RECOMMENDED FOR FULL-TEXT PUBLICATION
Pursuant to Sixth Circuit Rule 206

File Name: 12a0076p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; R. J. REYNOLDS TOBACCO COMPANY; COMMONWEALTH BRANDS, INC.; AMERICAN SNUFF COMPANY, LLC, fka Conwood Company, LLC,
Plaintiffs-Appellants/Cross-Appellees,

v.

UNITED STATES OF AMERICA; UNITED STATES FOOD & DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,
Defendants-Appellees/Cross-Appellants.

Nos. 10-5234/5235

Appeal from the United States District Court
for the Western District of Kentucky at Bowling Green.
No. 09-00117—Joseph H. McKinley, Jr., Chief District Judge.

Argued: July 27, 2011

Decided and Filed: March 19, 2012

Before: CLAY and STRANCH, Circuit Judges; BARRETT, District Judge.[*]

COUNSEL

ARGUED: Noel J. Francisco, JONES DAY, Washington, D.C., for Appellants. Mark B. Stern, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Noel J. Francisco, Robert F. McDermott, Jr., Hashim M. Mooppan, JONES DAY, Washington, D.C., E. Kenly Ames, Charles E. English, ENGLISH, LUCAS, PRIEST & OWSLEY LLP, Bowling Green, Kentucky, Floyd Abrams, Joel Kurtzberg, CAHILL GORDON & REINDEL LLP, New York, New York,

[*]The Honorable Michael R. Barrett, United States District Judge for the Southern District of Ohio, sitting by designation.

LeAnne Moore, NATIONAL TOBACCO COMPANY, L.P., Louisville, Kentucky, for Appellants. Mark B. Stern, Alisa B. Klein, Mark R. Freeman, Sarang V. Damle, Samantha Chaifetz, Daniel Tenny, Benjamin S. Kingsley, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., Karen E. Schifter, United States DEPARTMENT OF HEALTH & HUMAN SERVICES, Silver Spring, Maryland, for Appellees. Robert Corn-Revere, Ronald G. London, DAVIS WRIGHT TREMAINE, LLP, Washington, D.C., Allison M. Zieve, Gregory A. Beck, PUBLIC CITIZEN LITIGATION GROUP, Washington, D.C., Richard A. Samp, WASHINGTON LEGAL FOUNDATION, Washington, D.C., Aaron J. Silletto, GOLDBERG SIMPSON, LLC, Louisville, Kentucky, Timothy L. Edelen, Tad T. Pardue, BELL, ORR, AYERS & MOORE, PSC, Bowling Green, Kentucky, Seth E. Mermin, Thomas Bennigson, PUBLIC GOOD LAW CENTER, Berkeley, California, for Amici Curiae.

CLAY, J., announced the judgment of the court and delivered the lead opinion, which constitutes the unanimous opinion of the court on Sections I and IV-VI, and on parts of the analysis for Sections II and VII, but constitutes the dissent on Section III and on parts of the analysis for Sections II and VII. STRANCH, J. (pp. 57–84), delivered a separate opinion joined in full by BARRETT, D. J., which constitutes the majority opinion of the court on Section III and on parts of the analysis for Sections II and VII, as specified on pages 57 and 58 of the opinion.

OPINION

CLAY, Circuit Judge. Plaintiffs Discount Tobacco City & Lottery, Inc., *et al.*, comprised of manufacturers and sellers of tobacco products, appeal the decision of the district court granting partial summary judgment to Defendants United States of America, *et al.*, and partial summary judgment on Plaintiffs' claim that certain provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), violate their rights to free speech under the First Amendment. Defendants cross-appeal.

For the reasons discussed below, we **AFFIRM** the decision of the district court upholding the Family Smoking Prevention and Tobacco Control Act's restrictions on the marketing of modified-risk tobacco products; bans on event sponsorship, branding non-tobacco merchandise, and free sampling; and the requirement that tobacco manufacturers reserve significant packaging space for textual health warnings. We further **AFFIRM**

the district court's grant of summary judgment to Plaintiffs on the Act's restriction of tobacco advertising to black and white text. We also **AFFIRM** the district court's decision to uphold the constitutionality of the color graphic and non-graphic warning label requirement, with Judge Clay dissenting on this issue.

We **REVERSE** the district court's determination that the Act's restriction on statements regarding the relative safety of tobacco products based on FDA regulation is unconstitutional and its determination that the Act's ban on tobacco continuity programs is permissible under the First Amendment.

BACKGROUND

I. Brief History of Tobacco Legislation

Congress began regulating tobacco products in 1965 and has since passed major legislation regarding tobacco industry practices on at least six occasions. *See* Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92, 79 Stat. 282 (introducing tobacco warning labels); Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87 (banning television and radio advertisement of tobacco products); Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98-24, 97 Stat. 175 (requiring the Department of Health and Human Services to research and report on tobacco); Comprehensive Smoking Education Act of 1984, Pub. L. 98-474, 98 Stat. 2200 (modifying warning labels); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30 (extending restrictions to smokeless tobacco); Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, Pub. L. 102-321, § 202, 106 Stat. 394 (creating incentives for states to enforce tobacco sales restrictions). In 1996, the United States Food and Drug Administration ("FDA") attempted to assert its jurisdiction to further regulate the tobacco industry, but the Supreme Court found that the attempted regulation exceeded the FDA's agency authority. *See Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

As part of the FDA's 1996 rulemaking process, the FDA made several significant findings regarding tobacco use among juveniles. At that time, the FDA found that, "approximately 3 million American adolescents currently smoke and an additional 1 million adolescent males use smokeless tobacco. Eighty-two percent of adults who ever smoked had their first cigarette before the age of 18, and more than half of them had already become regular smokers by that age." 61 Fed. Reg. 44396-01, 44398 (Aug. 28, 1996). Relying on United States Surgeon General reports and studies from various medical journals, the FDA concluded that, "[a]n adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease. Moreover, the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking." *Id.* at 44399. The FDA found that one-third of young people who become smokers "will die prematurely as a result," *id.* (internal citations omitted), becoming part of the approximately "440,000 people [who] die of diseases caused by smoking or other form of tobacco use[, constituting] . . . about 20 percent of all deaths in our nation." Family Smoking Prevention and Tobacco Control Act: Hearing on H.R. 1256 Before the Subcomm. on Commerce, Trade, and Consumer Protection, Comm. on Energy and Commerce, 111th Cong. 1 (2004) (statement of Vice Admiral Richard H. Carmona, United States Surgeon General).

More recently, the President's Cancer Panel reported that, "[e]very day, approximately 4,000 children under age 18 experiment with cigarettes for the first time; another 1,500 become regular smokers. Of those who become regular smokers, about half eventually will die from a disease caused by tobacco use." The President's Cancer Panel, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk*, 64 (2007).

This brief overview barely begins to scratch the surface of the problem of juvenile tobacco use and the government's repeated interventions into the practices of the tobacco industry. The government, in this case, has filed thousands of pages of medical studies and governmental reports supporting the conclusion that the use of

tobacco, especially by juveniles, poses an enormous threat to the nation's health, and imposes grave costs on the government. The government has supplemented this information with copious documentation of the practices used by the industry, oftentimes directly aimed at juveniles and other times seriously effecting them, to maintain and increase tobacco use and dependency.

There can be no doubt that the government has a significant interest in preventing juvenile smoking and in warning the general public about the harms associated with the use of tobacco products. (*See, e.g.*, U.S. Dep't of Health and Human Serv., *Preventing Tobacco Use Among Young People; A Report of the Surgeon General*, 5 (1994) (concluding that "[n]early all first use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco").) The Supreme Court made clear that for these reasons, "[t]he State's interest in preventing underage tobacco use is substantial, and even compelling."[1] *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001).

Nonetheless, as the Supreme Court has recognized, "the sale and use of tobacco products by adults is a legal activity. [The courts] must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products." *Id.*

II. The Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or the "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009). The stated purpose of the Act is to provide authority to the FDA to regulate tobacco products, in order to "address issues of particular concern to public health officials, including the use of tobacco by young people and dependance on tobacco."

[1]Similarly, the Supreme Court has stated that the government "has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

Pub. L. No. 111-31, § 3(2). In addition, the Act seeks "to promote cessation [of tobacco use] to reduce disease risk and the social costs associated with tobacco-related diseases." *Id.* § 3(9). As part and parcel of this purpose, the Act regulates not only the sale of tobacco products, but also the advertising and marketing of those products, which are the provisions of the Act at issue in this case.

Now challenged are the Act's requirements (1) that tobacco manufacturers reserve a significant portion of tobacco packaging for the display of health warnings, including graphic images intended to illustrate the hazards of smoking; (2) restrictions on the commercial marketing of so-called "modified risk tobacco products;" (3) ban of statements that implicitly or explicitly convey the impression that tobacco products are approved by, or safer by virtue of being regulated by, the FDA; (4) restriction on the advertising of tobacco products to black text on a white background in most media; and (5) bar on the distribution of free samples of tobacco products in most locations, brand-name tobacco sponsorship of any athletic or social event, branded merchandising of any non-tobacco product, and distribution of free items in consideration of a tobacco purchase (i.e., "continuity programs").

In promulgating the Act, Congress made several legislative findings that are of particular relevance to this case (the "Legislative Findings"). Congress found that (1) "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," Pub. L. No. 111-31, § 2(1); (2) "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products," *id.* § 2(4); (3) "past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents," *id.* § 2(6); (4) "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth," *id.* § 2(15); (5) "[c]hildren are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people

who begin to use tobacco," *id.* § 2(20); and (6) "[c]hildren are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands." *Id.* § 2(23).

On August 31, 2009, Plaintiffs, a group of manufacturers and sellers of tobacco products,[2] brought suit against the United States of America in the district court, claiming that the challenged provisions of the Act violate their free speech rights under the First Amendment, constitute an unlawful taking under the Fifth Amendment, and are an infringement on their Fifth Amendment due process rights. Plaintiffs also alleged that the Act's authorization of further restrictions by federal agencies, states and Indian tribes was an unconstitutional delegation of legislative authority. Plaintiffs sought a preliminary injunction and a judgment declaring the challenged provisions unconstitutional.

Both parties filed motions for summary judgment. After an evidentiary hearing and the submission of declarations and supporting materials by both parties, the district court, on November 5, 2009, granted summary judgment to Plaintiffs on their claims that the ban on color and graphics in advertising and the ban on statements implying that tobacco products are safer due to FDA regulation violated their First Amendment speech rights. The district court granted summary judgment to the government on all other claims.

[2]Plaintiffs are Discount Tobacco City & Lottery, Inc.; Lorillard Tobacco Company; National Tobacco Company, L.P.; R.J. Reynolds Tobacco Company; Commonwealth Brands, Inc.; and American Snuff Company, LLC (fka Conwood Company, LLC).

DISCUSSION

I. Standard of Review

We review *de novo* a district court's decision to grant or deny summary judgment. *Rodgers v. Monumental Life Ins. Co.*, 289 F.3d 442, 448 (6th Cir. 2002). Summary judgement may only be granted where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether summary judgement is appropriate, all inferences are to be made in favor of the non-moving party, and all evidence construed in the light most favorable to that party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

"In reviewing the constitutionality of a statute, courts must accord substantial deference to the predictive judgments of Congress." *Turner Broad. Sys., Inc. v. Fed. Commc'ns Comm'n*, 520 U.S. 180, 195 (1997). The Court must also give deference to Congress' evaluation of the evidence informing its legislative decisions. "The question is not whether Congress, as an objective matter, was correct [in its] determin[ations] . . . . Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress." *Id.* at 211.

