

ORAL ARGUMENT SCHEDULED FOR APRIL 10, 2012

No. 11-5332

In The United States Court of Appeals
For the District of Columbia

R.J. REYNOLDS TOBACCO COMPANY et al.,

Plaintiffs-Appellees,

vs.

FOOD AND DRUG ADMINISTRATION et al.,

Defendants-Appellants.

Appeal from the United States District Court
For the District of Columbia

BRIEF OF *AMICUS CURIAE* STATES IDAHO, ALASKA, ARIZONA,
ARKANSAS, CALIFORNIA, CONNECTICUT, DISTRICT OF COLUMBIA,
HAWAI'I, ILLINOIS, IOWA, MAINE, MARYLAND, MISSISSIPPI,
MONTANA, NEW HAMPSHIRE, NEW MEXICO, OHIO, RHODE ISLAND,
SOUTH DAKOTA, UTAH, VERMONT, VIRGIN ISLANDS, WASHINGTON,
and WEST VIRGINIA

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GLOSSARY

The *Amici* adopt and incorporate by reference the Glossary of the United States Department of Justice in their brief on appeal in this matter. *Amici* add the following four terms:

CDC	Centers for Disease Control and Prevention
FTC	Federal Trade Commission
MSA	Tobacco Master Settlement Agreement of November 23, 1998
TCA	Family Smoking Prevention and Tobacco Control Act of 2009

PRELIMINARY STATEMENT AND INTEREST OF AMICUS

The Master Settlement Agreement (“MSA”), executed November 23, 1998, is a “landmark agreement”, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 533 (2001), that settled the claims of 46 States and six other governmental entities (“Settling States”)¹ against the major tobacco manufacturers. The MSA constituted a major step by the Settling States in addressing youth tobacco use, which the Supreme Court has recognized as posing “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).

The MSA released the Settling States’ claims against the tobacco companies that signed it in exchange for, among other things, restrictions on the companies’ advertising, marketing and promotion of tobacco products (MSA § III); substantial annual payments to the States based on the companies’ domestic cigarette sales (MSA § IX); and the companies’ agreement to fund a foundation “to support (1) the study of and programs to reduce Youth Tobacco Product usage and Youth substance abuse in the States, and (2) the study of and educational programs to

¹ The MSA was signed by the Attorneys General of 46 States, the Commonwealth of Puerto Rico, the District of Columbia, and four territories. Four other States (Florida, Minnesota, Mississippi and Texas) settled their claims against the tobacco companies before the MSA was executed. Each of those settlements included some of the same advertising and marketing restrictions that are found in the MSA; all included provisions prohibiting material misrepresentations concerning the health consequences of using tobacco products. Accordingly, what is said in this brief regarding the MSA is equally true of those agreements.

prevent diseases associated with the use of Tobacco Products in the States” (MSA § VI(a)).²

Significantly, the States’ claims against the companies included allegations of fraud in denying the addictiveness of, and harm caused by, their products, and the MSA advertising restrictions were designed in part to remedy that fraud by, among other things, prohibiting the companies from materially misrepresenting the health consequences of using those products. MSA § III(r). Since 1998, the *Amici* States have brought numerous actions to enjoin violations of the MSA’s marketing provisions, and have resolved many other MSA violations by agreement with tobacco companies. Both through the litigation that led to the MSA and through the enforcement of the Agreement since 1998, the undersigned attorneys general have developed a comprehensive understanding of the public health consequences of tobacco use in the United States and of the need for provisions to make the public aware of the unique dangers these products present. The States have a particularly strong stake in establishing effective measures to ensure that underage consumers, who comprise the large majority of new smokers, understand the risks of smoking.

The requirement for cigarette package warning labels designed to communicate effectively to young people at risk of addiction to cigarettes is a

² The MSA is available at <http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/>.

matter of signal importance to the States, which bear a large portion of the public health burden of tobacco use. The *Amici* States therefore submit this brief setting forth their strongly held view that the new warning labels required by Congress and implemented by the Food and Drug Administration are consistent with the United States Constitution.

ARGUMENT

The First Amendment does not prevent the government from requiring that lethal and addictive products carry warning labels that effectively inform consumers of the risks those products entail. This case involves the deadliest product sold in America, and one of the most addictive. Over forty years' experience with small, obscurely placed text-only warning labels on cigarette packs has demonstrated that they simply do not work; studies confirm that they are no longer even noticed.

In 2009, this Court affirmed a judgment of the district court finding that the major cigarette companies—accounting for 99 percent of the US cigarette market at the time the lawsuit was initiated—had engaged in a conspiracy of unprecedented magnitude and duration to deceive the American public about the lethal consequences of smoking and to addict them to a product the companies knew was lethal. *United States v. Philip Morris USA, Inc.*, 449 F.Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*

130 S.Ct. 3501 (2010). Furthermore, the court found that the tobacco industry's marketing had targeted children and adolescents—the most vulnerable segment of the population and the one least capable of making reasoned judgments about risk.

