[ORAL ARGUMENT SCHEDULED FOR APRIL 10, 2012]

No. 11-5332

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

R.J. REYNOLDS TOBACCO COMPANY et al.,

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION et al.,

Defendants-Appellants.

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

REPLY BRIEF FOR APPELLANTS

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GLOSSARY

CPSC	Consumer Product Safety Commission
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IOM Report	Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007)
1994 IOM Report	Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youth* (1994)
RIA	Regulatory Impact Analysis
RICO	Racketeer Influenced and Corrupt Organizations Act
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act of 2009

SUMMARY OF ARGUMENT

The cigarette health warnings mandated by Congress accurately state the health consequences of smoking. The public interest in conveying accurate information about these preventible risks is overwhelming: "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). In determining the size, placement and format of the new warnings, Congress looked to the experience of other countries that have adopted prominent warnings that make use of both text and images. That experience, as discussed in our opening brief (pp. 27–32), demonstrates that warning messages are conveyed more effectively when the text is accompanied by pictorial content.

The impact on plaintiffs' First Amendment interests is comparatively small. After operating under similar warning requirements in Canada for a decade, plaintiffs have offered no evidence that the requirements have prevented them from communicating *any* information to consumers. Thus, the Tobacco Control Act requirements and implementing regulation easily survive the scrutiny accorded to restrictions on commercial speech or to commercial disclosure requirements.

Plaintiffs argue that the health warnings are not really health warnings at all, but a requirement to include "policy-laden and controversial advocacy" on their

packages. Pl. Br. 18. But plaintiffs do not dispute the accuracy of the mandated text, and the detailed discussion in the proposed and final rules makes clear that the images were not chosen "for their shock value," Pl. Br. 26, or to inspire irrational fear of cigarettes. The studies on which Congress and FDA relied show that images work to convey the same message as the text, not a message that is unrelated to the health consequences of smoking.

Plaintiffs complain that the cigarette health warnings, unlike other product warnings, do not "inform consumers how to use a product properly." Pl. Br. 30. Under that view, the challenged warnings would presumably be permissible if they warned consumers of the consequences of smoking "improperly." Unlike other products, however, cigarettes "are 'dangerous to health' when used in the manner prescribed," and "there are no directions that could make tobacco products safe for obtaining their intended effects." *Brown & Williamson*, 529 U.S. at 135. That cigarettes are addictive and lethal when used as directed does not make the health warnings any less accurate or the public interest any less compelling.

ARGUMENT

The Health Warnings Mandated by the Tobacco Control Act Directly Advance the Government's Compelling Interests.

A. Congress can properly require prominent disclosure of health risks on product packaging.

Purveyors of goods and services are routinely required to disclose the dangers of their products. The use of symbols and images to convey serious product risks is commonplace; perhaps the most familiar of these graphics is the "skull-and-crossbones" symbol. *See*, *e.g.*, 16 C.F.R. § 1500.121(b)(5); *id.* § 1500.14(b)(3)(i). The size, placement, and content of such disclosures will depend in each case on the nature and importance of the risk.

In some cases, experience demonstrates that warnings initially selected are inadequate. The charcoal bag warning cited by plaintiffs, Pl. Br. 29, is illustrative. *See* 16 C.F.R. § 1500.14(b)(6)(ii). The Consumer Product Safety Commission (CPSC) mandated the current warnings based on evidence that, despite earlier warnings, consumers continued to burn charcoal in enclosed spaces, resulting in about 28 deaths per year from carbon monoxide poisoning. 61 Fed. Reg. 19,818, 19,819 (May 3, 1996). The CPSC changed the format of the warnings to make them "more noticeable and more easily read and understood." *Id*. at 19,818. The new warnings include pictures that illustrate the conduct to be avoided. The CPSC

did not select pictures that illustrate the health consequences of burning charcoal indoors; had it done so, however, the requirement would have been equally constitutional.