"Even in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Id.* at 196.

In this case, Plaintiffs label their claims as both facial and as-applied challenges to the Act, but because the "plaintiffs' claim and the relief that would follow . . . reach beyond the particular circumstances of these plaintiffs," the claims that are raised are properly reviewed as facial challenges to the Act. *John Doe No. 1 v. Reed*, 130 S. Ct. 2811, 2817 (2010). "To succeed in a typical facial attack, [a plaintiff] would have to

establish that no set of circumstances exists under which [the statute] would be valid, or that the statute lacks any plainly legitimate sweep." *United States v. Stevens*, 130 S. Ct. 1577, 1587 (2010) (internal citations and quotation marks omitted).

In reviewing a facial challenge to legislation, we must bear in mind that, facial challenges are disfavored for several reasons. Claims of facial invalidity often rest on speculation. As a consequence, they raise the risk of "premature interpretatio[n] of statutes on the basis of factually barebones records." *Sabri v. United States*, 541 U.S. 600, 609 (2004) (internal quotation marks omitted). We must also be mindful that, "'[a] ruling of unconstitutionality frustrates the intent of the elected representatives of the people.'" *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 329 (2006) (quoting *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984)).

II. Restrictions on Commercial Speech

In order to determine whether the challenged provisions of the FSPTCA pass constitutional muster, we must first consider the level of scrutiny applicable to the Act. Plaintiffs argue that we should review the Act under strict scrutiny, though they concede that precedent dictates that we review most provisions of the Act as restrictions on commercial speech, which are analyzed under a different and less rigorous standard. (First Br. at 19 n.4.) We see no reason to now upend the longstanding approach that the courts have taken respecting restrictions on commercial speech in favor of Plaintiffs' suggestion. We review the Act's restrictions on commercial speech, subject to the framework initially set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), and *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct. of Ohio*, 471 U.S. 626 (1985). We now turn to that framework.

A. Non-Misleading Commercial Speech

It is well-established that, "[e]ven though government is under no obligation to provide a person, or the public, a particular benefit, it does not follow that conferral of the benefit may be conditioned on the surrender of a constitutional right." *44*

Liquormart, Inc. v. R.I., 517 U.S. 484, 513 (1996). Therefore, in determining whether a restriction to the tobacco industry's commercial speech is permissible under the First Amendment, we first look to the test outlined in *Central Hudson*. Under that test, we first,

> determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

447 U.S. at 566.

The last two steps of the *Central Hudson* test are complementary. They involve "asking whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Lorillard Tobacco Co.*, 533 U.S. at 556 (internal quotation marks omitted); s*ee also Posadas de Puerto Rico Assoc. v. Tourism Co. of P.R.*, 478 U.S. 328, 341 (1986) (describing "[t]he last two steps of the *Central Hudson* analysis [as] basically involv[ing] a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends").

In analyzing "the *Central Hudson* factor concerning whether the regulation of commercial speech directly advances the governmental interest asserted," the Supreme Court has stated,

> that the Government carries the burden of showing that the challenged regulation advances the Government's interest in a direct and material way. That burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.

Rubin v. Coors Brewing Co., 514 U.S. 476, 486–87 (1995) (internal citations and quotation marks omitted). Though we must arrive at our own conclusions regarding the

"fit" of the Act, "[o]ur commercial speech cases recognize some room for the exercise of legislative judgment." *44 Liquormart, Inc.*, 517 U.S. at 508.

The Supreme Court has clarified that, "the least restrictive means is not the standard; instead, the case law requires a reasonable fit between the legislature's ends and the means chosen to accomplish those ends, a means narrowly tailored to achieve the desired objective." *Lorillard Tobacco Co.*, 533 U.S. at 556 (alteration in original) (internal citation and quotation marks omitted). Even though this Court must only find a reasonable fit between means and ends to uphold each challenged provision of the Act, "if there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable." *City of Cincinnati v. Discovery Network, Inc*., 507 U.S. 410, 417 n.13 (1993); *see also Rubin*, 514 U.S. at 491 (finding that "the availability of alternatives that would prove less intrusive to the First Amendment's protections for commercial speech" further highlighted the statute's defects.)

B. Potentially Misleading Commercial Speech

Because the *Central Hudson* test does not govern commercial speech that is false, deceptive or misleading, if commercial speech is so categorized, we apply a different test to determine whether a restriction, or disclosure requirement, is unconstitutional. *See Sorrell v. IMS Health Inc*., 131 S. Ct. 2653, 2674 (2011) (Breyer, J., dissenting) (citing cases where "the [Supreme] Court has found that 'sales practices' that are 'misleading, deceptive, or aggressive' lack the protection of even this 'intermediate' [*Central Hudson*] standard"). We have recently clarified our approach to misleading or deceptive commercial speech. In our decision in *International Dairy Foods*, we held that, "*Zauderer* applies where a disclosure requirement targets speech that is *inherently* misleading . . . [it also] also controls our analysis where . . . the speech at issue is *potentially* misleading." *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 641 (6th Cir. 2010).

This approach is consistent with well-settled precedent. The Supreme Court has stated that:

> Untruthful speech, commercial or otherwise, has never been protected for its own sake. Obviously, much commercial speech *is not provably false, or even wholly false*, but only deceptive or misleading. We foresee no obstacle to a State's dealing effectively with this problem. The First Amendment, as we construe it today does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely.

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 771–72 (1976) (internal citations omitted) (emphasis added). As set forth in *Zauderer*, in the case of misleading or potentially misleading commercial speech, "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers," and not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651.

Though the government has more leeway to regulate potentially misleading commercial speech than it does in the context of truthful and nonmisleading commercial speech, it "may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *In re R.M.J.*, 455 U.S. 191, 203 (1982).

III. The Mandated Warnings on Tobacco-Product Packaging and Advertising

We begin our analysis by considering whether the new mandated warnings on tobacco-products packaging and advertising violate the First Amendment.

A. The Provision

In addition to continuing and expanding upon the requirement that tobacco packaging carry one of the approved "Surgeon General's Warning" labels, the FSPTCA requires that tobacco manufacturers reserve a significant portion of their packaging—the top 50% of the front and back of cigarette packaging, 30% of the front and back of

smokeless tobacco packaging, and 20% of tobacco advertising—for full color, graphic health warnings issued by the FDA. 15 U.S.C. §§ 1333, 4402(2)(A). The Act mandates that the FDA shall, within 24 months of the enactment of the FSPTCA, "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements." Pub. L. No. 111-31, § 201(d).

Plaintiffs contend that "the scale and intrusiveness of the new warnings far outweighs any legitimate interest in conveying factual information to prevent consumer confusion, particularly since consumers *already overestimate* these health risks." (First Br. at 19 (emphasis in original).) Because consumers already understand the health risks of smoking, Plaintiffs argue, the additional scope of the warning labels is unjustified. (*Id*. at 21.) Plaintiffs further state that the new warning requirements are unduly burdensome because they effectively overshadow and dominate Plaintiffs' speech. (*Id.* at 24–25.) Lastly, Plaintiffs argue that the required graphic images extend beyond mere factual warnings, and instead "force Plaintiffs to market to consumers Congress' belief that tobacco use is socially unacceptable," (*id*. at 26), through way of "subjective and highly controversial message[s]." (*Id*. at 27.) In sum, Plaintiffs argue that, "since the scale and intrusiveness of the new warnings are not remotely necessary to convey factual information that is effectively conveyed by the existing warnings and already universally known, they are unconstitutional." (Third Br. at 45.)

Citing, among other sources, a 2007 Institute of Medicine of the National Academies report, the government counters that an information deficit still exists, especially among juveniles, regarding the dangers of tobacco use. According to the report, "research suggests 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. . . . These distorted risk perceptions are associated with adolescents' decisions to initiate tobacco use, a decision that they will later regret." Institute of Medicine Report, *Ending the Tobacco Problem: A Blueprint for the Nation*, 93 (2007) (hereafter, 2007 IOM Report).

Although the government concedes the Plaintiffs' repeatedly cited contention that adolescents significantly overestimate the risk of developing lung cancer as a result of smoking, the government provides evidence that adolescents underestimate the degree to which smoking can shorten life and the likelihood that they will suffer tobacco-related disease, and that both adolescent and adult smokers were more than twice as likely as nonsmokers to doubt that tobacco use, even for a period of 30 to 40 years, would cause death. (*Id.* at 89–90); *see also United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 578 (D.D.C. 2006) (finding that "[m]ost people do not have a complete understanding of the many serious diseases caused by smoking, the true nature of addiction, or what it would be like to experience either those diseases or addiction itself. Rather, most people have only a superficial awareness that smoking is dangerous.").

The government argues that the purpose of the new warning label requirement "'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.'" (Second Br. at 22 (quoting *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010)). Furthermore, conveying the health risks of tobacco use in the manner mandated by the Act is not unduly burdensome on Plaintiffs' speech, the government argues, as "'half of cigarette packs, 70% of smokeless tobacco packages, and 80% of advertisements remain available for [Plaintiffs'] speech.'" (*Id.* at 28 (quoting *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 531)).

B. Analysis

1. Level of Scrutiny

Plaintiffs argue that "the Government must survive strict scrutiny [because it is] attempt[ing] to convert commercial speakers into its mouthpiece for a 'subjective and highly controversial' marketing campaign expressing its disapproval of their lawful products." (First Br. at 19 (quoting *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006).)

As a threshold matter, there is no indication that the textual element of the new warning labels, when viewed in isolation, express either completely "subjective" or "highly controversial" messages. The Act requires that cigarette packaging bear one of nine textual health warnings, and smokeless tobacco products one of four warnings, which each convey factual information regarding the health consequences of smoking or smokeless tobacco use.[3] These exact, or similar, warnings have been required on cigarette packaging since 1965. Plaintiffs submit no evidence that the content of any of the health warnings are in dispute within the scientific or medical community.[4]

Similarly, the Act requires that the images issued by the FDA visually "depict[] the negative health consequences of smoking" in accompaniment with the label's textual warnings. Pub. L. No. 111-31, § 201(d). But, in contrast to the textual warnings, there can be no doubt that the FDA's choice of visual images is subjective, and that graphic, full-color images, because of the inherently persuasive character of the visual medium, cannot be presumed neutral.

Because visual images are subjective and cannot be categorized as mere health disclosure warnings, Plaintiffs' argument for strict scrutiny is not wholly unpersuasive. Relying on a case from the Seventh Circuit, *Entm't Software Ass'n v. Blagojevich*, Plaintiffs argue that the new warning labels must be analyzed as a content-based restriction on speech, subject to strict scrutiny. *See* 469 F.3d at 645–46 (employing strict scrutiny to review of an Illinois law restricting sales of certain video games to minors

---

[3]For smokeless tobacco: "WARNING: This product can cause mouth cancer," "WARNING: This product can cause gum disease and tooth loss," "WARNING: This product is not a safe alternative to cigarettes," or "WARNING: Smokeless tobacco is addictive." Pub. L. No. 111-31, § 204 (amending the Comprehensive Smokeless Tobacco Health Education Act of 1986,15 U.S.C. 4402). For cigarettes: "WARNING: Cigarettes are addictive," "WARNING: Tobacco smoke can harm your children," "WARNING: Cigarettes cause fatal lung disease," "WARNING: Cigarettes cause cancer," "WARNING: Cigarettes cause strokes and heart disease," "WARNING: Smoking during pregnancy can harm your baby," "WARNING: Smoking can kill you," "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers," "WARNING: Quitting smoking now greatly reduces serious risks to your health." Pub. L. No. 111-31, § 201 (amending the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333).