The same year, after receiving a report from the Institute of Medicine recommending that warning labels be changed for the first time since 1984, Congress passed legislation specifying the text, size, and placement of new warning labels and directed the FDA to choose pictorial images to illustrate the warnings. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (hereafter "TCA"). Nothing in First Amendment jurisprudence prevents the implementation of this statutory requirement. The warning labels reflect the unique magnitude of the problem they address, the deadly and addictive nature of the product, and the unparalleled threat this product and its marketing pose to America's youth.

I. THE DISTRICT COURT'S OPINION FAILED TO RECOGNIZE THE SEVERE PUBLIC HEALTH THREAT CIGARETTES POSE AND THE LONG HISTORY OF DECEPTION BY CIGARETTE MANUFACTURERS.

The federal government requires warning labels on many goods, from prescription drugs to household appliances. These labels provide information to consumers about dangers posed by the improper use of these products. Without them, consumers might have inadequate information to decide whether the benefits

of using a product outweigh the risks or how the product should be used to minimize risk. The labels' content varies with the nature of the product and the risk it presents: some drug labels, for example, are extremely long and detailed while others consist of only a few words. Warning labels may comprise a combination of text, images, or symbols, such as a skull and crossbones.

The appropriateness of a product warning depends upon the dangers posed by the product, the likelihood that its users will suffer harm, the likelihood that the warning will be noticed, and the capacity of those dependent on the warning to understand its import and act in response to it. The urgency of a warning for a product that could cause the death of children may differ markedly from that of a warning for a product that could cause an upset stomach. In all cases, however, a warning is effective only if it is noticed, and only if it communicates its message.

The district court's opinion in this case evaluates the warnings at issue in a vacuum that ignores this vital context.

The unique severity of the public health threat posed by cigarettes is indisputable. Cigarette smoking is the largest "preventable cause of disease, disability, and death in the United States." Centers for Disease Control and Prevention (CDC), *Tobacco Use: Targeting the Nation's Leading Killer* (2011).³

³ Available at http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2011/Tobacco_AAG_2011_508.pdf.

Half of those who become regular smokers will die of tobacco-related disease. CDC, *Vital Signs: Adult Smoking in the US* (Sept. 2011).⁴ Moreover, cigarettes are the only product sold legally that, when used as intended, cause death and disease. There is no way to formulate a warning that informs consumers how they can safely smoke cigarettes.

Cigarettes are deliberately engineered to be highly addictive. Those who believe they are merely experimenting with cigarettes often become addicted before they realize it.

The population most at risk is uniquely vulnerable. Nearly all those who become regular smokers begin smoking while they are underage. Their judgment and perception of risk is not informed by experience. Moreover, as this Court has found, the cigarette industry has for many decades done everything in its power to promote smoking as glamorous and attractive and engaged in a campaign to minimize young people's perception of risk.

This combination of factors makes the issue of warning labels for cigarettes unique.

⁴ Available at <http://www.cdc.gov/vitalsigns/pdf/2011-09-vitalsigns.pdf>.

II. THE PROPOSED WARNING LABELS SEEK TO COUNTER THE EFFECTS OF CONDUCT THAT THIS COURT HAS FOUND TO BE DECEPTIVE, FRAUDULENT, AND ONGOING.

This case involves commercial speech. The Constitution protects commercial speech that is not misleading or deceptive. However, it is well established that “the government may require commercial speech to ‘appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.’” *Philip Morris*, 566 F.3d at 1142 (quoting *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)). “[T]he First Amendment does not preclude corrective statements where necessary to prevent consumers from being confused or misled.” *Philip Morris*, 449 F.Supp. 2d at 926.

The warning labels should not be evaluated in isolation. They should, instead, be viewed in the context of the years of deception that preceded them, and to which they respond. This Court has long recognized the necessity, and constitutionality, of such a contextual approach to governmentally prescribed communication to consumers. Even with regard to a far less serious legacy of misrepresentation, for example, this Court noted the need for effective corrective speech:

To be sure, current and future advertising of Listerine, when viewed in isolation, may not contain any statements which are themselves false or deceptive. But reality

counsels that such advertisements cannot be viewed in isolation; they must be seen against the background of over 50 years in which Listerine has been proclaimed—and purchased—as a remedy for colds. When viewed from this perspective, advertising which fails to rebut the prior claims as to Listerine's efficacy inevitably builds upon those claims; continued advertising continues the deception, albeit implicitly rather than explicitly....

Under this reasoning the First Amendment presents no direct obstacle. The Commission is not regulating truthful speech protected by the First Amendment, but is merely requiring certain statements which, if not present in current and future advertisements, would render those advertisements themselves part of a continuing deception of the public.

