits of including warnings of a particular size and format with specified text and accompanying graphics—Congress itself had made that judgment, and, as discussed above, had ample basis for doing so. FDA had no authority to second-guess that legislative determination, and was statutorily precluded from accepting plaintiffs' recommendation to order that the 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. In contrast, the decisions on which plaintiffs rely involved statutes that specifically directed an agency to consider costs and benefits in determining *whether* to promulgate a regulation. *See, e.g.*, *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1212 (D.C. Cir. 2004) (considering rule promulgated under a statute that mandated that "[b]efore prescribing or revising any . . . requirement, [the agency] shall

consider the costs and benefits of the requirement" (quoting 49 U.S.C. § 31506(d)).

The Executive Orders that require a regulatory impact analysis do not permit FDA to second-guess congressional judgments. The orders apply generally to all federal rulemaking and are designed to "improve the internal management of the Federal Government." Executive Order 12,866, § 10, 58 Fed. Reg. 51,735, 51,744 (1993). They include the requirement that agency rulemaking be accompanied by a regulatory impact statement, but they explicitly declare that they do "not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person." *Ibid.*; *see also* Executive Order 13,563, § 7(d), 76 Fed. Reg. 3821, 3823 (2011) (similar language). Plaintiffs' misunderstanding of the purpose of the impact statement is illustrated by their assertion that FDA's statement in this instance improperly failed to account for the "the healthcare, social security, and other cost *increases* caused by increased longevity." Compl. ¶ 46. For the limited purpose of complying with the Executive Orders, FDA did consider the rule's indirect effects on such costs. *See* 76 Fed. Reg. at 36,714. But that analysis is irrelevant to the issues before the Court. Congress legislated on the premise that keeping people alive is a good thing. The Constitution does not require Congress to adopt plaintiffs' accounting standards and to treat the achievement of that goal as a "cost" rather than a "benefit."

Plaintiffs' discussion of the Regulatory Impact Statement also provides no support for their constitutional claims. First, as already discussed, *supra* 31–34, the constitutionality of the statute does not turn on statistical predictions of the impact of warnings on national smoking rates. Second, the impact analysis does not, in fact, predict that the new warnings will have little if any impact on smoking rates. The impact analysis compared data from Canada for the years 2000 to 2009 with data from the United States for the same period. Between 2000 (prior to the effective date of the

Canadian warnings) and 2010, the smoking rate dropped 7 percentage points, from 24 percent to 17 percent. Over the same period, the smoking rate in the United States dropped less than 3 percentage points, from 23 percent to 20.5 percent. 76 Fed. Reg. at 36,720.

The impact statement observed that it could not be assumed that "the introduction of graphic warning labels in the United States will cause the U.S. smoking rate to fall by seven, or even the three percentage points needed to reach the Canadian rate." *Ibid.* The reasons for some uncertainty are evident. The federal and state governments, as well as public health organizations, have taken a variety of measures to increase public awareness of the risks of tobacco use. Attempting to quantify the extent to which any one measure, acting alone, will contribute to a decline, or avoid an increase, in smoking rates poses major challenges. Thus, although the impact statement sought to "isolate the impact of graphic warning labels on the Canadian smoking rate," it recognized that its analysis was no more than a "rudimentary approach" that "may be producing results that are off by one or more orders of magnitude." *Ibid.*[15]

With these major caveats, the impact statement estimated that the updated warnings will have the effect of reducing the United States' adult smoking population by more than 200,000 people, an 0.088-percentage-point drop in the smoking rate from what could be expected without the updated warnings. *Id.* at 36,721.