[4]Plaintiffs rely on the declaration of their expert, Dr. Kip Viscusi, to refute most of the scientific and factual evidence presented by the government. In addition to employing sometimes questionable scientific reporting methodology, (*see* R.71–3 at 45 n.41), Dr. Viscusi has previously admitted at trial, in *Philip Morris*, that his conclusions are largely based on research commissioned by tobacco industry law firms specifically for use in litigation. (*See* Trial Tr., *Philip Morris*, No. 99-2496, at 17930.)

and requiring a label deeming a game "sexually explicit"). This approach finds a measure of additional support in the Supreme Court's recent decision in *Brown v. Entm't Merchants Ass'n*, 131 S. Ct. 2729, 2738 (2011).

In *Entertainment Merchants*, the Supreme Court reviewed a California law that prohibited the sale of "violent" video games to minors and required labels bearing the number "18" to be placed on certain video games sold to minors. The Court applied strict scrutiny to the law, having determined that the requirements imposed by the state constituted a "restriction on the content of protected speech." *Id.*

But both *Entertainment Merchants* and *Blagojevich* are distinguishable from the case now before us, because both involved not just warning requirements, but also affirmative limitations on speech (in the form of sales restrictions). Furthermore, these cases involved a state attempting to restrict core speech in the form of "art and literature" based on the state's determination that certain words were "too harmful to be tolerated" and so were not protected under the First Amendment. *Id.* at 2734. Here, the warning labels required by the Act do not impose any restriction on Plaintiffs' dissemination of speech, nor do they touch upon Plaintiffs' core speech. Instead, the labels serve as disclaimers to the public regarding the incontestable health consequences of using tobacco.

Nearly fifty years ago, the Supreme Court upheld the proposition that, "[t]o avoid giving a false impression that smoking [is] innocuous, the cigarette manufacturer who represents the alleged pleasures or satisfactions of cigarette smoking in his advertising must also disclose the serious risks to life that smoking involves." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992) (quoting 29 Fed. Reg. 8356 (1964)). Like other disclosures governed by the *Zauderer* standard, these tobacco disclosures may "appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive." *Va. State Bd. of Pharmacy*, 425 U.S. at 772 n.24. Plaintiffs argument for strict scrutiny is therefore unsupported.

2. Dissenting Opinion on the Requirement of Color Graphic Images

Although I join in this opinion, the issues presented by § 201(d) of the Act concerning the use of color graphic warning labels should have resulted in a reversal of this aspect of the district court's opinion, and for that reason I disagree with my two colleagues on this issue.[5] In doing so, I believe that the district court, although acknowledging the absence of the regulation, addressed the color graphics requirement both facially and as-applied. The issue was also adequately briefed and argued by both parties, and since the record is sufficient it is judicially efficient for this Court to consider the issue at this time.

There is general agreement in this Court that even though disclosure requirements, such as the warning labels mandated by the Act, may be constitutionally permissible, all forms of required warnings will not survive First Amendment scrutiny. "We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. But we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 651.

There is also agreement that Plaintiffs' argument that consumers are already adequately aware of the health risks associated with tobacco is not widely accepted. As

---

[5]Though neither party briefs the issue of severability, the portions of the provision requiring graphic label statements are severable. "'Generally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem,' severing any 'problematic portions while leaving the remainder intact.'" *Free Enter. Fund v. Public Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3161 (2010) (quoting *Ayotte*, 546 U.S. at 328–29).

"The standard for determining the severability of an unconstitutional provision is well established: Unless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as a law." *New York v. United States*, 505 U.S. 144, 186 (1992) (quoting *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987)). Here, the provision governing the new labeling requirements remains fully operative absent the portions regarding the inclusion of graphic images. Furthermore, it is evident that Congress would have enacted the remainder of the warning label provision without the inclusion of the graphics requirement. This conclusion is borne out by the fact that Congress, since the inception of the tobacco warning label requirement, has on several occasions expanded the breadth and altered the appearance of the textural warning. *See* Comprehensive Smoking Education Act of 1984, Pub. L. 98-474, 98 Stat. 2200 (amending form of warning label); Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87 (amending required warning language).

summarized above, the government has presented abundant evidence to support Congress' findings that juveniles are not sufficiently aware of the actual risks of tobacco use. Furthermore, the record reveals that current tobacco warning labels fail to convey health information effectively. The primary deficiency in the form of the current warnings is that they are easily overlooked. *See* Family Smoking Prevention and Tobacco Control Act: Hearing on H.R. 1108, Before the H. Subcomm. on Health of the Comm. on Energy and Commerce, 110th Cong. 42 (2007) (finding that "more than 40 percent of subjects did not even view the warning," and "an additional 20 percent looked at the warning but failed to actually read it"); (*see also* Lila J. Finney Rutten et al., *Smoking knowledge and behavior in the United States: Sociodemographic, smoking status, and geographic patterns*, 10 Nicotine & Tobacco Research 10, 1570 (Oct. 2008) (concluding that "much work remains to be done to accurately and evenly inform American adults of the health consequences of tobacco use").)

Where I part with the majority is on what I consider to be a constitutional flaw in the requirement for color graphic warning labels. Though the government attempts to analogize the graphic pictorial warnings of the type mandated by the Act to the extensive warnings imposed on over-the-counter drugs, such an analogy is not convincing. First, while the government mandates extensive textual warnings on drugs, it does not require color graphics. Secondly, drug warnings present purely factual information, with no subjective component. The requirement imposed by the FSPTCA—that a product manufacturer place a large scale color graphic on a product warning label—is simply unprecedented.

Although the government has demonstrated that an information deficit still exists among potential tobacco consumers, which may render warning-less tobacco products inherently deceptive, it has not adequately shown that the inclusion of color graphic warning labels is a properly or reasonably tailored response to address that harm. It appears, from the government's own evidence, that the color graphic warning labels are intended to create a visceral reaction in the consumer, in order to make a consumer less emotionally likely to use or purchase a tobacco product.

As summarized by one of the few available studies addressing the issue of graphic tobacco warning labels on the U.S. audience:

> One of the ways that more graphic warning labels can help consumers appreciate the risks of smoking is to create unfavorable emotional associations with the behavior. Bland descriptions of the health hazards of smoking, such as currently displayed on cigarette packs in the United States, are unlikely to create such associations, because they fail to attract attention or to make the health danger sufficiently compelling.

Ellen Peters et al., *The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers*, 9 Nicotine & Tobacco Research 4, 474 (2007) (internal citations omitted).

While it is permissible for the government to require a product manufacturer to provide truthful information, even if perhaps frightening, to the public in an effort to warn it of potential harms, it is less clearly permissible for the government to simply frighten consumers or to otherwise attempt to flagrantly manipulate the emotions of consumers as it seeks to do here.

As the government acknowledges in its argument in support of upholding the Act's ban on color and graphics in tobacco industry advertisements, colorful graphic images can evoke a visceral response that subsumes rationale decision-making. This principle applies equally when seeking to discourage behavior.

The government failed to provide sufficient evidence to persuade me that the color graphics requirement is a reasonably tailored solution. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002) (finding that "[i]t is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it'") (quoting *Edenfield v. Fane*, 507 U.S. 761, 770, (1993)). In *Thompson*, licensed pharmacists challenged the provisions of the Food and Drug Administration Modernization Act ("FDAMA"), which prohibited advertising and promotion of particular compounded drugs. The provisions of the FDAMA required pharmacists who advertised compounded drugs to undergo FDA approval. Respondents specialized in

drug compounding and frequently distributed information and promotional materials to "inform patients and physicians of the use and effectiveness of specific compounded drugs." *Id*. at 365. Respondents argued that the FDAMA provisions violated the First Amendment and were unconstitutional restrictions on commercial speech. The government identified three substantial interests in the FDAMA: (1) "preserv[ing] the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides;" (2) "preserv[ing] the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA"; and (3) "[a]chieving the proper balance between those two independently compelling but competing interests is itself a substantial governmental interest." *Id*. at 368. The Supreme Court held that the FDAMA provisions prohibiting advertising and promotion of compounded drugs unconstitutional because the government "has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process." *Id*. at 373.

This Court has also accepted the proposition that the state must fully consider other options when weighing the suppression of speech to address a public policy concern. *See Bell South Telecommunications, Inc. v. Farris*, 542 F.3d 499, 508–509 (6th Cir. 2008) (finding that provisions in the Kentucky's Tax Injunction Act, which prohibited telecommunications providers from identifying a new tax on consumers' bills, violated the First Amendment because the government failed to consider other alternatives before suppressing speech to address a policy problem). In all instances, any government solution must take into account both the intended and the unintended restriction on the rights afforded by the First Amendment.

While the majority argues that the color graphics requirement materially advances the government's stated interest in counteracting the informational deficit regarding health hazards, such a finding is far from conclusive, as color graphics cannot accurately convey all of the health risks associated with tobacco use. Although elements

of the color graphics requirement may remain constant, the underlying message that they convey will vary with the interpretation and context of its viewer. The color graphics can be seen one way by some smokers, yet another by other smokers—one way by some non-smokers and yet an entirely different interpretation by other non-smokers. While the images depicted by the color graphics may rest on different individual viewpoints and ideologies, the requirements of the Constitution firmly tips the balance towards disqualifying a government regulatory requirement that abridges the right of citizens to engage in free speech. For that reason, the majority's reliance on the color graphics warning requirement as a constitutionally protected solution in light of the circumstances is simply overstated.

Though the hurdle that *Zauderer* erects for the government is a relatively low one, it is still a hurdle that the government must surmount in order to uphold the form of the warning label requirement that it seeks to impose on the tobacco industry. While courts have been resistant to strike down disclosure requirements under *Zauderer*, if *Zauderer* does in fact create a line, then it is clear that some types of disclosure requirements must cross that line. The requirement embodied in § 201(4)(d) of the Act crosses the line. Accordingly, I would find the portion of the provision requiring color graphic images to accompany the textual warnings on tobacco product packaging unconstitutional, and I would REVERSE the decision of the district court on that issue.[6]

[6]The recent decision from the D.C. district court also supports my analysis and conclusion that the color graphic warning requirement constitutes compelled speech which violates the First Amendment. The D.C. district court explained that the government's proposed color graphic images were "neither designed to protect the consumer from confusion or deception, nor to increase consumer awareness of smoking risks; rather, they were crafted to evoke a strong emotional response calculated to provoke the viewer to quit or never start smoking." *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Admin.*, 2012 LEXIS 26257, at * 16 (D.D.C. Feb. 29, 2012). In reaching this conclusion, the D.C. district court found that the government's mandatory graphic images not only conveyed false and misleading information about smoking, but the government also failed to consider other alternatives that are less restrictive and burdensome for the plaintiffs while still permitting the government to educate the consumer about the health risks associated with tobacco use. *Id*. at * 28.

3. Non-Graphic Aspects of Warning Labels

With regard to the increased size and placement requirement of the textural warnings on tobacco packaging, the government has demonstrated that the Act's requirements are reasonably tailored to overcoming the informational deficit regarding tobacco harms. *See Zauderer*, 471 U.S. at 651. The government has illustrated, as Congress found, that larger warnings materially affect consumers' awareness of the health consequences of smoking and decisions regarding tobacco use.