Warner-Lambert Co. v. FTC, 562 F.2d 749, 769 (D.C. Cir. 1977) (upholding FTC order requiring manufacturer to include in its advertisements the disclaimer “Listerine will not help prevent colds or sore throats or lessen their severity”); *see also Novartis Corp. v. FTC*, 223 F.3d 783, 789 (D.C. Cir. 2000) (applying standard in context of drug advertising).

Because of the pervasive effects and long history of tobacco industry deceit and its effect on consumer perceptions, even cigarette labeling that would not appear deceptive in isolation is likely to constitute “part of a continuing deception of the public,” *Warner-Lambert*, 562 F.2d at 769, absent highly visible, vividly conveyed warnings. *See Philip Morris*, 449 F.Supp. 2d at 927 (finding this precedent “particularly applicable.”) As this Court has found:

[w]hen deciding whether to smoke cigarettes, tobacco consumers must resolve initial reservations (or lingering qualms) about the potential for cancer, the risk of addiction, or the hazardous effects of secondhand smoke....Defendants' prevarications about each of these issues suggests full awareness of this obvious fact; reasonable purchasers of cigarettes would consider these statements important.

566 F.3d at 1123.

In sum, warning labels are needed not merely to provide truthful and potentially life-saving information, but also to counteract decades of deception by the cigarette manufacturers. A comparison of the FDA's warning labels with the judgments of the district court and this Court in *United States v. Philip Morris* demonstrates that the major cigarette companies engaged in a conspiracy to defraud the public about *every one* of the subjects addressed in the warning labels. That conspiracy created a social context that makes it attractive for vulnerable young people to experiment with cigarettes.

Addiction. The text of the first warning label states, "Cigarettes are addictive." This Court found that the major cigarette manufacturers

intimately understood the addictiveness of nicotine and manipulated nicotine delivery in cigarettes to create and sustain addiction.... Defendants publicly denied and distorted the truth about the addictive nature of their products, suppressed research revealing the addictiveness of nicotine, and denied their efforts to control nicotine levels and delivery.

566 F.3d at 1107. The district court exhaustively documented not only the companies' deception in denying the addictiveness of cigarettes, but also that the companies "researched, developed, and implemented many different methods and processes to control the delivery and absorption of the optimum amount of nicotine which would create and sustain smokers' addiction." 449 F.Supp. 2d at 383.

Death and Disease. Four other warnings deal directly with death and disease resulting from smoking. They state, respectively, "Cigarettes cause fatal lung disease"; "Cigarettes cause cancer"; "Cigarettes cause strokes and heart disease"; and "Smoking can kill you." This Court found 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 acknowledged as fact that smoking causes disease and other health hazards." 566 F.3d at 1106. The district court's exhaustive findings concluded that "[c]igarette smoking causes disease, suffering, and death. Despite internal recognition of this fact, Defendants have publicly denied, distorted and minimized the hazards of smoking for decades." 449 F.Supp. 2d at 146.

Secondhand smoke. Two of the warnings address the effects of secondhand smoke: "Tobacco smoke can harm your children" and "Tobacco smoke causes fatal lung disease in non-smokers." The district court found that "Defendants crafted and implemented a broad strategy to undermine and distort the evidence

indicting passive smoke as a health hazard.” 449 F.Supp. 2d at 693. The district court made voluminous findings documenting defendants’ misrepresentation of evidence regarding secondhand smoke. 449 F.Supp. 2d at 692-801. In affirming, this Court found that “Defendants became aware that secondhand smoke poses a health risk to nonsmokers but made misleading public statements and advertisements about secondhand smoke in an attempt to cause the public to doubt the evidence of its harmfulness.” 566 F.3d at 1107.

Smoking during pregnancy. The text of another warning label states, “Smoking during pregnancy can harm your baby.” This Court found that “‘Defendant companies willfully stat[ed] something which they knew to be untrue.’ For example, the [district] court found that, in a televised interview in 1971, Philip Morris President Joseph Cullman III denied that cigarettes posed a health hazard to pregnant women or their infants, ‘contradicting the information[.]Philip Morris’s Vice President for Corporate Research and Development, had given him two years earlier.’” 566 F.3d at 1118-19 (quoting *Philip Morris*, 449 F.Supp. 2d at 193-94). Cullman, backed by the industry-controlled Tobacco Institute, notoriously observed that the lower birth-weight of smokers’ babies was not a matter of concern because “[s]ome women would prefer to have smaller babies.” 449 F.Supp. 2d at 193-94.