Plaintiffs repeatedly quote the sentence fragment that this estimate is "not statistically distinguishable from zero," without reference to the rest of the sentence in which that statement

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[15] Plaintiffs point out that FDA could not account for certain "confounding factors" other than the presence of graphic warnings that contributed to the trends in smoking rates in the United States and Canada. Pl. S.J. Br. 9–10. As FDA explained, the effects of these factors were difficult to quantify, and plaintiffs suggest no means of doing so. Moreover, accounting for some such factors would tend to increase the estimate of the effect of the warnings while others would tend to decrease it, and thus FDA's "estimates could as easily be underestimates as overestimates." 76 Fed. Reg. at 36,711. Plaintiffs offer no response to this conclusion.

appears. *See, e.g.*, Pl. S.J. Br. 8, 24, 33; Comment Letter exh. B, Statement of Robert S. Maness, at 2. The sentence does not declare that the likely impact on smoking rates is zero. It is, instead, an acknowledgment that the parameters of the economic analysis required by the Executive Orders inject enormous uncertainty into its quantitative conclusions. The full sentence declares: "Although both of the estimation methods" discussed in the statement "lead to the conclusion that graphic warning labels will reduce smoking rates, FDA has had access to very small data sets, so our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate." 76 Fed. Reg. at 36,776. The agency explained that the proper approach to uncertain estimates is *not* to "set[] estimates of effects equal to zero when their estimates are statistically insignificant," but rather to present the best estimate along with an analysis of the uncertainty. *Id.* at 36,712.

2. The Consumer Research Study

Plaintiffs offer various criticisms of the study of 18,000 consumers that FDA conducted in to determine the relative effectiveness of the proposed warnings. These criticisms are both inaccurate and immaterial.

Plaintiffs note that, as to some of the warnings, the study did not find "a statistically significant effect on consumers' awareness of smoking risks." Pl. S.J. Br. 7. The study was not designed to make an assessment of the kind suggested by plaintiffs. Instead, as FDA explained, the study simply provided one means of assessing the *relative* impact of different pictorial warnings based on participants' exposure to one warning on one occasion. 76 Fed. Reg. at 36,639. The warning did so by comparing the effects of images on several different variables—including the salience metrics discussed above. As explained, *supra* 34–37, 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). And, of course, plaintiffs themselves have never suggested that some warnings have greater salience than others or that any would, in their view, be constitutionally permissible.

Moreover, the impact of warnings on consumer awareness results not from a single viewing, as in FDA's study, but from repeated exposure to multiple warnings over an extended time. FDA emphasized that a pack-a-day smoker will be exposed to a package warning "more than 7,000 times per year." 76 Fed. Reg. at 36,682. In recognition of this fact, the study specified that it was not intended to furnish conclusions about "longer-term outcomes" that will be achieved by multiple viewings of the warnings. FDA Study Report at 1-2. As explained above, studies that have examined the long-term impact of pictorial warnings concluded that such warnings increase consumers' understanding of the health effects of smoking. *See supra* 16–18.

Plaintiffs are equally wide of the mark in claiming that the survey design—in which FDA studied the reactions of three different populations to the 36 prospective pictorial health warnings—created the likelihood that the study results were the result of "random error." Pl. S.J. Br. 13–14. The study was designed in this manner because scientific research demonstrated that the "effectiveness of health warnings in communicating the health risks of smoking may vary according to the audience" and that "[a] variety of health warnings facilitates better targeting of specific groups whose primary concerns about smoking tend to vary." 75 Fed. Reg. at 69,534. Because FDA considered a finding to be statistically significant if there was only a 5% chance that it was coincidence, 76 Fed. Reg. at 36,648, by definition, one would expect only 5% of the total number of findings to be statistically significant if random error were the only contributing factor. As the data from the study demonstrates, however, the actual number of significant findings was greater

by an order of magnitude. *See generally* FDA Study Report, app. C, at C-1. In addition, many of the findings were significant at the .001 confidence level, meaning that "there is less than one chance in a thousand that the finding happened by coincidence." 76 Fed. Reg. at 36,648.

Plaintiffs also argue that the consumer study (as well as other studies in the record) "suffer from the methodological flaw of 'social desirability bias,'" because survey participants systematically over-report their intention to quit smoking. Pl. S.J. Br. 12–13, 27. FDA directly addressed that point during the rulemaking, explaining that "[t]he more recent scientific literature shows that statements by smokers concerning their intentions to quit smoking are predictive of their making subsequent quit attempts." 75 Fed. Reg. 52,352, 52,354 (Aug. 25, 2010). Plaintiffs offer no basis for finding this conclusion to be arbitrary or capricious.