In contrast to the 28 annual deaths caused by improper use of charcoal, cigarettes cause more than 400,000 deaths each year. *Brown & Williamson*, 529 U.S. at 134; Legislative Finding 13.[1] If consumers could avoid the dire health consequences of smoking by smoking cigarettes "properly," Pl. Br. 30, plaintiffs presumably would not oppose warnings that advised smokers how to avoid such harms.

Plaintiffs object that the cigarette health warnings are unlike other product warnings in that they do not "inform consumers how to use a product properly." Pl. Br. 30. But, as plaintiffs do not dispute, there is no way to use a cigarette "properly." Unlike products that have adverse effects only when misused, cigarettes are lethal and addictive when used as intended by the manufacturers. That is why the Supreme Court concluded that cigarettes would be banned if they were regulated as drugs under the Federal Food, Drug, and Cosmetic Act. *Brown & Williamson*, 529 U.S. at 136. The Court stressed that cigarettes "are 'dangerous

[1] The Legislative Findings of the Tobacco Control Act are codified at 21 U.S.C. § 387 Note.

to health' when used in the manner prescribed," and "there are no directions that could make tobacco products safe for obtaining their intended effects." *Id*. at 135.

B. The cigarette health warnings do not mandate political speech or restrict plaintiffs from conveying accurate information.

1. A health warning does not become political advocacy merely because it discourages the conduct that causes the harm. That is what health warnings generally do. Plaintiffs seize on the inevitability of the risks inherent in smoking to transmogrify the health warnings into what they call an "anti-smoking policy message." Pl. Br. 30; *see id.* at 27 (warnings convey the government's "preferred policy choice about tobacco use"); *id.* at 18 (warnings are "policy-laden and controversial advocacy"); *id.* at 35 (warnings "compel[] commercial actors to disseminate non-factual, controversial policy statements"); *id.* at 36 (warnings require plaintiffs "to disseminate the Government's policy view"); *id*. at 37 (same). But plaintiffs cannot explain why warnings that disclose the undisputed health consequences of using cigarettes are made less appropriate, or less constitutional, because the addiction, disease, and death caused by the product cannot be avoided by "proper" use. Cigarette warnings are no less accurate than warnings that provide information about the risks of improper product use.

Like the district court, plaintiffs rely on the line of cases involving laws that "'prescribe[d] what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force[d] citizens to confess by word or act their faith therein.'" *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985) (quoting *West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943)). Plaintiffs quote at length from *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557 (1995), *see* Pl. Br. 20, without acknowledging that the decision applied *Wooley v. Maynard*, 430 U.S. 705 (1977), and other political speech cases to hold that a state could not "require private citizens who organize a parade to include among the marchers a group imparting a message the organizers do not wish to convey." *Hurley*, 515 U.S. at 559.

In relying on this line of cases, plaintiffs treat political speech and product warnings as if they were constitutionally interchangeable. Only by conflating these sharply distinct categories of speech can they assert that the cigarette health warnings are analytically indistinguishable from a statute that "forced Plaintiffs' packaging to 'urge [their] customers to vote for a particular slate of legislative candidates.'" Pl. Br. 36 (quoting *Pacific Gas & Electric Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 15–16 (1986) (plurality opinion)). Plaintiffs see no difference

between a requirement to endorse political candidates and a requirement to disclose the health consequences of using their product. Similarly, plaintiffs see no difference between the cigarette health warnings, on the one hand, and the requirement in *Pacific Gas* that a public utility turn its newsletter into a forum for opposing viewpoints, on the other. But the Supreme Court explained that the speech in *Pacific Gas* was not commercial speech, much less a requirement to disclose product dangers. 475 U.S. at 5, 8–9.[2]

2. Plaintiffs also invoke a new and equally inapt line of authority, asserting that the cigarette health warnings are "[p]aternalistic speech regulations aimed at manipulating consumer choice [that] are 'just as unacceptable in a commercial context as in any other.'" Pl. Br. 23 (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 492–93 (1995) (Stevens J., concurring)). The *Rubin* line of cases