Plaintiffs' argument that the provision is unduly burdensome because the scale of the warning label drowns out their speech is unpersuasive. The government has provided ample evidence supporting the size requirement for the new labels, (*see, e.g.*, World Health Organization, *WHO Framework Convention on Tobacco Control*, art. 11.1(b) (2003)), and Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to place their brand names, logos or other information. Instead, Plaintiffs primary argument is that the use of such significant labels might dissuade certain smokers from buying their product by making it appear unhealthy or otherwise unattractive. But this is, in some ways, the purpose of the labels—to provide truthful information regarding the health consequences of the product in order to decrease "the use of tobacco by young people and dependance on tobacco." Pub. L. No. 111-31, § 3(2).

C. Summary

For these reasons, we **AFFIRM** the district court's determination and hold that the Act's requirement that tobacco packaging and advertising that includes color graphic and non-graphic warning labels satisfies the requirements of the First Amendment. However, Judge Clay dissents on the issue of the color graphic warning label requirement.

IV. Restrictions of Speech Concerning Modified Risk Tobacco Products

We now consider whether the Act's requirement that harm reduction claims relating to modified risk tobacco products pass pre-market review is an unconstitutional restriction of free speech.

A. The Provision

Under the so-called modified risk tobacco product rule ("MRTPR"), Plaintiffs may only commercially market a product as a "modified risk" if, after application to the FDA, it is determined that the product, "as it is actually used by consumers, will—(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." Pub. L. No. 111-31, § 911(g)(1) (codified at 21 U.S.C. § 387k(g)(1)).

Under the Act, "[t]he term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 911(b)(1). A tobacco product will be considered to be "sold or distributed" for the these purposes if:

> (i) the label, labeling, or advertising of which represents explicitly or implicitly that—
>
> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
>
> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
>
> (III) the tobacco product or its smoke does not contain or is free of a substance;
>
> (ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or
>
> (iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise . . .

> respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

Id. § 911(b)(2)(A).

Plaintiffs argue that the provision is overbroad because, as they explain, it applies to "Plaintiffs' participation in the public-health debate concerning tobacco harm reduction, even when that debate plays out in scientific symposia, regulatory press releases, or news programming such as *60 Minutes*, and even when Plaintiffs limit their speech to discussions of generic product categories like smoke-free tobacco products." (First Br. at 29–30.) Therefore, Plaintiffs contend, the MRTPR effectively "shut[s them] out of the public-policy debate over the role of reduced-risk products in a tobacco harm-reduction strategy," (*id.* at 28), and constitutes an impermissible "viewpoint-based restriction on one class of speakers in a political debate," (*id*. at 16), and a prior restraint on free speech. (*Id*. at 28.)

The government categorizes the MRTPR as a "pre-market review of purported reduced-risk tobacco products parallel[ing] preexisting FDCA provisions applicable to drugs." (Second Br. at 34.) It is the government's position that "[t]he purpose of pre-market review is to evaluate the manufacturer's evidence that the product will, in fact, achieve its claimed purpose," (*id*. at 36), and as such the MRTPR does not implicate the First Amendment. (*Id*. at 34.) Alternatively, the government argues that the MRTPR meets the test set forth in *Central Hudson* for government regulation of commercial speech.

B. Analysis

1. Prior Restraint

Plaintiffs argue that the MRTPR is a prior restraint on intertwined political and commercial speech, which must be reviewed under strict scrutiny. (First Br. at 28.) The district court agreed with this categorization, and analyzed the MRTPR accordingly. *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 533.

Though the MRTPR is a regulatory scheme that prohibits Plaintiffs from making certain statements about tobacco products before receiving approval from the FDA, Plaintiffs offer no authority to support the conclusion that this regulation of commercial speech requires the strict scrutiny and presumption of constitutional invalidity afforded to laws effecting a prior restraint on protected non-commercial speech. Instead, the Supreme Court has, on several occasions "observed that commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it." *Central Hudson*, 447 U.S. at 571 n.13; *see also Zauderer*, 471 U.S. at 668 n.13; *Virginia State Bd. of Pharmacy*, 425 U.S. at 771–72 n.24.[7]

Plaintiffs attempt to circumvent the distinction between commercial and non-commercial speech by arguing that their "supposedly 'commercial speech' is 'inextricably intertwined with otherwise fully protected speech' and thus still governed by the 'test for fully protected expression.'" (First Br. at 30–31 (quoting *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988).) Plaintiffs might be correct if this were a circumstance where the Court "cannot parcel out the speech," *Riley*, 487 U.S. at 796, but this is not such a case. In this case, the MRTPR only applies to products where (1) the labeling or advertising of the specific product makes particular health claims, (2) the labeling or advertising of the product uses key words, or (3) the "tobacco

[7]It is important to note that many of the seminal commercial speech cases, including *Central Hudson* itself, dealt with prophylactic bans on speech. *See Central Hudson*, 447 U.S. 557 (involving a ban on promotional advertisement by utility); *Zauderer*, 471 U.S. 626 (evaluating a ban on illustrations in attorney advertisement); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978) (considering a ban on in-person solicitation by attorneys). None of these cases applied the framework reserved for prior restraints on protected speech.

product manufacturer of which has taken any action *directed to consumers* through the media or otherwise . . . *respecting the product*." 21 U.S.C. § 387k(b)(2)(A) (emphasis added). Because the restriction applies to consumer-directed claims regarding a manufacturer's specific products, there is no reason to believe that it touches upon Plaintiffs' non-commercial speech "in the public-health debate concerning tobacco harm reduction . . . in scientific symposia, regulatory press releases, or news programming such as *60 Minutes*," or that the MRTPR applies "when Plaintiffs limit their speech to discussions of generic product categories like smoke-free tobacco products." (First Br. at 29–30.) Neither the government, nor the text of the statute itself, suggests otherwise.

The Supreme Court has stated that utterances may:

> constitute commercial speech notwithstanding the fact that they contain discussions of important public issues . . . . We have made clear that advertising which links a product to a current public debate is not thereby entitled to the constitutional protection afforded noncommercial speech. A company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection when such statements are made in the context of commercial transactions. Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues.

Bolger v. Youngs Drug Prod. Corp., 463 U.S. 60, 67–68 (1983) (internal citations and quotation marks omitted).

In this case, because Plaintiffs' ability to make "direct comments on public issues" remains untouched, "[t]here is no basis in the record to believe that the Act will be interpreted or applied to infringe significantly on noncommercial speech rights." *San Francisco Arts & Athletics, Inc. v. United States Olympic Comm.*, 483 U.S. 522, 537 n.15 (1987). Thus, this Court is left with Plaintiffs' "action directed to consumers

through the media or otherwise . . . respecting the product," 21 U.S.C. § 387k(b)(2)(A), which we find to be commercial speech properly analyzed under *Central Hudson*.[8]

2. Constitutionality

Plaintiffs argue that "[t]he MRTPR plainly ensnares truthful, non-misleading speech," because the provision restricts them from making claims of individual harm reduction, "even if Plaintiffs' speech unambiguously disavows any population-wide health benefit," (First Br. at 33); the provision restricts them from marketing tobacco products as additive-free to appeal to naturalists and smokers who prefer organic products, even when such preferences are not linked to perceptions of health benefit, (*id*. at 34); and the provision, though it explicitly exempts the marketing of smokeless tobacco products as "smokeless" or "smoke free," prevents manufacturers from "explain[ing] the relative health significance" of those designations. (*Id*. at 34–35.) Finally, Plaintiffs argue that the restrictions embodied in the MRTPR do not materially advance the government's interests, and are not narrowly tailored to those interests. (*Id*.)

The government responds that "[t]he statutory provision requiring pre-market review of purported reduced-risk tobacco products parallels preexisting FDCA provisions applicable to drugs and, like the drug provisions, it presents no First Amendment problem." (Second Br. at 34.) Alternatively, the government argues that the MRTPR survives analysis under *Central Hudson*. (*Id*. at 40.) To the government's primary argument, Plaintiffs reply that "there is no cognizable First Amendment difference between a law that directly proscribes promotional speech and one that renders a product's sale illegal based on promotional speech." (Third Br. at 48.) As

---

[8]Plaintiffs alternatively argue that "[e]ven if (erroneously) treated as a commercial-speech restriction, the MRTPR is still subject to strict scrutiny . . . [because] [u]nder the MRTPR, government agencies, ideological anti-tobacco organizations, and commercial manufacturers of tobacco-cessation products are all free to publicly denigrate the relative health risks of Plaintiffs' products. Plaintiffs, however, cannot respond without first receiving FDA pre-approval." (First Br. at 31–32.) Therefore, they argue, the statute constitutes viewpoint discrimination based on the identity of the speaker. (*Id*.) This argument is uncompelling. It is well-settled that "[t]he government may ban forms of communication more likely to deceive the public than to inform it." *Central Hudson*, 447 U.S. at 563. Under the MRTPR, Plaintiffs are able to directly respond to comments claiming that modified-risk tobacco products do not constitute a valid harm reducing alternative to traditional products, if and when the veracity of the health claims they make in response have been demonstrated.

such, Plaintiffs state that the provision must withstand First Amendment analysis. We agree with Plaintiffs, and therefore proceed to the government's alternative argument. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 142 (rejecting attempt to make similar analogy to the FDA's regulation of drugs).

Under *Central Hudson*, we first "determine whether the expression is protected by the First Amendment." 447 U.S. at 566. While the government's position is largely based on its claim that Plaintiffs' speech regarding modified risk tobacco products is, and has historically been, misleading, the MRTPR must still survive the scrutiny dictated by *Central Hudson*, as the provision undoubtedly ensnares some speech which may be completely truthful and nonmisleading. The regulation of such truthful commercial speech is not exempted from the First Amendment analysis in *Central Hudson*, and we therefore proceed to step two, which requires us to determine whether the interest declared by the government is substantial.

Contrary to Plaintiffs' assertions, the interest that the government seeks to advance through the MRTPR is not the risk that the public will become overly informed regarding the relative risks of various tobacco products, but instead the risk that the tobacco industry will make fraudulent claims regarding the relative health benefits of the products that it markets. (*See* Second Br. at 32 ("Congress's decision to require pre-market review was informed by the tobacco industry's long history of marketing of 'low tar' cigarettes with misleading health claims." (citing Legislative Findings 38 and 39, Pub. L. No. 111-31, §§ 2(38)-(39)))); *see also Philip Morris*, 449 F. Supp. 2d at 430 (finding that, "[f]or several decades, [the major tobacco manufacturers] have marketed and promoted their low tar brands as being less harmful than conventional cigarettes. That claim is false . . . [and b]y making these false claims, [the major tobacco manufacturers] have given smokers an acceptable alternative to quitting smoking, as well as an excuse for not quitting"); *United States Surgeon General Report, The Health Consequences of Smoking*, 25 (2004) (concluding that "[s]moking cigarettes with lower machine-measured yields of tar and nicotine provides no clear benefit to health").

When a prohibition is intended to prevent consumer deception, the burden lies with the government to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg., Bd. of Accountancy*, 512 U.S. 136, 146 (1994). "[A] State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it," *44 Liquormart, Inc.*, 517 U.S. at 497, and will not support a finding of a substantial state interest. This limitation is enforced even where the pervasiveness of such information might persuade the public to make what the government perceives as a bad choice, because "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Id.* at 503.