Quitting. The final warning label states “Quitting smoking now greatly reduces serious risks to your health.” Judge Kessler found that cigarette manufacturers intentionally misled young people into becoming addicted to cigarettes:

Defendants knew that youth were highly susceptible to marketing and advertising appeals, would underestimate the health risks and effects of smoking, would overestimate their ability to stop smoking, and were price sensitive. Defendants used their knowledge of young people to create highly sophisticated and appealing marketing campaigns targeted to lure them into starting smoking and later becoming nicotine addicts.

449 F.Supp. 2d at 691. *See also id.* at 565 (noting power of image-marketing “particularly for young people, in suppressing perception of risk and encouraging [smoking] behavior”).

Judge Kessler also made extensive findings demonstrating that tobacco companies worked to keep smokers from quitting. For example, the firms marketed “light” cigarettes as a purportedly safer alternative that would make quitting unnecessary. 449 F.Supp. 2d at 488-500. This Court found that

Defendants marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false....Defendants were aware that lower tar cigarettes are unlikely to provide health benefits because

they do not actually deliver the low levels of tar and nicotine advertised.

566 F.3d at 1107.

The district court in the present case considered the warnings in a historical vacuum. But the scope of the conspiracy—its devastating impact on millions of Americans, its duration, its continuing effect on the more than 40 million Americans who smoke, and its potential effect on future generations of American youth—is highly relevant in determining the appropriateness of warnings designed to counter its effects.

III. THE WARNING LABELS COMPORT WITH THE REQUIREMENTS OF THE FIRST AMENDMENT.

The history of deception documented in *Philip Morris* is largely responsible for the fact that cigarette smoking continues to kill 443,000 Americans every year, that more than 40 million Americans still smoke, and that millions of adolescents continue to become addicted. Effective warning labels are needed to counter the continuing effects of this deception.⁵ In order to overcome those effects, the

⁵ Plaintiffs may argue that the findings of the district court and this Court in *Philip Morris* are not relevant to the consideration of warning labels because only the major tobacco companies were defendants in that case and the warning labels would apply to all cigarettes, including the small share of the market held by non-defendants. However, the point of the warning labels is not to punish the companies but rather to dispel the misinformation about smoking that was created by decades of fraudulent behavior by companies that constituted virtually the entire market. The results of that deception affect the entire cigarette market—and indeed

warning labels must be powerful, graphic and trenchant. That they are all of these things does not make them inconsistent with the First Amendment.

To the contrary, the warnings convey precisely the type of truthful and vital information that provides the justification for First Amendment protection for commercial speech in the first place. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 563 (1980) (“The First Amendment’s concern for commercial speech is based on the informational function of advertising”). Indeed, constitutional protection for commercial speech has always been accompanied by the caveats that “much commercial speech is . . . deceptive or misleading” and that the First Amendment represents “no obstacle to [the government’s] dealing effectively with this problem. The First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely.” *Va. Bd. of Pharmacy*, 425 U.S. at 771-72.

The history of systematic deception by cigarette companies is relevant under any applicable First Amendment standard, because it explains why smaller or less powerful warnings would be insufficient. As warning messages required in the commercial context, the images and text are subject to—and readily withstand—review under the standard articulated by the Supreme Court in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and recently reaffirmed in *Milavetz*,

our entire society—and the resulting need for adequate warning labels is not limited to brands of the defendant companies.

Gallop & Milavetz v. United States, 130 S. Ct. 1324, 1339 (2010). Under that standard, because of the legacy of industry deception, warnings larger and more visually compelling than is the norm are neither “unjustified” nor “unduly burdensome.” *Zauderer*, 471 U.S. at 651. Similarly, even if the extent or nature of the specific warnings were subject to the test set forth in *Central Hudson*—the warnings would readily survive review. The background context of pervasive deception explains why large, visually compelling warnings do not impose a speech requirement “more extensive than necessary to serve the interests that support it.” *Reilly*, 533 U.S. at 556, (quoting *Greater New Orleans Broadcasting Ass’n v. United States*, 527 U.S. 173, 184 (1999)).

A. The Labels Accord Fully with the Requirements of the *Zauderer* Standard.

This case does not involve any prohibition of commercial speech. Rather, it involves a requirement that cigarette manufacturers provide additional information to consumers. When, as here, the government requires commercial speakers to disclose factual and uncontroversial information, the test is simply whether “the disclosure requirements are reasonably related to the State's interest.” *Zauderer*, 471 U.S. at 651. The reason for the relatively lenient inquiry is that when the government “requires the disclosure of beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional

protection to commercial speech.” *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (plurality opinion); *Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24 (1976) (it is “appropriate to require that a commercial message. . . include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive”). There is a single additional limitation: the government should avoid “unjustified or unduly burdensome disclosure requirements [that] might offend the First Amendment by chilling protected commercial speech.” *Zauderer*, 471 U.S. at 651.