3. Other APA Challenges

Plaintiffs summarize their APA claims as follows: "(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 . . .; and (5) FDA failed to disclose numerous studies and other data on which the Rule is predicated." P.I. Reply 17.

We have already addressed many of these arguments. *First,* plaintiffs' arguments regarding the warnings' likely impact on smoking rates is incorrect and offers no basis for setting aside the rule. *See supra* 31–34. *Second,* the cost-benefit calculations in FDA's regulatory impact analysis were not meant to justify the graphic warnings requirement, and plaintiffs' claims regarding supposed errors in those calculations are irrelevant to any APA challenge. *See supra* 46–49. *Third*, plaintiffs' claim that FDA "failed to assess numerous less burdensome alternatives" to the mandated

warnings fails to appreciate that it was Congress, not FDA, that required the inclusion of images with the warning statements. *See supra* 21.

Plaintiffs' remaining arguments require little discussion. Plaintiffs fault the FDA for rejecting a comment that some of the graphic images would cause a so-called "rebound" or "boomerang" effect, *i.e.*, they would "increase cigarette use by causing consumers to avoid the warnings or increasing the appeal of cigarettes to some young people." Pl. S.J. Br. 40. But as FDA explained, the companies relied on studies that were dated and that "did not specifically address graphic warnings on cigarette packages and advertisements." 76 Fed. Reg. at 36,634. Recent empirical research studying graphic warnings in other countries has found no such "boomerang" effect. *Ibid.* (citing studies). Nor did FDA apply a "different standard[] of analysis" to comments addressing studies that supported the proposed pictorial warnings. Pl. S.J. Br. 39–40. Unlike the evidence presented by the tobacco companies, these comments were not directly contradicted by newer scientific research. *See* 76 Fed. Reg. at 36,645–46.

Nor can plaintiffs plausibly claim on this record that FDA "failed to provide a meaningful opportunity to comment" on the proposed rule by failing to disclose certain internal studies and reports. Pl. S.J. Br. 41–42. FDA went to great lengths to ensure that the rule was subject to exhaustive public notice and comment. Eight months after the passage of the Tobacco Control Act (a full sixteen months before the congressionally mandated deadline for issuing pictorial warnings), FDA issued a notice describing the design of its consumer research study and seeking public comment. *See* 75 Fed. Reg. 7,604 (Feb. 22, 2010). The agency responded to those comments on August 25, 2010, and sought further comment. *See* 75 Fed. Reg. 52,352. Then on November 12, 2010, FDA issued its notice of proposed rulemaking, unveiling 36 prospective warning images and a preliminary regulatory impact analysis. *See* 75 Fed. Reg. 69,524. Following issuance of the

proposed rule, FDA placed the results of its consumer study on the public docket of the pending rulemaking, and announced that fact in a Federal Register notice to allow public comment on the results. *See* 75 Fed. Reg. 75,936 (Dec. 7, 2010). In these circumstances, there is no basis for plaintiffs' claim that they were not afforded a "reasonable opportunity to participate in the rulemaking process." *WJG Tel. Co., Inc. v. FCC*, 675 F.2d 386, 389 (D.C. Cir. 1982).

In any event, the information that plaintiffs identify as missing from the record did not in any respect prevent plaintiffs from commenting on matters before the agency. Plaintiffs' claim that FDA "failed to disclose key technical data and assumptions it used" in the regulatory impact analysis is incorrect and, in any event, beside the point. As explained above, FDA's cost-benefit analysis played no role in justifying the rule, and so there is no reason why plaintiffs would have needed this information. Dr. Viscusi's assertion that FDA "neglected to describe . . . in meaningful detail" the process by which FDA selected the warning text and the 36 prospective images is similarly mistaken. Pl. S.J. Br. 42 (quoting Viscusi Statement at 37–38). The warning text was required by Congress, and plaintiffs do not explain why knowledge of the process by which the prospective images were selected would have aided their ability to participate in the rulemaking: once FDA revealed the prospective images, plaintiffs were free to (and did) comment on them before FDA promulgated its final rule.