"Evidence in the congressional record demonstrating a pattern of [potentially deceptive] advertisements . . . [may be] adequate to establish . . . the likelihood of deception." *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1340 (2010). There is ample caselaw, cited by the government, to support the conclusion that tobacco manufacturers have historically "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." *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1107 (D.C. Cir. 2009); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 87–91 (2008) (providing an overview of the tobacco industry's misleading use of descriptors such as "low tar" and "light").

The same can be said for the tobacco industry's marketing of smokeless tobacco products as safe alternatives to smoking. *See, e.g.*, National Survey on Drug Use and Health, *Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*, 4 (Mar. 2009) ("Combined data from 2002 to 2007 indicate that an annual average of 1.1 million persons initiated use of smokeless tobacco in the past 12 months. . . . Initiation of smokeless tobacco in the past 12 months was more likely to occur among youths aged 12 to 17 than among young adults aged 18 to 25. . . . Both of

these age groups had higher rates of initiation than adults aged 26 or older."). This evidence is sufficient to satisfy the government's burden of demonstrating a pattern of deception.

There is no question that the harm caused by the tobacco industry's use of misleading advertising and marketing tactics regarding the relative risks of certain tobacco products is real and significant. Exemplifying this is the fact that the market share for "low tar" cigarettes increased from 2% of sales in 1967 to 81.9% in 1998. Federal Trade Commission, *Cigarette Report for 1999*, 20 (2001)). Such a drastic shift from conventional products to "modified risk products" occurred in a single generation, though it was later discovered that these products delivered far more tar and nicotine than the tobacco industry claimed. *See* Legislative Findings 38 and 39, Pub. L. No. 111-31, §§ 2(38)-(39); *Altria Group, Inc.*, 555 U.S. at 87–90. Accordingly, we find that the government has demonstrated a substantial interest and therefore satisfied step two of *Central Hudson*.

The government has also satisfied the final inquiries under *Central Hudson*, regarding the fit and the tailoring of the measure. As discussed above, the MRTPR only applies to claims "directed to consumers through the media or otherwise . . . respecting the product," or on the labeling or advertising of the product. *See* Pub. L. No. 111-31, § 911(b)(2)(A). There is no indication that the provision suppresses non-commercial speech relating to nonspecific tobacco products. Plaintiffs' claims that the MRTPR also encompasses their marketing of tobacco products as "additive-free" to appeal to naturalists and smokers who prefer organic products, even when such preferences are not linked to perceptions of health benefit, (First Br. at 34), does not alter this conclusion. Plaintiffs have presented no evidence to suggest that "consumers who prefer organic products for environmental or other reasons . . . [but do not] perceive [them] . . . to convey a health benefit," (*id.*), actually exist. On the contrary, we may safely presume that naturalists and those who subscribe to organic products do not engage in unmotivated or arbitrary behavior—common sense dictates the conclusion that they prefer such products precisely because they believe that natural and organic products

confer health advantages over conventional products. *See* Centers for Disease Control and Prevention ("CDC"), *Low-Yield Cigarettes and Cigarette-Like Products*, 1 (2009) (finding that "[m]any smokers consider smoking . . . additive-free cigarettes to be safer than smoking regular cigarettes"). Consequently, Plaintiffs' attempt to de-link hypothetical consumers' preferences for "organic" and "additive-free" products from general health concerns is unsustainable.

The MRTPR's requirement that Plaintiffs demonstrate harm reduction at both the individual and general level also survives *Central Hudson*'s fit and tailoring test. A claim that a product is less risky if it reduces harm to an individual, when that harm is externalized to others, is inherently misleading. Further, if the marketing of a product as "modified risk" raises the aggregate number of people (especially juveniles) who use tobacco because it leads them to believe than an unsafe product is *relatively* safe, instead of merely affecting the apportionment of current users, then the government's compelling interest in reducing juvenile tobacco use is not met. *See* 21 U.S.C. § 387k(g)(4) (specifically listing risk "that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application" and "likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application"); (C.M. Carpenter et al., *Developing smokeless tobacco products for smokers: an examination of tobacco industry documents*, 18 Tobacco Control 54, 54 (2009) (concluding that "[h]eavy marketing of new SLT [smokeless tobacco] products may encourage dual use and result in unknown public health effects. . . . These products may pose significant challenges to efforts by federal agencies to reduce harm caused by tobacco use").

Lastly, though Plaintiffs argue that there are several less restrictive methods available to remedy the harms addressed by the MRTPR—including mandating consumer disclaimers, limiting the MRTPR to post-dissemination review of advertisements, more vigorously enforcing fraud laws, or "sponsor[ing] public advertising campaigns about smokeless tobacco products, emphasizing that, regardless of whether such products are safer than cigarettes, consumers are still better off not using

tobacco products at all," (First Br. at 39–41)—we find that the MRTPR is not more extensive than necessary to address the government's interests. Plaintiffs would have us believe that the government has only recently come to recognize the harms associated with false tobacco safety claims, and that the MRTPR is the government's first up at bat. But on this issue, the government is at play in the major leagues, and the alternatives suggested by Plaintiffs have already been tried and found wanting.

We have no reason to upend—or intrude upon—Congress' determination and "express[] reject[ion of] the idea that requiring disclaimers for modified risk tobacco products would be effective . . . [based on the finding] that consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." (Second Br. at 43 (citing Legislative Findings 41 and 42, Pub. L. No. 111-31, §§ 2(41)-(42).) Nor do we see reason to externalize the costs of "public advertising" campaigns, presumably to counteract misleading claims made by the tobacco industry, to the government and to taxpayers. And, although the idea of post-market review of deceptive claims may be appealing to the tobacco industry, the government has made a reasonable determination that, in the context of a deadly and highly addictive product, it would be a virtual impossibility to unring the bell of misinformation after it has been rung. Thus, none of these alternatives supports a conclusion that the MRTPR is more extensive than necessary to serve its purpose.

Finally, Plaintiffs argue that the MRTPR is more extensive than necessary because "narrow tailoring requires Congress to 'distinguish[] the truthful from the false, the helpful from the misleading, and the harmless from the harmful.'" (First Br. at 37 (quoting *Zauderer*, 471 U.S. at 646).) But, of course, effectuating this distinction is exactly what the MRTPR is designed to do.

C. Summary

Because the MRTPR does not regulate non-commercial speech, and meets the criteria set forth in *Central Hudson* for the regulation of noncommercial speech, we **AFFIRM** the district court's determination that the provision does not violate the First Amendment.

V. Marketing Bans on Brand-Name Sponsorship and Merchandise, Sample Tobacco Products, and Continuity Products

The next issue that we confront is whether the Act's bans on brand name event sponsorship, non-tobacco merchandise, free samples and the distribution of non-tobacco products in consideration for tobacco purchases violates the First Amendment.

A. The Provision

The FSPTCA directs the FDA to reissue certain provisions of its 1996 regulation barring the distribution of free samples of tobacco products; the distribution of any non-tobacco item bearing the logo or name of a tobacco brand; the distribution of free gifts in consideration for a tobacco purchase (i.e., continuity programs); and the sponsorship by a tobacco company of

> any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

21 C.F.R. § 1140.34 (2010).

Plaintiffs argue that the government has failed to present "evidence that the marketing bans will 'directly' advance the Government's interest in decreasing youth tobacco use." (First Br. at 53.) Alternatively, they argue that the government has not shown that any reduction in juvenile tobacco use would be of such magnitude that it would be material. (*Id.*)

Plaintiffs further contend that the bans are overly-inclusive because they encompass marketing that is geared toward and largely received by adults, and is "critical . . . in inter-brand competition for adult consumers." (*Id*. at 54.) Lastly, Plaintiffs argue that there are several less restrictive alternatives to the bans, including "restricting media coverage of brand-name-sponsored events or limiting the brand-name merchandise ban to the types of items that can become 'walking advertisements,'" (*id*. at 55), strengthening laws prohibiting the sale of tobacco products to minors, (*id*. at 56), improving the state's use of funds negotiated through the 1998 Master Settlement Agreement ("MSA"),[9] (*id*.), "raising the legal age of purchase to 19 years-old, which would remove legal-age tobacco users from high schools; penalizing youth use by suspending offenders' drivers' licenses; public advertising campaigns; and social-influence-focused interventions." (*Id*. at 57.)

B. Legal Standard

The district court held that "the Act's restrictions on [Plaintiffs'] ability to offer free samples of tobacco products; [and] provide gifts with the purchase of tobacco products . . . [do not] implicate, let alone violate, Plaintiffs' free speech rights." *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 538. The government continues with this line of reasoning on appeal, arguing that "[p]rovisions that regulate conduct without a significant expressive element do not implicate the First Amendment, and any minimal speech interest that plaintiffs might assert is far outweighed by the need to curb underage tobacco use." (Second Br. at 77 (internal citation omitted).)

Plaintiffs reply that "sampling and continuity programs are protected speech" because they "are promotional methods that convey the twin messages of reinforcing

[9]The MSA ended a lawsuit between the attorneys general of 46 states and the major tobacco companies. In addition to proscribing particular advertising and marketing practices of the tobacco industry, the MSA also provided monetary payments from certain tobacco manufacturers to the states. Some, though not all, of Plaintiffs in this suit are signatories to the MSA.

brand loyalty and encouraging switching from competitors' brands." (First Br. at 58.) We agree.[10]

"Because regulation of the noncommunicative aspects of a medium often impinges to some degree on the communicative aspects, it has been necessary for the courts to reconcile the government's regulatory interests with the individual's right to expression." *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 502 (1981). "To qualify as a regulation of communicative action . . . the State's regulation must be unrelated to expression. Here, [the state's] restriction is an attempt to regulate directly the communicative impact [of the conduct]." *Lorillard Tobacco Co.*, 533 U.S. at 567; *see also Tx. v. Johnson*, 491 U.S. 397, 406 (1989) ("The government generally has a freer hand in restricting expressive conduct than it has in restricting the written or spoken word . . . . It may not, however, proscribe particular conduct because it has expressive elements" (internal citations omitted)).

In this case as well, the Act's regulation of sampling and continuity programs is an attempt to regulate the "communicative impact" of the activity, not the activity itself. The government has not articulated an interest in generally regulating the distribution of T-shirts, baseball caps, bobblehead dolls, or any other merchandise that may be available as part of a continuity program, or of regulating continuity programs themselves. Nor has it articulated an interest in regulating the act of providing free samples of products across consumer categories. Because the government has not

---

[10]In addition to miscategorizing the nature of the bans, the district court failed to conduct the proper analysis of a regulation of communicative activity. Once the district court determined that sampling and continuity programs were a regulation of conduct, it was required to analyze those provisions of the Act under *United States v. O'Brien*, which it did not do. Under *O'Brien*:

> when 'speech' and 'nonspeech' elements are combined in the same course of conduct, a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms . . . . [A] government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.

United States v. O'Brien, 391 U.S. 367, 376–77 (1968).

advanced these, or similar, interests, the district court erred in concluding that the Act's regulation of the expressive activity embodied in the tobacco industry's practices of sampling and maintaining continuity programs was an incidental consequence of the regulation of non-expressive conduct.