1. Requiring warning labels that are noticed is not unconstitutional.

Warning labels cannot fulfill their function unless they are noticed. In spite of this fact, the district court disparaged the FDA’s reliance on salience (i.e., noticeability) as a measure of effectiveness. (Slip. op. at 14.) When it enacted the TCA, Congress concluded that increasing the size of warning labels, changing their placement, and introducing pictorial images illustrating the mandated textual warnings was necessary to enable the warnings to communicate their message. In an action previously brought by many of the plaintiffs in this case, a federal district court upheld the constitutionality of these requirements. *Commonwealth Brands, Inc. v. FDA*, 678 F.Supp. 2d 512 (W.D. Ky. 2010). *Commonwealth Brands* found that “the government’s goal is not to stigmatize 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.” 678 F.Supp. 2d at 530 (emphasis in original).

Yet the district court in this case found that “the analysis and ruling in the *Commonwealth Brands* case is of little value here.” (Slip op. at 13.) The district court’s peremptory rejection of *Commonwealth Brands* is curious, since the text and size of the warning labels, their exact placement on the packs, and the requirement of pictorial warnings were expressly mandated by the statute and hence were before the court in *Commonwealth Brands*. The only difference between *Commonwealth Brands* and this case was (1) the choice of particular pictorial images and (2) the existence of a massive administrative record compiled subsequent to the *Commonwealth Brands* decision and supporting the need for pictorial warning labels.

2. It is not unconstitutional to require a warning label that elicits an emotional reaction.

The district court’s opinion creates a false dichotomy between statements that are “factual” or “noncontroversial” and statements that elicit emotional reactions. Pictorial images chosen to illustrate admittedly factual and non-controversial textual statements do not become “non-factual” or “controversial” merely because they also elicit emotional reactions. The opposite of “factual” is not “emotional”; the opposite of factual is “in error” or “not in conformity with the

facts or evidence.” Roget’s Int’l Thesaurus (4th ed. 1977). If a textual statement is true (i.e., factual), then a pictorial image meets the *Zauderer* test if it reasonably illustrates the statement or helps to convey its message. Similarly, a textual statement is noncontroversial if it consists of assertions about which there is a broad scientific consensus. The pictures the FDA chose to accompany the admittedly factual and noncontroversial textual warnings, therefore, satisfy the *Zauderer* test because they help convey the message of the accompanying textual warnings or reasonably illustrate their text.

Warning labels call the attention of consumers to important information in order to inform decision-making. The Surgeon General concluded that “to have an impact on consumers, warning labels must be designed to take account of those factors that might influence consumer response.” Preventing Tobacco Use Among Young People: A Report of the Surgeon General 262-63 (1994). The district court in this case, however, held that warning labels must be limited to statements of “cold, hard facts.” (Slip. op. at 16.) If consumers depended solely on “cold, hard facts” in the evaluation of risk, such a rule might make sense. Modern psychology has made it clear, however, that consumer decision-making is far more complex. Reason and emotion are not separate and opposed, but rather function interdependently. Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, in *Smoking: Risk, Perception & Policy* (2001).

As the FDA found, “The overall body of scientific literature indicates that health warnings that evoke strong emotional reactions enhance an individual’s ability to process the warning information.” 76 Fed. Reg. 36646. Statements, like the existing warning labels, that ignore emotive responses are ineffective at gaining people’s attention, let alone influencing decision-making. In essence, the district court’s opinion holds that warning labels are permissible only if they are guaranteed to be ineffective.

Ironically, in light of the district court’s holding that warning labels should be limited to “cold, hard facts,” the evidence shows that decisions made by adolescents to initiate smoking are influenced by many factors besides a coherent, accurate assessment of risk. In *Philip Morris*, the district court found that “adolescent smoking initiation is an immature behavior, one driven by the psychosocial development of adolescents and the cigarette brand imagery that corresponds precisely to adolescent aspirations.” 449 F.Supp. 2d at 573 (referencing testimony of Dr. Michael Ericksen). No one knows this better than the major tobacco companies themselves. The court in *Philip Morris* cited evidence that cigarette advertising and promotion was a major factor in inducing young people to smoke and was characterized by appeals to the vulnerabilities of adolescent judgment and to adolescent aspirations to conform to an idealized image.

Current research suggests that pervasive tobacco promotion has two major effects: it creates the perception that more people smoke than actually do, and it provides a conduit between actual self-image and ideal self-image—in other words, smoking is made to look cool. Whether causal or not, these effects foster the uptake of smoking, initiating for many a dismal and relentless chain of events.

449 F.Supp. 2d at 566-67 (quoting Report of the Surgeon General (1994)).

These findings demonstrate the crucial role of considerations that cannot be reduced to a recitation of “cold, hard facts.” The effective delivery of a message requires engagement with the consumer—particularly the adolescent consumer—at an emotional level. Restricting cigarette warning labels to a recitation of facts would prevent the effective delivery of their message.