IV. There Is No Authority To Issue an Injunction that Would Delay Enforcement of the Warning Requirements Established by Statute.

The effective date of the updated health warnings was established by Congress in the Tobacco Control Act. Congress provided that, "[n]ot later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in the statute." 15 U.S.C. § 1333 Note. Congress further provided that the Act's amendment to the pre-existing warning

requirements "shall take effect 15 months after the issuance of the regulations." *Ibid*. Consistent with Congress's directive, FDA issued its graphics regulations on June 22, 2011. *See* 76 Fed. Reg. 36,628. Accordingly, the updated health warnings will take effect on September 22, 2012.

In their motion for a preliminary injunction, plaintiffs asked the Court to delay the effective date for 15 months if it *rejects* their challenges. We explained in our opposition to that motion that this relief cannot properly be awarded as a "preliminary injunction," and there would likewise be no basis for issuing final judgment sustaining the validity of the statute and regulation but postponing the effective date established by Congress.

Plaintiffs' summary judgment motion does not argue that the Court could disregard the effective date established by Congress if their challenge to the warning requirements is unsuccessful. Instead, they ask the Court to issue a "declaration invalidating and setting aside the Rule," Pl. S.J. Mot. iii ¶ 1, and, further, to enjoin FDA from enforcing the warning requirements established by statute "until 15 months after issuance by FDA of regulations . . . that are substantively and procedurally valid and permissible." *See id*. ¶¶ 2, 3.

Because plaintiffs' challenge to the rule has no merit, their request for further relief is moot. Even assuming, however, that some aspect of the rule were ultimately declared invalid, there would be no basis for the relief that plaintiffs seek. Plaintiffs' assertion that Congress itself foreclosed "multiple . . . overhauls of their packaging and advertising" (Pl. S.J. Br. 44-45) is belied by the plain terms of the Tobacco Control Act, which expressly authorizes the Secretary to make further adjustments to the warning requirements through rulemaking. *See* 15 U.S.C. § 1333(b)(4) (authorizing the Secretary to "adjust the format and type sizes for the label statements"); *see also* 21 U.S.C. § 387f(d)(1) (authorizing restrictions on advertising and promotion of tobacco products to protect public health). Thus, Congress expressly contemplated that there would be multiple

rounds of changes to the warnings.

Assuming *arguendo* that some aspect of the rule were ultimately declared invalid, the proper course would be a remand to FDA to determine in the first instance whether the particular provision is severable from other warning requirements, whether additional rule-making proceedings are necessary or appropriate, and when any revised rule should take effect. In any such rulemaking, plaintiffs and other interested parties would have the opportunity to submit their views regarding the revised rule as well as its effective date, and plaintiffs could attempt to show that an additional lengthy delay is appropriate even though they implemented the Canadian warning requirements over the course of 180 days. *See* Tobacco Products Information Regulations, SOR/2000-272 (Can.).[16]

FDA's final determinations on such matters would be subject to judicial review on the basis of the administrative record. The APA authorizes judicial review of final agency action, *see* 5 U.S.C. § 706; it does not permit a court to address in advance the contours or effective date of action not yet taken by an agency. *Cf. Nat'l Petrochemical & Refiners Ass'n v. EPA*, 630 F.3d 145, 164 (D.C. Cir. 2010) ("when Congress has delegated 'a determination of policy or judgment which the agency alone is authorized to make and *which it has not made*, a judicial judgment cannot be made to do service for an administrative judgment") (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 88, 63 S.Ct. 454, 87 L.Ed. 626 (1943) (emphasis in *Nat'l Petrochemical*)).

CONCLUSION

For the foregoing reasons, plaintiffs' motion for summary judgment should be denied, and the government's motion for summary judgment should be granted.

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

Respectfully submitted,

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