"Just as the inevitable effect of a statute on its face may render it unconstitutional, a statute's stated purposes may also be considered." *Sorrell*, 131 S. Ct. at 2663 (internal quotation marks and citation omitted). The stated purpose of the FSPTCA is the prevention of tobacco use among minors and the reduction of dependance on tobacco, Pub. L. No. 111-31, § 3(1), through addressing, in part, the "[a]dvertising, marketing, and promotion of tobacco products." Pub. L. No. 111-31, §§ 2(5), (6), (10), (15), (23). We see no reason not to take the government at its word in this circumstance, and in doing so, find that the primary intent of the marketing bans is the regulation of commercial expression.

Having determined that the Act's marketing bans regulate activity protected under the First Amendment, we return to *Central Hudson*.

C. Analysis

Though Plaintiffs would have us believe that there is no causal connection between product advertising and the consumer behavior of children, such a claim stretches the bounds of credulity, even in the absence of the extensive record submitted by the government, which indicates the contrary. The tobacco industry spent approximately $13 billion in advertising to promote its products in 2005, *see* CDC, *Economic Facts About U.S. Tobacco Use and Tobacco Production* (2009), and though Plaintiffs claim that all of it was spent to attract and retain adult consumers, it is impossible to believe that promotion so successful in the adult context that it is valued by Plaintiffs at $13 billion dollars had absolutely no effect on anyone below the age of eighteen. *See* U.S. Department of Health and Human Services, *Reducing Tobacco Use: A Report of the Surgeon General* 14 (2000) (stating that "[c]onsiderable evidence has accumulated showing that advertising and promotion are perhaps the main motivators

for adopting and maintaining tobacco use"); National Cancer Institute Smoking and Tobacco Control Monograph No. 14, *Changing Adolescent Smoking Prevalence: Where It Is And Why*, 202 (2001) (finding that "[h]istorical analyses show that variations in advertising are associated with concomitant variations in smoking uptake among youths.").

Plaintiffs' position is also belied by evidence that adult tobacco users are extremely brand loyal and are unlikely to switch products. As the United States Surgeon General found:

> [M]ost [Americans begin] smoking during their adolescence . . . . Very few people begin to use tobacco as adults; almost all first use has occurred by the time people graduate from high school.

U.S. Department of Health and Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General ii* (1994); *see also Philip Morris,* 449 F. Supp. 2d at 561 (finding that "[e]ach cigarette manufacturing company gains a small amount (less than 10%) of smokers through 'switching' or changing brands. Only about 9% of adult smokers switch among [the major tobacco manufacturer's] brands."); National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use, Tobacco Control Monograph No. 19*, 57 (2008) (hereafter, 2008 NCI Report) ("The rationale for directing promotions toward youth is that the pivotal period for smoking initiation in the United States is early adolescence. Smokers are also known to be extremely brand loyal, so the brand choice of consumers during the early stages of their smoking 'careers' becomes crucial.").

Therefore, the record suggests that the massive amount of money invested by the tobacco industry in advertising and marketing is largely devoted to (1) attracting new young adult and juvenile smokers, and (2) brand competition in the young adult and juvenile market. The record shows that tobacco advertising has a dramatic impact on juveniles' decision to use tobacco products. *See Philip Morris*, 449 F. Supp. 2d at 567 (quoting 1998 United States Surgeon General Report stating that "[a]dvertising is an important influence on tobacco use initiation and maintenance. . . . Cigarette advertising

and promotion may stimulate cigarette consumption by . . . encouraging children and adolescents to experiment with and initiate regular use of cigarettes" (alterations in original)); W.S. Choi et al., *Progression to Established Smoking: The Influence of Tobacco Marketing*, 22 American Journal of Preventive Medicine 4, 228 (2002) (examining "the influence of tobacco advertising and promotions on the transition from experimentation to established smoking.") (hereafter, 2002 Progression to Established Smoking Report).

The same conclusion has been reached by the courts on numerous occasions. *See, e.g.*, *Lorillard Tobacco Co.*, 533 U.S. at 557–61 (acknowledging "the theory that product advertising stimulates demand for products, while suppressed advertising may have the opposite effect," and providing a detailed summary of evidence that tobacco advertising specifically stimulated demand among juveniles). Furthermore, courts have found that, historically, juveniles have not just been peripherally affected by tobacco marketing, but have instead been directly targeted by the advertising campaigns of the tobacco industry. *See, e.g.*, *Philip Morris*, 449 F. Supp. 2d at 580 (reviewing extensive evidence supporting a finding that major tobacco manufacturers "tracked youth in order to determine how best to induce them to start, and continue, smoking cigarettes"); *State of Washington v. R.J. Reynolds Tobacco Co.*, 211 P.3d 448 (Wash. App. Ct. 2009).

Finally, credible evidence has been presented to support the conclusion that the advertising and marketing practices of the tobacco industry more heavily influence juveniles than adults. *See Philip Morris*, 449 F. Supp. 2d at 691 (finding that, as a result of directed marketing techniques, "88% of youth smokers buy the three most heavily advertised brands—Marlboro, Camel, and Newport. Fewer than half of smokers over the age of twenty-five purchase these three brands"); CDC Fact Sheet, *Tobacco Industry Marketing* (2009) ("The three most heavily advertised brands, Marlboro, Newport, and Camel, continue to be the preferred brands of cigarettes smoked by established student smokers in middle and high school").

Plaintiffs have presented no credible evidence in rebuttal. Therefore, we find that there is a substantial state interest in curbing juvenile tobacco use that can be directly advanced by imposing limitations on the marketing of tobacco products.

1. Free Samples

As discussed above, the government has presented overwhelming evidence that its interest in preventing and reducing juvenile tobacco use is substantial, and that preventing juveniles from viewing tobacco advertising materially impacts their decision to use tobacco. Plaintiffs argue that the marketing ban on sampling is not narrowly tailored, because it "cast[s] an unduly broad net that sweeps in vital speech to Plaintiffs' adult tobacco customers." (First Br. at 54 (internal quotation marks omitted).)

But the government's position regarding its ban on product sampling is perhaps its most easily supported. The government has presented extensive documentation that free samples of tobacco products are "easily accessible source of these products to young people," 61 Fed. Reg. 44460, and freely obtainable, even with the tobacco industry's "voluntary codes that supposedly restrict distribution of free samples to underage persons." *Id.* at 45244-45 & nn.1206-08.

Providing an opportunity for an underage nonsmoker to actually try a tobacco product, at no cost, may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth. But placing cigarettes and other tobacco products into the hands of minors clearly undermines the purposes and interests undergirding the Act. Banning such practices embodies a narrow fit between the harm articulated and the restriction employed.

2. Distribution of Branded Non-Tobacco Products

In addition to numerous other sources, the government has cited a "Gallup poll [that found] that nearly half of adolescent smokers—and more than a quarter of non-smokers—owned at least one tobacco-related promotional item." *Commonwealth*

Brands, Inc., 678 F. Supp. 2d at 527 (citing 61 Fed. Reg. 44525-26); *see also* 2002 Progression to Established Smoking Report.

The government has also presented studies that show that obtaining tobacco branded non-tobacco products "precedes, and reliably predicts, smoking initiation, even when controlling for other factors that have been shown to influence smoking uptake." *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 527 (quoting National Cancer Institute, *Changing Adolescent Smoking Prevalence* (2001); *see also Philip Morris*, 449 F. Supp. 2d at 569 (quoting John P. Pierce et al., *Tobacco Industry Promotion of Cigarettes and Adolescent Smoking*, 279 Journal of the American Medical Association 511–15 (1998) (finding that "tobacco promotional items are causally related to the onset of smoking")). In light of the record, we find that the government has met its burden of demonstrating that regulation of the distribution of tobacco branded products materially advances its interest in preventing the initiation of tobacco use by juveniles.

Plaintiffs argue that the ban is more extensive than required, because "more tailored solutions were available to address the court's youth-spill-over concerns, such as . . . limiting the brand-name merchandise ban to the types of items that can become 'walking advertisements' (e.g., caps and t-shirts, but not matchbooks or key chains)." (First Br. at 55 (quoting *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 528.).)

As a factual matter, the Act contains an exception for the free distribution of branded matchbooks. The Act states:

> For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

Pub. L. No. 111–31, § 906(d)(3)(B). The fact that the Act includes an exception for matchbooks, one of the only two items that Plaintiffs highlight as being unreasonably swept up by the regulation, strongly supports our finding that the provision is sufficiently tailored to survive scrutiny under *Central Hudson*.

3. Event Sponsorship

The government has offered substantial evidence supporting Congress' finding, as reflected in the district court's decision, that "'the exposure (which includes television broadcasts) that young people have to sponsored events is substantial.'" *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 526 (quoting 111 Fed. Reg. at 44529). "Even though cigarette advertising is not permitted on television in the United States, tobacco companies continue to receive millions of dollars' worth of national television exposure for their brands through sponsoring sports events such as auto racing." 2008 NCI Report. At the time of the 1996 FDA rulemaking, it was estimated that more than 64 million children each year were exposed to tobacco advertising on television through auto-racing sponsorship alone. *See* 61 Fed. Reg. at 44528.

Just as in traditional advertising mediums, tobacco advertising through event sponsorship has an effect on juvenile tobacco consumption. *See, e.g.*, Margaret Morrison et al., *Inhaling and Accelerating: Tobacco Motor Sports Sponsorship In Televised Auto Races, 2000-2002*, 15 Sports Marketing Quarterly 7 (2006); Michael Siegel, *Counteracting Tobacco Motor Sports Sponsorship as a Promotional Tool: Is the Tobacco Settlement Enough?*, 91 American Journal of Public Health 7, 1100–06 (2001)); *see also Philip Morris*, 449 F. Supp. 2d at 667 (quoting 1992 marketing review wherein Philip Morris identified the objectives of televised motorsports sponsorship as "[r]egain[ing] momentum in the hearts and minds of our target market—young adult smokers under 25"; and (2) "look[ing] at current and new program opportunities to extend our reach with starters and young adult smokers."). On this record, the government has met its burden of showing that the regulation of event sponsorship advances its stated interest.

Plaintiffs again charge that the ban is not appropriately tailored and is overly broad because it covers, for instance, "Lorillard's Newport Pleasure Draw blackjack tournament in a youth-restricted casino, for which there is no evidence whatsoever of any media coverage, . . . thereby demonstrating both the bans' facial lack of tailoring as well as their unconstitutionality as applied to Lorillard's event." (First Br. at 55.) The government counters that the restriction is narrowly tailored because none of the marketing restrictions "affect a manufacturer's ability to sponsor events in its corporate name," and so Plaintiffs may still sponsor such adult events. (Second Br. at 71.)

For the same reasons that the government prevails in its regulation of the distribution of branded non-tobacco merchandise, it also succeeds here. Just as branded non-tobacco merchandise reaches a wide audience of juveniles and contributes to their decisions to use tobacco products, so too does branded event sponsorship. *Cf. Philip Morris*, 449 F. Supp. 2d at 575 (finding that "television, outdoor advertising (billboards), and in-store or point-of-sale displays are less selective and tend to reach more people than more targeted vehicles like magazines."). The incidental effect of suppressing a tobacco company's ability to brand a single "youth-restricted" event does not constitute a constitutional claim. While the government has met the criteria set forth in *Central Hudson* regarding tobacco branded event sponsorship, Plaintiffs have failed to show that anything other than a nominal amount of protected speech is swept into the regulation.