Pictorial warnings make abstract statements particular, concrete, personal and vivid. Virtually all smokers initiate smoking before they are 18—before their judgmental capacities are mature.⁶ Many of them believe—erroneously—that they can safely experiment with cigarettes without becoming addicted. Indeed, most of them become addicted while they still believe they are only experimenting. Once they are addicted, smoking is no longer a matter of choice.

In *United States v. Philip Morris*, the district court found that

⁶ Cornelia Pechmann et al., *Impulsive and Self-Conscious: Adolescents' Vulnerability to Advertising and Promotion*, 24 J. Public Policy Marketing 202 (2005).

[m]ost smokers only begin to think of risk after they have started to smoke regularly and have become addicted. At that point, more than 80% of smokers wish they had never begun to smoke. As people become more experienced smokers, they overwhelmingly regret having started smoking....

449 F.Supp. 2d at 576-77.

Those at the greatest risk of becoming addicted are particularly lacking a realistic understanding of the consequences of smoking. As the district court found in *Philip Morris*:

Underage smokers and potential smokers are particularly vulnerable to cigarette marketing because they are not capable of making a fully informed decision whether to start or continue smoking....

[T]he 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.

449 F.Supp. 2d at 578-80.

As the FDA concluded in explaining why it adopted the particular graphic warnings, “eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warning is better processed, understood and remembered. Thus, these responses can

enhance the effective communication of the health warning message.” 76 Fed. Reg. at 36641.

3. The warning labels are factually noncontroversial, reasonably related to the government’s interest in preventing deception, and are neither unduly burdensome nor unjustified.

The relevant analysis of the warnings, then, is straightforward. First, the text of the warnings conveys “factual and uncontroversial information.” Plaintiffs do not contend otherwise. Their objections to the manner of communication—the graphic illustrations and the size of the warnings—are not challenges to the substance of the textual information conveyed. That information is neither subjective nor controversial.

There is no justification for the district court’s conclusion that “the fact *alone* that some of the graphic images here appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of ‘purely factual.’” (Slip op. at 14). First, existing law contemplates both written and pictorial warnings. *See, e.g.*, 29 C.F.R. § 1910.1200(c) (defining mandated hazard warnings as “words, pictures, symbols, or combination thereof”); *Zauderer*, 471 U.S. at 647 (“The use of illustrations or pictures ... serves important communicative functions”). Second, existing law contains no requirement that either textual warnings or images be literal. *See, e.g.*, 7 U.S.C. § 136(q)(2)(D)

(requiring certain pesticides to be labeled with skull and crossbones). Here, as the FDA observed in promulgating the warnings, “each of the nine graphic warnings required by the final regulations communicates negative health consequences of smoking that are well-established in the scientific literature.” 76 Fed. Reg. at 36641.

Nor does the district court’s contention that “the images were unquestionably designed to evoke emotion ... undercut[] the Government’s argument that the images are purely factual and not controversial.” (Slip op. at 14). The impact about which the tobacco companies complain is nothing other than an appropriate response to the appalling—but uncontroversially accurate—facts about the health effects and addictiveness of cigarettes

Second, the warnings are reasonably related to the government’s interest in preventing deception of consumers.⁷ As the district court found in *United States v. Philip Morris*, the cigarette companies created their market by combining a highly

⁷ Prevention of deception is not the only valid basis for governmental disclosure requirements. See *New York State Rest. Ass’n v. New York City Bd. of Health*, 556 F.3d 114, 133 (2d Cir. 2009) (“*Zauderer*’s holding was broad enough to encompass ... disclosure requirements” not concerned with preventing consumers from being misled); *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (finding “no cases limiting *Zauderer*” to “potentially deceptive advertising”).

sophisticated marketing strategy aimed at adolescents with a product deliberately designed to be as addictive as possible.

Finally, the new warnings are neither “unjustified” nor “unduly burdensome.” Judge Kessler’s RICO decision required over 600 pages to detail six decades of deceptive marketing of tobacco products, *Philip Morris*, 449 F.Supp. 2d at 208-839, including ongoing deception involving some of those products. *Id.* at 507-08. That background of deceit, along with the grave health consequences faced by those who use tobacco, *Brown & Williamson*, 529 U.S. at 134-35, amply justify the warnings. It is true that the labels are unusually prominent and that they reduce the portion of the package available for the tobacco companies’ own text and images. For almost any other product, their salience and emotional impact might well be disproportionate. But that is not the case with cigarettes. The tobacco companies

repeatedly, consistently, vigorously—and falsely—denied the existence of any adverse health effects from smoking. Moreover, they mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease, claiming that the link between the two was still an “open question.” Finally, in doing so, they ignored the massive documentation in their internal corporate files....