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[2] *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 651–52 (7th Cir. 2006), the only case cited by plaintiffs that applied strict scrutiny in a commercial speech context, invalidated a law requiring video game manufacturers to place a warning label on 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—a definition that incorporated "widely divergent local standards" of offensiveness, *id.* at 650, making it "subjective and highly controversial," *id.* at 652. The court expressly distinguished cigarette health warnings. *See ibid*. Contrary to plaintiffs' suggestion, Pl. Br. 36, the Ninth Circuit declined to follow *Blagojevich*. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966 n.20 (9th Cir. 2009) ("We do not adopt the *Blagojevich* court's approach here because it is not clear what authority supported its application of strict scrutiny . . . .").

invalidated statutes that prevented sellers from disclosing accurate information about their products. For example, the statute in *Rubin* prohibited beer manufacturers from displaying alcohol content on beer labels. *See Rubin*, 514 U.S. at 478; *see also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (ban on advertising the price of drugs); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (ban on advertising the price of alcohol); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) (ban on advertising the availability of compounded drugs).

Plaintiffs also rely heavily on *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), which involved a statute imposing "restrictions on the sale, disclosure, and use" of records that revealed the prescribing practices of individual doctors. *Id*. at 2663. The purpose of these restrictions was to prevent pharmaceutical companies from tailoring their promotions of drugs to particular doctors and thereby "communicating with physicians in an effective and informative manner." *Id*. at 2659–60, 2663. In that context, the Supreme Court stated that "the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech." *Id*. at 2670-71 (quoting *Thompson*, 553 U.S. at 274). The Court stressed that this principle applies "with full force when the

audience, in this case prescribing physicians, consists of sophisticated and experienced consumers." *Id*. at 2671 (quotation marks omitted).

Here, by contrast, it is plaintiffs that seek to suppress truthful information about the health consequences of smoking by relegating it to a format that is essentially "invisible." 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) (testimony of Richard Bonnie). And the audience they seek to keep "in the dark" does not consist of "sophisticated" consumers, *Sorrell*, 131 S. Ct. at 2671 (citations omitted), but the millions of adolescents who replenish the ranks of plaintiffs' customers each year and the adults who became addicted while still underage. Legislative Finding 31.

C. The cigarette health warnings readily withstand review under *Zauderer* and *Central Hudson*.

"[T]he Constitution accords less protection to commercial speech than to other constitutionally safeguarded forms of expression." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64–65 (1983). A requirement that a seller provide accurate warnings or other disclosures is upheld if it is "reasonably related" to the government's interest and is not so "unjustified or unduly burdensome" as to "chill[] protected commercial speech." *Zauderer*, 471 U.S. at 651. Restrictions on

commercial speech are upheld as long as they are narrowly tailored to directly advance a substantial government interest. *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566 (1980). The cigarette health warnings are clearly constitutional under these standards and, indeed, would satisfy strict scrutiny if that standard were thought to be applicable.

1. The government has a compelling interest in ensuring effective disclosure of the health risks of cigarettes.

The government has a compelling interest in ensuring that the health consequences of smoking are disclosed in a manner that is noticed and understood. To market these deadly and addictive products without warnings commensurate to their acknowledged risks would be affirmatively misleading in the same way as the marketing practices of bankruptcy attorneys at issue in *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324 (2010). There, the legislative record indicated that many bankruptcy attorneys and other professionals offered assistance to individuals with consumer debt without disclosing in advance that their services might include filing for bankruptcy. Responding to that practice, Congress defined as "debt relief agencies" attorneys who provide advice to debtors and required such attorneys to use this new nomenclature in their advertising by stating prominently: "'We are a debt relief agency. We help people file for

bankruptcy relief under the Bankruptcy Code.'" *Id*. at 1330. Although the government had "adduced no evidence" that the attorney advertisements were "misleading," the Court concluded that "[e]vidence in the congressional record demonstrating a pattern of advertisements that hold out the promise of debt relief without alerting consumers to its potential cost . . . is adequate to establish that the likelihood of deception in this case 'is hardly a speculative one.'" *Id*. at 1340 (quoting *Zauderer*, 471 U.S. at 652).