4. Continuity Programs

Plaintiffs argue that "continuity programs, like frequent flyer programs, 'are designed to maintain the loyalty of existing customers, not to attract new ones, . . . [by] offer[ing] an added benefit for existing customers that may help prevent brand-switching.'" (First Br. at 59 (quoting R.71–10: Lindsey Aff. ¶ 54).) Therefore, Plaintiffs argue, a ban on such programs is overbroad.

In 1996, the FDA "concluded that non-tobacco items (identified with a tobacco brand), either sold, given away, or provided for proof of purchase are an instrumental form of advertising in affecting young people's attitudes toward and use of tobacco.

Moreover, banning this form of advertising is essential to reduce tobacco consumption by young people." 61 Fed. Reg. at 44527. This determination was based on a 1992 Gallup poll which reported that "about half of adolescent smokers and one quarter of non-smokers owned at least one of these items [Marlboro Miles or Camel Cash]," and approximately the same percentage owned-tobacco branded clothing, 60 Fed. Reg. 41314-01, 41336 (Aug. 11, 1995), and another study found that, in 1996,

> many teens report participating in promotional activities, with participation ranging from 25.6 percent of 12- to 13-year-olds and 42.7 percent of 16- to 17-year-olds owning a promotional item. The report found that 68.2 percent of current smokers participated, and 28.4 percent of non-smokers participated. The report concluded that there is an association between participating in promotions and a person's susceptibility to tobacco use.

Id.

The record provides no more extensive, or more recent, evidence to support the government's position that banning continuity programs advances its interest in any material way. The datedness and relative dearth of evidentiary support showing that juveniles are significantly influenced by continuity programs stands out starkly in the context of this case, where the government has presented overwhelming evidence to support the vast majority of its other contentions.

Furthermore, because there is no real dispute that "[a]dults consume more than 98% of all tobacco products sold in this country," (First Br. at 3), and continuity programs are by nature directly linked to consumption (e.g., Camel Cash or Marlboro Miles come with the purchase of packages of cigarettes), logic dictates that the overwhelming beneficiaries, both numerically and comparatively, of these continuity programs are adult consumers.

D. Summary

Because the government has failed to show that continuity programs have a material effect on juvenile tobacco use, or that the ban of such programs would result in

a material reduction of juvenile use, we find that the government has failed to sustain its burden under *Central Hudson* with regard to this provision, and we **REVERSE** the determination of the district court. We **AFFIRM** the district court's determination as to all other marketing bans at issue.

VI. Restriction on the Use of Color and Imagery in Tobacco Product Advertising

We now turn to the Act's restrictions on the use of color and imagery in most tobacco advertising.

A. The Provision

The FSPTCA adopts the language of the 1996 FDA regulation, and provides that:

> [E]ach manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:
>
> (1) In any facility where vending machines and self- service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or
>
> (2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:
>
> (i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and
>
> (ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

21 C.F.R. § 1140.32(a) (adopting 21 C.F.R. § 897.32(a), as amended).

The consequence of this restriction is that tobacco advertisers may "use only black text on a white background" to advertise cigarettes or smokeless tobacco products in most formats in which they currently advertise. (First Br. at 4 n.2.)

The district court invalidated this provision of the Act, holding that, "[b]ecause Congress could have exempted large categories of innocuous images and colors—e.g., images that teach adult consumers how to use novel tobacco products, images that merely identify products and producers, and colors that communicate information about the nature of a product, at least where such colors and images have no special appeal to youth," the provision was unconstitutionally overbroad. *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 525–26.

The government maintains that the tobacco industry's history of targeting juveniles through colorful and graphic advertising justifies the breadth of the restriction. Illustrative of the contention that "'[t]he tobacco industry has a long and disturbing history of marketing its products to appeal to young people,'" (Second Br. at 53 (quoting 155 Cong. Rec. S5988 (June 3, 2009))), is evidence that Plaintiff R.J. Reynolds, one of the leading American tobacco companies, explicitly discussed in internal memos the importance of marketing its tobacco products to the "young adult market, the 14-24 age group," because that market would constitute "a key share of the total cigarette volume—for at least the next twenty-five years." (*Id.* at 54 (citing *Philip Morris*, 449 F. Supp. 2d at 607–16).)

The government asserts that "[t]he industry's campaign to attract minors is not waged with tools of rational persuasion that invoke the 'merits' of taking up tobacco use. Instead, the industry relies on peripheral cues and irrational associations to distract would-be users from the fact that tobacco products are lethal and addictive." (*Id.* at 55.) The evocation of "irrational associations," reinforced through color and image, the government argues, is more effective with juveniles than with adult consumers. (*Id.*) The government further argues that this provision of the Act is properly tailored, as it "does not apply to advertising that appears in an adult publication . . . . [and i]t does not

affect the packaging of tobacco products." (*Id*. at 60.) Furthermore, "[t]he restriction does not constrain a manufacturer's ability to communicate product information through text." (*Id*. at 64.)

Addressing the argument that the Act could impose less restrictive prohibitions on advertising, the government argues that any further exceptions to the ban on color and graphics would create loopholes that "would easily be exploited by the tobacco industry." (*Id*. at 65, *see also* Fourth Br. at 16.) The government asserts that, "Congress was not required to replicate a scheme that is demonstrably subject to evasion. Ample evidence supports Congress's determination that a 'less restrictive and comprehensive approaches have [sic] not and will not be effective' in reducing underage tobacco use." (Second Br. at 68 (quoting Legislative Finding 31, Pub. L. No. 111-31, § 2(31).)

Plaintiffs counter that the ban effectively prevents the tobacco industry from communicating with adult consumers; attracting attention and differentiating their products in the retail environment; communicating useful commercial information about their products to consumers, including how to use novel products; and "depicting in advertising their products' packaging or their packaging's distinctive logos and colors." (Third Br. at 10–12.) Plaintiffs further respond that the provision is not properly tailored, because the ban on imagery extends to direct mail to adults, certain magazines that are "primarily directed to persons 21 years of age and older," (*id*. at 13 (quoting R.71–8: Dunham Decl. ¶ 12)), most tobacco retailers, and taverns that allow juveniles "to enter for meals with their parents or during restricted times." (*Id*. at 14). Lastly, Plaintiffs argue that the provision is overly burdensome to the industry because it requires Plaintiffs to verify the youth readership of a magazine in order to meet the criteria of the "adult publication" exception. Plaintiffs assert that they would be required to conduct a costly private readership survey before waging an advertising campaign in each new publication, which "for a single large national magazine costs as much as $50,000-$100,000, which could dramatically exceed the cost of the advertisement itself." (*Id*. (quoting R.71–8: Dunham Decl. ¶ 23).)

B. Analysis

"Misleading advertising may be prohibited entirely." *In re R.M.J.*, 455 U.S. at 203. This includes speech that "is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive." *Id.* at 202. But, "[t]ruthful advertising related to lawful activities is entitled to the protections of the First Amendment." *Id*. at 203.

Though the government may have an interest in decreasing the use of a product, "the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." *Sorrell*, 131 S. Ct. at 2671.

In this case, the government contends that the tobacco industry's graphic color advertisements are deceptive because "[t]obacco imagery . . . seeks to distract potential users from the fact that tobacco products are lethal and addictive." (Second Br. at 63; *see also* 2007 IOM Report, at 322 ("The images used in tobacco marketing associate smoking with lifestyles and experiences that appeal to young people, and these positive associations tend to displace or override risk information in adolescent decision making.")). Consequently, the government's claim is not that tobacco advertisements make deceptive or misleading claims, but that they create positive associations in the minds of consumers, such as linking the use of tobacco products to "part of a desirable lifestyle that includes activities such as mountain biking, tug-of-war, and sex," along with concepts such as "fun" and "relaxation." (Second Br. at 62.)

Plaintiffs respond that, "if the Government were correct, it could similarly ban attractive advertisements for *all* age-restricted products, including beer, R-rated movies, lottery tickets, and fast cars, simply because those advertisements are appealing, not just to the adults at whom they are aimed, but to youth who happen to see them." (Third Br. at 25.) These advertisements, too, undoubtedly attempt to entice consumers by creating desirable lifestyle associations, not by dryly conveying informational content.

Plaintiffs fail to appreciate that there are ways for a person to drink beer, watch R-rated movies, buy lottery tickers, and drive fast cars, that do not necessarily cause harm to that person. In contrast, there is no method by which a person can smoke a cigarette or use smokeless tobacco in a manner that is health-neutral. This distinction—lost on Plaintiffs—renders their analogy to non-tobacco products somewhat less than helpful. Nonetheless, we find Plaintiffs' argument availing.

Though many products available on the market are use-neutral or use-negative, product advertisement always seeks to create positive associations between the product and certain lifestyles or symbols. Perfume and cologne do not make people more beautiful, chewing gum does not make them more athletic, coffee does not make them more intelligent or urbane. By the same token, though the government would have us believe otherwise, using tobacco does not necessarily preclude a person from mountain biking, playing games, or engaging in romantic relationships.

It is worth quoting the Supreme Court, at some length, on this issue of the constitutionality of blanket bans of color and imagery in advertising:

> . . . acceptance of the State's argument would be tantamount to adoption of the principle that a State may prohibit the use of pictures or illustrations in connection with advertising of any product or service simply on the strength of the general argument that the visual content of advertisements may, under some circumstances, be deceptive or manipulative. But . . . broad prophylactic rules may not be so lightly justified if the protections afforded commercial speech are to retain their force. We are not persuaded that identifying deceptive or manipulative uses of visual media in advertising is so intrinsically burdensome that the State is entitled to forgo that task in favor of the more convenient but far more restrictive alternative of a blanket ban on the use of illustrations . . . . Given the possibility of policing the use of illustrations in advertisements on a case-by-case basis, the prophylactic approach taken by [the State] cannot stand.

Zauderer, 471 U.S. at 649.

All use of color and imagery in tobacco advertising, of course, is not deceptive or manipulative. As Plaintiffs underscore, some advertising, like that for the "Camel

Crush" product, is largely informational. (Third Br. at 11.) Other tobacco advertising is used to reinforce consumer preference "by simply showing the package" of the customer's preferred brand. (*Id*. at 10.) Finally, some uses of color imagery are simply attention grabbing in a crowded marketplace, letting consumers know that their preferred brand or product is available at a particular retailer. (*Id*.) Furthermore, there are surely certain color graphic tobacco ads that have nominal to zero appeal to the youth market. Each of these forms of advertising has great expressive value for the tobacco industry, and its suppression would be an undue burden on Plaintiffs' free speech.

The government's argument that "[c]olor is used to convey a mood—such as red for passion and power, green for harmony and health—and to circumvent other advertising restrictions," (Second Br. at 56–57 (citing 2008 NCI Report, at 64–65; 2007 IOM Report, at 297)), is no more convincing. Packaging shape, product shape and color, display location, and any number of other factors may also convey meaning through association. As discussed above, the fact that these associations "may, under some circumstances, be deceptive or manipulative," is not enough to justify such a sweeping ban.

Instead of instituting a blanket restriction on color and graphics in tobacco advertising, the government may instead restrict only the speech necessary to effect its purposes. "To the extent that studies have identified particular advertising and promotion practices that appeal to youth, tailoring would involve targeting those practices while permitting others." *Lorillard Tobacco Co.*, 533 U.S. at 563. As the district court correctly stated, instead of instituting such a sweeping and complete ban, "Congress could have exempted large categories of innocuous images and colors—e.g., images that teach adult consumers how to use novel tobacco products, images that merely identify products and producers, and colors that communicate information about the nature of a product, at least where such colors and images have no special appeal to youth." *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 525–26.