Philip Morris, 449 F.Supp. 2d at 208. Given this history, the burden on plaintiffs’ marketing cannot be called “undue.” Moreover, as the court in *Commonwealth*

Brands found, the tobacco companies still have 50% of the surface area of the pack and 80% of advertising space to promote their product. 678 F.Supp. 2d at 531.

The cases plaintiffs have relied on do not support a contrary conclusion. The potential misunderstanding sought to be avoided by the regulations at issue in *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136, 146-47 (1994), was of a fundamentally different type and scale from the actual deception to which the labels here respond; indeed, the attorney there was specifically found to have no history of misconduct. *Id.* at 144. The disapproval of video game ratings in *Entertainment Software Association v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) is no more apposite. Indeed, the *Blagojevich* court explicitly distinguished the “surgeon general's warning of the carcinogenic properties of cigarettes.” *Id.* at 652; *see infra* n.8.

The bottom line is that tobacco warning labels are different. The legacy of industry deception and of addictiveness that they must counteract is distinct from any other product. Manufactured fears that similar warnings might extend to fast food or alcohol, *see* Pls.’ MSJ at 22, are illusory: tobacco’s adjudicated history of deceptive marketing and its proven ongoing devastating effect on the health of the nation make clear that tobacco is *sui generis*. Congress explicitly provided as much in the TCA itself: “Nothing in this division . . . shall be construed to . . . establish a

precedent with regard to any other industry, situation, circumstance, or legal action.” *TCA* § 4(a).

B. If Analyzed as Something Other than Factual Disclosures, the Warning Labels Pass the *Central Hudson* Test.

The warnings also pass muster under the more searching inquiry of the *Central Hudson* test—the standard that applies to government requirements not governed by *Zauderer*. The warnings “directly advance[] a substantial governmental interest” in preventing youth smoking and counteracting decades of deception, and are “drawn to achieve that interest.” *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2667-68 (2011).

1. Strict scrutiny does not apply in this context.

If the warnings are found not to be “factual and noncontroversial” or to be “unduly burdensome,” *Zauderer*, 471 U.S. at 651, then the proper test to apply is not strict scrutiny but rather the intermediate *Central Hudson* test customarily applied to commercial speech restrictions. *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1140 (D.C. Cir. 2001).

There is no legal basis for the district court’s determination that strict scrutiny must be employed to examine the warning label requirement. The warnings are mandated in the commercial context. Consequently, if the size or nature of the warnings requires that they be subjected to a level of scrutiny greater

than that accorded other disclosure requirements, then the warnings must be analyzed under the *Central Hudson* test, the standard applied to compelled commercial speech that does not fall within the ambit of *Zauderer*. See *Milavetz*, 130 S. Ct. at 1339 (contemplating *Central Hudson* regime as alternative to “less exacting scrutiny described in *Zauderer*”); *Zauderer*, 471 U.S. at 650 (same); *NEMA*, 272 F.3d at 113-14 (same). See also *Bd. of Trustees v. Fox*, 492 U.S. 469, 474 (1989) (assuming compelled commercial speech subject to less than strict scrutiny); *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996) (applying *Central Hudson* scrutiny to compelled commercial speech, after finding requirements fell outside scope of *Zauderer*).⁸

2. The Warning Label Requirements Withstand *Central Hudson* Review.

The warnings survive scrutiny under *Central Hudson*. The steps of that analysis here are straightforward.

⁸ The district court’s sole authority for applying strict scrutiny here, see *Blagojevich*, 469 F.3d at 652, is entirely inapposite. Most saliently, the required labels there were affixed to video games, themselves fully protected core speech. The *Blagojevich* court never analyzed whether the speech at issue was commercial or noncommercial—that is whether the *Zauderer* regime should have applied at all. The court overlooked crucial distinctions between commercial and core speech in the context of disclosures, adducing instances of factual commercial speech to illustrate its conclusions about the entirely separate standard for compelled opinion and examining only noncommercial cases to support its analysis of what appears to have been commercial speech. *Id.* at 652-53. Compare *Philip Morris*, 566 F.3d at 1143 (properly applying commercial speech standard).

The warnings are constitutional under *Central Hudson* because they (1) further a substantial government interest, (2) directly and materially advance that interest, and (3) offer a “reasonable fit” between the government’s ends and the means it has chosen to achieve those ends. *Lorillard*, 533 U.S. at 555-56; *Fox*, 492 U.S. at 474.

There is no question about the importance of the government’s interest here. *See* Br. of the United States at 51 (noting government’s “substantial—indeed, compelling—interest in communicating the health risks of smoking”).

The record before the FDA also establishes, at length and through an independent study, that graphic warning labels directly and materially advance that goal. *See* 76 Fed. Reg. 36636-44. The government relied on substantial “evidence in the scientific literature that larger, graphic health warnings promote greater understanding of the health risks of smoking.” 76 Fed. Reg. 36629, citing 75 Fed. Reg. 69531-33.