The "potential cost" of smoking dwarfs the consequences of consulting a bankruptcy attorney or filing for bankruptcy. And the risk of deception, in the sense that *Zauderer* used the term, is manifest. Indeed, cigarette manufacturers exploited that potential for nearly half a century by fraudulently maintaining that the "link between smoking and disease" is an "open question." *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1120 (D.C. Cir. 2009).

In any event, a legislature's authority to require sellers to disclose health and safety risks is not open to dispute. Warnings need not "prevent 'consumer confusion or deception' per se" but may simply "inform consumers about the products they purchase." *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 133 (2d Cir. 2009); *see also Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (rejecting the argument that

"*Zauderer* is limited to potentially deceptive advertising" and finding "no cases limiting *Zauderer* in such a way").

2. The health warnings are tailored to address the serious consequences of using plaintiffs' products and do not significantly restrict plaintiffs' commercial speech.

By any standard, the cigarette health warnings mandated by Congress are tailored to address the grave risks inherent in the use of plaintiffs' products.

a. Plaintiffs assert that "[t]he sheer size and placement of the graphic warnings go far beyond anything necessary to provide consumers with purely factual and uncontroversial information." Pl. Br. 27. They persuaded the district court that "the dimensions *alone* strongly suggest" that the warnings were designed to advance the government's "obvious anti-smoking agenda!" JA 34.

Plaintiffs do not dispute, however, that the current Surgeon General warnings are effectively "invisible." *Hearing Before the House Subcommittee on Health*, *supra*, 110 Cong. 42. Their insistence 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," JA 210–11, is thus an attempt to make accurate health-risk information invisible.

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. They do not dispute that approximately 80% of smokers are addicted by the age of 18, but they nevertheless declare that "young people overestimate the dangers of smoking to an even greater degree" than adults. Pl. Br. 10–11. As they have for many years, plaintiffs rely on reports provided by Dr. W. 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. 98-2 at A16, *Commonwealth Brands v. United States*, No. 1:09-cv-117 (W.D. Ky.)).

Countless independent studies contradict Viscusi's position. The Institute of Medicine explained 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." Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 93 (2007) ("IOM Report"). 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 of suffering tobacco-related disease. *Id*. at 89-90. 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); *see also* 76 Fed. Reg. 36,628,

36,632–33 (June 22, 2011) (detailing numerous other studies showing significant information gaps regarding the harms of smoking, particularly among adolescents who overwhelmingly represent the market of new smokers).

Viscusi's report disregards this body of findings, and his limited discussion of scientific studies is inaccurate. For example, 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]." JA 262. Drs. Weinstein and Slovic were experts for the government in *United States v. Philip Morris USA, Inc.*, and what they actually found is that "most people have only a superficial awareness that smoking is dangerous," 449 F. Supp. 2d 1, 578 (D.D.C. 2006) (citing 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 district court in *Philip Morris* 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.[3]

Plaintiffs are on no firmer ground when they claim that the consumer study and Regulatory Impact Analysis ("RIA") conducted by FDA during the rulemaking demonstrated that the health warnings are "unlikely to affect either smoking prevalence or consumer knowledge of smoking risks." Pl. Br. 4. The consumer study, discussed in our opening brief (pp. 37–39) and below (p.18–20), compared viewer responses to the 36 proposed warnings. As explained, the study was designed to assess image salience, and thus help FDA to select images that were effective at conveying the warning messages.

The RIA, in turn, is an economic analysis that must be included in all federal rulemaking to "improve the internal management of the Federal Government." Executive Order 12,866, § 10, 58 Fed. Reg. 51,735, 51,744 (1993).[4] The RIA

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[3] Plaintiffs' claims about other studies are likewise at odds with the conclusions reached by the studies' authors. *See, e.g.*, Patrick Jamieson & Daniel Romer, *What Do Young People Think They Know About the Risks of Smoking? in* Smoking: Risk, Perception & Policy 51, 55 (Paul Slovic ed., 2001) (concluding that "antismoking campaigns have failed to inform many young people of the extent of life potentially lost due to smoking").

[4] An RIA does "not create any right or benefit, substantive or procedural, enforceable at law or equity." Executive Order 12,866, § 10, 58 Fed. Reg. 51,735, 51,744 (1993); *see also* Executive Order 13,563, § 7(d), 76 Fed. Reg. 3821, 3823 (2011) (similar).

noted that smoking rates in Canada dropped steeply after its warnings were revised to include pictorial content, and then made the unremarkable point that is difficult determine with statistical precision the relative causal impact of the relevant contributing factors. The sentence, from which plaintiffs quote selectively, simply observes the limitations of the FDA's own study: "Although both of the estimation methods [discussed in the RIA] 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[.]" 76 Fed. Reg. at 36,776. The agency explained 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.*[5]

The RIA was not intended to second-guess Congress's judgment regarding the value of new health warnings. Even in the First Amendment context, Congress's predictive judgments are entitled to deference, *see Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997), and there is ample support for Congress's judgment that warnings of the type used in Canada and other countries should

[5] FDA also 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. 76 Fed. Reg. at 36,712.

appear on a product that is lethal and addictive. The significant decline in Canadian smoking rates in the decade following the introduction of graphic warnings is not disputed; that a "rudimentary" economic analysis could not determine the role of the warnings with statistical confidence does not suggest that the warnings did not increase consumer knowledge or contribute to the decline in smoking prevalence.

b. Whereas the government's interest in communicating the health risks of smoking is compelling, the intrusion on plaintiffs' First Amendment interests is comparatively insubstantial. As in *Milavetz* and *Zauderer*, plaintiffs' "constitutionally protected interest in *not* providing the required factual information is 'minimal.'" *Milavetz*, 130 S. Ct. at 1339; *see Zauderer*, 471 U.S. at 650 (noting that there are "material differences between disclosure requirements and outright prohibitions on speech" because disclosures do not prevent advertisers "from conveying information to the public," but only require them to provide "more information than they might otherwise be inclined to present").

The health warnings do not significantly affect plaintiffs' ability to convey information to the public. More than half of their cigarette packs and 80% of their advertisements remain available for their speech. *See Commonwealth Brands v. United States*, 678 F. Supp. 2d 512, 531 (W.D. Ky. 2010). Although plaintiffs

have operated under comparable warning requirements in Canada for a decade, they offered no evidence that they have been prevented from communicating *any* information to consumers. The Canadian Supreme Court unanimously rejected a challenge to cigarette health warnings 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." *J.T.I. MacDonald Corp. v. Canada*, 2007 SCC 30, ¶139 (2007).

3. The health warnings include images in order to more effectively convey the message of the accompanying text.

FDA explained that "the addition of graphics to warnings for cigarettes is a difference in form only and does not change the fundamental content of the messages, which convey factual information about the health consequences of smoking." 76 Fed. Reg. at 36,696. Plaintiffs do not contend that the images convey a message different from that of the accompanying text. Instead, they broadly assert that the inclusion of images serves only to elicit emotion and does nothing to further the factual message conveyed by the text.

Plaintiffs mischaracterize the concept of "salience," which they described in district court as "a euphemism for shock value." P.I. Hr'g Tr. 12. Echoing that contention, they now insist that "[t]he graphics were not selected for their ability to

provide factual information, but rather, for their shock value." Pl. Br. 26. As our opening brief explained, these assertions disregard the way images and text work in tandem to ensure that "the warnings are better understood and remembered." 76 Fed. Reg. at 36,697.

The FDA study measured responses to the 36 proposed warnings by exposing participants to one of the warnings—text together with image—on a single occasion (or, for the control group, to a text-only warning). FDA used several measures to test the relative efficacy of the 36 proposed warnings, including measures to assess their "salience (*i.e.*, noticeability and readability)." *Id.* at 36,696. To determine salience, FDA considered both "[e]motional reactions" and "cognitive reactions," explaining that "[u]se of these measures is well-established in the scientific literature." *Id*. at 36,696–97. "[E]liciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warnings are better understood and remembered." *Id*. at 36,697. FDA selected the final set of images because it found (among other things) that the images elicited the emotional and cognitive reactions that enhance long-term recall and understanding. *Id.* at 36,635.