The situation in this case is therefore wholly distinct from that in *Sorrell v. IMS Health*, for example, where “the State [failed to] argue that the provision challenged . . . will prevent false or misleading speech” and “[t]he State’s interest in burdening . . . speech” rested on “nothing more than a difference of opinion.” 131 S.Ct. at 2672. Here, by contrast, the warning labels provide an antidote to

decades of deceit, and are backed not by opinion but by voluminous empirical analyses. *See* 76 Fed. Reg. 36629.

Finally, the warnings exhibit a “fit” between the government’s means and ends. *Sorrell*, 131 S.Ct. at 2668, (quoting *Fox*, 492 U.S. at 480). The TCA and the record before the FDA cite copious studies establishing that pictorial warnings are more effective than text-only warnings, especially among youth, and that utilization of cessation services increases when smokers are made aware of their availability. 76 Fed. Reg. 36633-34. The warnings are precisely in line with the evidence gathered by Congress and the FDA.

This Court has explicitly held that the government may act to thwart tobacco companies’ “prospective efforts ... to capitalize on their prior deceptions by continuing to advertise in a manner that builds on consumers’ existing misperceptions.” *Philip Morris*, 566 F.3d at 1144-45.

The FTC’s standard for corrective speech is relevant here as well. “[W]hether a corrective remedy imposes a [speech] restriction ‘greater than necessary to serve the interest involved’” can be analyzed under a two-pronged standard. *Novartis Corp*, 223 F.3d at 789, (quoting *Warner-Lambert* 562 F.2d at 758. That standard consists of “two factual inquiries: (1) did [respondent’s] advertisements play a substantial role in creating or reinforcing in the public’s mind a false belief about the product? and (2) would this belief linger on after the

false advertising ceases?”” *Id.* at 787 (quoting *Warner-Lambert*, 562 F.2d at 762). Judge Kessler’s comprehensive decision, affirmed by this Court, leaves no doubt that cigarette advertising campaigns were intended to and did deceive consumers for decades. Studies have established that those campaigns continue to infect the beliefs of both older smokers and young people today. *Philip Morris*, 449 F.Supp. 2d at 927. The nine images and textual messages selected by the FDA target precisely those continuing misconceptions.

Furthermore, there is no discriminatory disfavoring of the tobacco companies here, *see Sorrell*, 131 S.Ct. at 2666-67, only a recognition of the disproportionate harm caused by cigarettes and the need to address one cause of that harm by providing powerful factual information at a crucial point in the decision whether to smoke. As the Supreme Court observed in *Sorrell*, the government “may choose to regulate . . . in one industry but not in others, because the risk of fraud . . . is in its view greater there.” *Sorrell*, 131 S.Ct. at 2672.

Finally, regulating speech through the warnings is plainly not the government’s “first . . . resort.” *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002). In the broader context of smoking prevention, measures at every level of government have taken myriad forms, from media campaigns to taxation, distribution, licensing, and marketing and age-restriction measures. *See, e.g.*, CDC, Smoking and Tobacco Use, Selected Actions of the U.S. Government Regarding

the Regulation of Tobacco Sales, Marketing and Use;⁹ CDC, State Tobacco Activities Tracking and Evaluation (STATE) System.¹⁰ Yet youth smoking rates have remained stubbornly high in spite of these measures and in spite of the fact that sales to youth are illegal in every State. Although smoking rates among high-school age students have declined, according to the latest figures almost one twelfth grader in five smokes cigarettes—virtually the same as the adult smoking rate. Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (December 14, 2011). “Decline in teen smoking resumes in 2011.” University of Michigan News Service: Ann Arbor, MI. <http://www.monitoringthefuture.org> (Dec. 14, 2011). In the specific context here—providing urgent health information—warning labels have been required on cigarette packs since 1966 but the current small, obscurely placed and text-only messages have been shown to be ineffective. 75 Fed. Reg. at 69530.

It is precisely because other measures had proved ineffective that Congress chose to mandate graphic warnings. *TCA* § 2(6). And it is through the striking yet carefully tailored warnings on cigarette packages that the FDA has implemented that decision and moved toward providing effective information at the point where it matters most.

⁹ *Available at* http://www.cdc.gov/tobacco/data_statistics/by_topic/policy/regulation/index.htm.

¹⁰ *Available at* http://apps.nccd.cdc.gov/statesystem/Default/Default.aspx?s_cid=tobacco_031

CONCLUSION

The States as *amici curiae* respectfully request that the Court hold the First Amendment does not bar government measures, such as the FDA's graphic warnings, that provide accurate and effective information to consumers.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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 6,986 words.

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of December, 2011, I caused the foregoing brief to be filed with the Court in hard copy and electronically and served through the Court's CM/ECF system.

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