FDA emphasized that "use of these reaction measurements does not demonstrate the Agency's intent to stigmatize tobacco products." *Id*. at 36,697.

"Rather, these measures are appropriate indicators of how effectively health warning messages are communicated, and were used in FDA's research study to provide valuable information regarding the relative ability of the 36 proposed required warnings to effectively convey the very real adverse health consequences of smoking to the public." *Ibid.*; *see Commonwealth Brands*, 678 F. Supp. 2d at 530 (noting that the "government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance").

The administrative record and the extensive literature discussed in the rulemaking make clear that salience is not "a euphemism for shock value." It is a scientifically demonstrated means of predicting how consumers will process warnings over a period of years, long after any initial impression has passed.

To buttress their claim that the warnings do not communicate information about health risks, plaintiffs repeatedly cite a statement from a 1994 report of the Institute of Medicine ("IOM") quoted in the IOM's 2007 Report. The passage stated that "'the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products, especially by children and youths, as a means of reducing tobacco-related death and disease.'" IOM Report at 291 (quoting Institute of Medicine, *Growing Up Tobacco Free:*

Preventing Nicotine Addiction in Children and Youth 236–37 (1994) ("1994 IOM Report")).

Contrary to plaintiffs' assertion, the IOM did not thereby suggest that cigarette warnings should not convey health information, or that they should dissuade consumption of cigarettes by appealing to consumer irrationality. The IOM made abundantly clear that the problem with the current cigarette health warnings is that they "fail to convey relevant information in an effective way." *Ibid*. The IOM explained that, "[i]n contrast to the experience with such warnings in the United States, the experiences with these warnings in Canada and other countries have been more promising." *Ibid*. National surveys conducted on behalf of Health Canada "indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the pictorial warnings have been effective in providing them with important health information." *Id*. at 294. By contrast, the IOM advised Congress that the U.S. health warnings are essentially "invisible." *Hearing Before the House Subcommittee on Health*, *supra*, 110 Cong. 42.

The IOM's statement that "the primary objective of tobacco regulation is not to promote informed choice" addressed the inability of minors to make an "informed choice" in starting to smoke. The 1994 report noted that "arguments about the rationality of choices by adults to initiate tobacco use are beside the point

because at least 70% of adult daily smokers already became daily smokers" and were addicted before they were 18. 1994 IOM Report at 13.

Plaintiffs do not dispute that 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. Nor do they deny that "most addicted adult smokers want to quit, try to quit, and would rather be nonsmokers." IOM Report at 148. Their assertion that the cigarette health warnings trammel on principles of "consumer choice" and "personal decision" simply ignores the facts that the industry concealed for decades. *See Philip Morris*, 566 F.3d at 1107, 1124 (noting that cigarette manufacturers "engineered their products around creating and sustaining this addiction," even as they "denied and distorted the truth as to the addictive nature of their products for several decades" and "concealed much of their nicotine-related research").

Plaintiffs trivialize the tenacity of nicotine addiction by offering far-fetched analogies to fast food, chocolate bars, and alcohol. Pl. Br. 32–34. It is now beyond dispute that cigarettes "are unlike ordinary consumer products," IOM Report at 153, because they have no safe or proper use. "Foods rich in fats or carbohydrates may lead to overweight and increase disease risks if consumed in

excess, but they are not addictive or inherently dangerous." *Ibid*. Chocolate is not deadly, and tooth decay can be prevented with a toothbrush. Alcohol can be consumed in moderation by most adults. *See ibid*.

The comparisons to chocolate bars and fatty foods echo the analogies that plaintiffs proffered when they claimed that smoking was not addictive but merely "caused an 'attachment' comparable to that produced by 'tennis, jogging, candy, rock music, Coca-cola, members of the opposite sex and hamburgers.'" *Philip Morris*, 566 F.3d at 1128 (citation omitted). Plaintiffs continue to decry the cigarette health warnings as "fear appeals," Pl. Br. 15, and to assert that the images form "part of a naked appeal to emotion." Pl. Br. 26. And, in an echo of their "open question" strategy, they continue to assert that the cigarette health warnings are an attempt "'to tilt public debate in a preferred direction.'" Pl. Br. 18 (quoting *Sorrell*, 131 S. Ct. at 2671). But even plaintiffs no longer can deny that the information in the warning text is accurate. *See* Pl. Br. 2. Cigarettes are deadly and addictive, and the facts disclosed in the health warnings are not matters of "public debate." Pl. Br. 18.

D. Plaintiffs' cursory discussion of specific warnings identifies no First Amendment defect.

In the rulemaking and throughout this litigation, plaintiffs have urged that inclusion of any of the 36 images considered by FDA would render the health warnings unconstitutional. Plaintiffs' limited discussion of specific images is conclusory and internally inconsistent. Representational images, such as a drawing of a baby in an incubator, are dismissed as "non-factual cartoon drawings"; realistic depictions of the consequences of smoking, such as images of diseases of the mouth and lungs, are assailed as too "gruesome." Pl. Br. 24. None of these objections has merit, and all ignore the ways in which the text and image work together to convey accurate information.

Plaintiffs argue that "[t]he graphic warnings use non-factual and controversial cartoon drawings, digital enhancements, and actors to dramatize the effects of smoking-related illness." Pl. Br. 24. The "non-factual cartoon drawing" is the image of a baby in an incubator that accompanies the statement "Smoking during pregnancy can harm your baby." As FDA explained, "[t]he style of the depiction—here, a graphic illustration—does not make it less factual." 76 Fed. Reg. at 36,696.

Plaintiffs do not explain why this warning fails to convey its indisputably accurate message in an "objective and evenhanded way." Pl. Br. 24. Indeed, it is unclear what plaintiffs mean by that phrase. In the past, plaintiffs castigated the Surgeon General for "endeavoring to scare pregnant women." *Philip Morris*, 449 F. Supp. 2d at 194. But even plaintiffs no longer dispute that "smoking during pregnancy has negative effects, including increasing rates of preterm delivery and the likelihood of low birth weight." 76 Fed. Reg. at 36,696.

Although plaintiffs object to the use of "digital enhancements" to show health effects such as diseased lungs and a cancerous lesion on a lip, Pl. Br. 24, they do not dispute that "the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking." 76 Fed. Reg. at 36,696. As FDA noted, the cancerous lesion 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," as compared to less visible, longer-term impacts. *Id*. at 36,652.

Plaintiffs' contention that the "[t]he graphics are affirmatively misleading and/or convey no information about the risks of smoking," Pl. Br. 25, determinedly ignores the way images and text function in tandem. For example, the text

"Cigarettes are addictive" is accompanied by 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 an 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; 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).

Plaintiffs urge that "[i]t is one thing to say that smoking is addictive" and another to show "photos of extreme situations." Pl. Br. 25. Plaintiffs are correct, but not in a way that advances their argument. It is, indeed, one thing to say that smoking is addictive, and another thing to comprehend what that statement means. The image, taken together with the text, conveys the tenacity of addiction in a way

that the text alone does not accomplish, and it provides a concrete representation of what otherwise might be treated as an abstract concept.

With respect to the warning "Cigarettes cause strokes and heart disease," which is accompanied by the image of a man wearing an oxygen mask, plaintiffs' sole objection is that the man in the photograph is an actor. Pl. Br. 24. Plaintiffs do not even attempt to explain the relevance of this objection. It is undisputed that smoking causes strokes and heart disease. FDA selected this image in part because "the person shown in this image is an older man," while other images "show younger people." 76 Fed. Reg. at 36,653. FDA explained that it had attempted to select "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.*

Plaintiffs similarly object to the image depicting a man with an autopsy scar that accompanies the text "Smoking Can Kill You," on the ground that "autopsies are not a common consequence of smoking." Pl. Br. 25. But the graphic does not accompany the message "Smoking Causes Autopsies." Plaintiffs do not deny that smoking kills 443,000 Americans each year, 76 Fed. Reg. at 36,629, or that, among children that become regular smokers, "about half eventually will die from a

disease caused by tobacco use," *Promoting Healthy Lifestyles*, *supra*, at 64. 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.

Plaintiffs cursorily claim that the warning "Tobacco Smoke Can Harm Your Children" which is accompanied by the image of smoke approaching a baby, and the warning "Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers," which is accompanied by the image of a woman crying, "do not portray any health consequences of smoking" and instead "use distressing images of women and children as part of a naked appeal to emotion." Pl. Br. 26. Plaintiffs again divorce the images from the text. Their assertion that the image of smoke approaching a baby does not purport to describe the health consequences of exposing children to second-hand smoke echoes comments that "the child does not appear to be suffering harms to his health" and "looks too healthy." 76 Fed. Reg. 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 secondhand smoke for children, some of which (such as impaired lung growth), are not necessarily externally visible in a photograph of a child exposed to secondhand smoke." *Id.* at

36,650. Had the visible effects of disease been shown, plaintiffs presumably would object that the image is too "gruesome."

With respect to the warning that addresses the effects of secondhand smoke, plaintiffs do not deny that "the image is a realistic portrayal of how the negative health consequences caused by exposure to secondhand smoke can affect people." 76 Fed. Reg. at 36,656. FDA explained that "[t]he 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.*

Plaintiffs offer similarly cursory observations regarding the warning "Quitting Smoking Now Greatly Reduces Serious Risks To Your Health," which is accompanied by a man wearing a t-shirt that says "I Quit." They declare that the image "provides no information about smoking risks (or even the benefits of quitting)." Pl. Br. 26. Plaintiffs' criticism, however, ignores the fact that the image appears in context of a textual statement about the undisputed benefits of quitting. The image of a man in evident good health who has quit smoking illustrates the information provided in the text. Plaintiffs do not deny that quitting smoking greatly reduces health risks. To the contrary, Santa Fe Natural Tobacco Company (a subsidiary of Reynolds American Inc., *see* Pl. Br. vii) declares on its

website: "[W]e cannot stress this enough: If you don't smoke, don't start."[6] Lorillard's website stresses 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."[7] And, in a recent submission to FDA, Reynolds declared it "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. 28, 2011); *accord* R.J. Reynolds, Guiding Principles and Beliefs ("The best course of action for tobacco consumers concerned about their health is to quit.").[8]

Plaintiffs do not advance their argument by objecting to the inclusion of a telephone number for a nationally recognized smoking cessation resource—1-800-QUIT-NOW—in the health warnings. FDA noted that the research literature "highlights the importance of including one or more warnings that provide solutions . . . in a set of warnings conveying the negative health consequences of smoking." 76 Fed. Reg. at 36,656. FDA explained, and plaintiffs do not dispute, that studies show that "health warnings are more effective if they are combined

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[6] http://www.sfntc.com (last visited Feb. 13, 2012). This message is seen if you indicate that you are not a smoker and click "Submit."

[7] http://www.lorillard.com/?s=quit+smoking (last visited Feb. 13, 2012).

[8] http://www.rjrt.com/prinbeliefs.aspx (last visited Feb. 13, 2012).

with cessation-related information." *Id.* at 36,681. The phone number to which plaintiffs object is that of the preexisting "National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1-800-QUIT-NOW." *Id.* at 36,681. Product warnings commonly give consumers information about how to avoid risks, and Lorillard's own web site advises smokers to call the same phone number that plaintiffs challenge here: "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."[9]

[9] http://www.lorillard.com/responsibility/smoking-and-health/addiction (last visited Feb. 13, 2012).

CONCLUSION

For the foregoing reasons, and for the reasons stated in our opening brief, the preliminary injunction should be vacated.

Respectfully submitted,

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

I hereby certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times New Roman font, and the word count is 6,740.

s/ Alisa B. Klein
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CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of February, 2012, I caused the foregoing brief to be filed with the Court and served on counsel through the Court's ECF system.

s/ Alisa B. Klein
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