There is no doubt that identifying and targeting certain advertising practices will be more arduous than banning all color and graphics in tobacco advertising. For instance, the government points to the controversy surrounding the "Camel Farm" advertising campaign, which has been the subject of extensive and ongoing litigation. *See R.J. Reynolds Tobacco Co.*, 211 P.3d 448 at 451 n.10 (summarizing litigation in more than a half-dozen courts nationwide). But this is the exact work required by the First Amendment. And, "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." *Lorillard Tobacco Co.*, 533 U.S. at 571.

C. Summary

Although the government can show a substantial interest in alleviating the effects of tobacco advertising on juvenile consumers, the provision of the Act banning the use of color and graphics in tobacco advertising is vastly overbroad, and therefore the government cannot meet its burden of demonstrating that the Act is properly tailored under *Central Hudson*.

VII. Restriction on Claims that a Tobacco Product is Safe or Less Harmful Due to FDA Regulation or Compliance with FDA Standards.

Finally, we focus our attention on the Act's restriction on claims or representations that tobacco products are made less harmful or safer by virtue of FDA regulation.

A. The Provision

The FSPTCA prohibits the:

> Making [of] any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that
>
> (1) the product is approved by the Food and Drug Administration;
>
> (2) the Food and Drug Administration deems the product to be safe for use by consumers;
>
> (3) the product is endorsed by the Food and Drug Administration for use by consumers; or
>
> (4) the product is safe or less harmful by virtue of--
>
> (A) its regulation or inspection by the Food and Drug Administration; or
>
> (B) its compliance with regulatory requirements set by the Food and Drug Administration;
>
> including any such statement or representation rendering the product misbranded under section 387c of this title.

21 U.S.C. § 331(tt).

Plaintiffs challenge only § 331(tt)(4), arguing that the provision's "flat ban on 'any' statement directed to consumers that 'conveys' that [the] FDA is achieving its objectives goes far beyond what is needed to prohibit 'misleading' speech." (Third Br. at 60.)

The district court found that the § 331(tt)(4) restrictions apply to speakers outside of the tobacco industry, including "journalists, doctors, scientists, politicians, and numerous other groups and individuals with access to the media," and therefore "the ban applies to more than just commercial speech and must satisfy strict scrutiny." *Commonwealth Brands, Inc.*, 678 F. Supp. 2d at 535. Having made the determination that strict scrutiny was the applicable standard, the district court, without further analysis, declared that "[b]ecause the government has not even attempted to justify the ban under the strict scrutiny standard, and because it seems clear that it cannot be so justified, the Court finds 21 U.S.C. § 331(tt)(4) facially unconstitutional." (*Id.*) As explained below, we now **REVERSE** the determination of the district court, and uphold § 331(tt)(4) as constitutional.

B. Analysis

1. Statutory Analysis

Our first task is to determine whether 21 U.S.C. § 331(tt)(4) regulates non-commercial speech as well as commercial speech. This is a matter of statutory interpretation.

"Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985). It is one of the cardinal rules of statutory interpretation that "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. 'It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *Brown & Williamson Tobacco Corp.*, 529 U.S. at 132–33 (quoting *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989)). Therefore, "[a]mbiguity is a creature not of definitional possibilities but of statutory context." *Brown v. Gardner*, 513 U.S. 115, 118 (1994).

In addition to the above considerations, our interpretation of statutory language is guided by the constitutional avoidance doctrine, which embodies the "cardinal principle of statutory interpretation . . . that when an Act of Congress raises a serious doubt as to its constitutionality, this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Zadvydas v. Davis*, 533 U.S. 678, 689 (2001) (internal citation and quotation marks omitted).

In this case, citing the legislative findings of the Act, the government argues that "it is clear from the statutory context that Congress did not intend to reach non-commercial actors such as 'news organizations' or 'politicians.'" (Second Br. at 48.) Legislative Finding 46 states:

> If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

Pub. L. No. 111-31, § 2(46).

This finding notwithstanding, an exercise of statutory interpretation yields the conclusion that § 331(tt)(4) is not intended to encompass non-commercial speech. In § 331(tt)(4), the phrase "through the media," which is the only phrase that could conceivably encompass non-commercial speech, follows directly after the terms "label or labeling" and immediately precedes the term "[through] advertising." Each of these terms is modified by the phrase "directed to consumers with respect to a tobacco product." *See Stevens*, 130 S. Ct. at 1588 (holding that "an ambiguous term may be given more precise content by the neighboring words with which it is associated") (internal quotation marks omitted). The only parties capable of consumer-directed labeling or advertising of tobacco products are tobacco manufacturers and distributors,

and such labeling and advertising would clearly fall with the category of commercial speech. In this context, a determination by this Court that § 331(tt)(4) can be reasonably interpreted to exclude non-commercial statements directed at tobacco users by "journalists, doctors, scientists, politicians" is not only "fairly possible," but well-supported.

Furthermore, the prohibitions preceding § 331(tt) in the Food, Drug and Cosmetic Act mandate bans on the sale of tobacco in violation of "no-sale" orders, *id.* § 331(oo), the "introduction into interstate commerce" of a mislabeled tobacco product, *id.* § 331(pp), the "counterfeiting" of tobacco products, *id.* § 331(qq), the distribution of such products to charity, *id.* § 331(rr), and criminalizes "[t]he failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade." *Id.* § 331(ss). Each of these prohibitions applies only to the tobacco industry, and only to consumer-directed actions.

In accordance with the constitutional avoidance doctrine, and giving due regard to the language of the provision, we find that § 331(tt)(4) does not restrict noncommercial speech by persons outside of the tobacco industry. Thus, to be found constitutionally permissible, 21 U.S.C. § 331(tt)(4) must meet the requirements outlined in *Central Hudson*.

2. Constitutionality

The government argues, consistent with the Act's legislative findings, that § 331(tt)(4) "is designed to prevent tobacco companies from confusing consumers about the role of FDA with respect to tobacco products, which differs in significant ways from FDA's role in regulating drugs and devices." (Fourth Br. at 31.)

The provision bars claims that tobacco products are "safe or less harmful *by virtue of*" FDA regulation, inspection or compliance. 21 U.S.C. § 331(tt)(4) (emphasis added). Though a tobacco manufacturer's compliance with, for instance, the pre-approval requirements set forth in the MRTPR may confirm that a tobacco product is

less harmful or poses a different risk than traditional tobacco products, such products are not made safe or less harmful "by virtue of" that FDA process. For the tobacco industry to claim or imply otherwise would constitute misleading speech.

Furthermore, as the government highlights, the role that the FDA undertakes regarding tobacco products is fundamentally different than the role that it undertakes with regard to food, drugs and cosmetics. In those contexts, the stated mission of the FDA is to, "protect the public health by ensuring that–

> (A) foods are safe, wholesome, sanitary, and properly labeled;
>
> (B) human and veterinary drugs are safe and effective;
>
> (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
>
> (D) cosmetics are safe and properly labeled . . . .

21 U.S.C. § 393(b)(2).

In the context of tobacco products, any statement explicitly declaring, or even implying, that compliance with FDA procedures has ensured safety is inherently misleading and patently false. Therefore, this regulation survives under either *Zauderer*, as prevention of deceptive and untrue advertising, or *Central Hudson*, as a narrowly tailored regulation of commercial speech.

C. Summary

This district court erred in interpreting 21 U.S.C. § 331(tt) as an unconstitutional restriction on non-commercial speech; we therefore **REVERSE** its decision.

CONCLUSION

For the reasons discussed above, we **REVERSE** the district court's determination that the Act's restriction on FDA claims is unconstitutional and its determination that the Act's ban on tobacco continuity programs is permissible under the First Amendment.

We **AFFIRM** the district court's determination upholding the constitutionality of color graphics and non-graphics on tobacco warning labels, with Judge Clay dissenting on the issue of the color graphics. The judgment of the district court is **AFFIRMED** in all other respects.

OPINION

JANE B. STRANCH, Circuit Judge. I write for the majority in concluding that the warnings mandated by the Family Smoking Prevention and Tobacco Control Act (the Act), Pub. L. No. 111-31, 123 Stat. 1776 (2009), are constitutional under the First Amendment. Plaintiffs' facial challenge fails because the required warnings for cigarette packaging and cigarette advertising pass muster under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985).

Before turning to our specific analysis of the Act's warnings, we describe how our majority position relates to the Discussion Sections of Judge Clay's lead opinion that include the issues on which he writes for the majority and in dissent:[1]

- We agree with the law and reasoning in Section I.
- We agree with the law and reasoning in Section II except to the extent that the opinion conflates restricting commercial speech with requiring disclosure of factual information in commercial speech. Laws that restrict speech are fundamentally different than laws that require disclosures, and so are the legal standards governing each type of law. *Compare Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-66 (1980) (setting forth the standard for restricting commercial speech), *with Zauderer*, 471 U.S. at 650-53 (setting forth the standard for requiring commercial-speech disclosures). Since the Act's warnings require the disclosure of factual information, *Zauderer* governs the warnings.
- In Section III, which addresses the Act's required warnings, we agree with the result that the textual warnings are constitutional, but not the reasoning, as we explain below. And we disagree fully with Section III's result and reasoning concerning graphic warnings.
- We agree with the result and analysis in Sections IV-VI.

[1]Where our opinions disagree on result or analysis, this opinion—joined in full by Judge Barrett— constitutes the majority.

- We agree with the result and reasoning on Section VII except to the extent that it implies that *Zauderer* governs *restrictions* on deceptive and untrue advertising. The restriction at issue—i.e., 21 U.S.C. § 331(tt)(4)'s ban on certain commercial statements—is constitutional because the prohibited statements are inherently misleading and false. *See Central Hudson*, 447 U.S. at 563 ("The government may ban forms of communication more likely to deceive the public than to inform it.").

We explain our specific disagreements and the majority position more fully below. We now turn to the Act's required warnings.

A. Standard of review: facial versus an as-applied challenge

Plaintiffs' challenge to the Act's warning requirements—including "graphics depicting the negative health consequences of smoking," Act § 201(a)—is only a facial challenge. This challenge means that Plaintiffs argue that the Act's graphic-warnings requirement is itself unconstitutional, not that the specific images the FDA chose to implement the requirement are unconstitutional. That Plaintiffs challenge the Act's warning requirements only facially is so for four reasons: timing; the district court's decision; Plaintiffs' admissions; and Supreme Court precedent.

First, the timing demonstrates that the challenge is facial. The Act, which was enacted in June 2009, mandates new textual and graphic warnings for cigarette packaging and advertising (§ 201) and new textual warnings for smokeless-tobacco products (§ 204).[2] Section 201 gives the FDA twenty-four months after the Act's enactment to issue regulations implementing the new cigarette warnings, including "graphics depicting the negative health consequences of smoking." Act § 201(a) (amending 15 U.S.C. § 1333(d)). In November 2010, the FDA began its rulemaking by submitting for public comment a proposed rule that included thirty-six graphic images that could be used with the nine new textual warnings.[3] The FDA settled on nine images

[2]Though the Act does not require graphic warnings for smokeless-tobacco products, the FDA may require graphic warnings for them through notice-and-comment rulemaking under 5 U.S.C. § 553. Act § 205(a).

[3]*Required Warnings for Cigarette Packages and Advertisements*, 75 Fed. Reg. 69524, 69534-35 (Nov. 12, 2010) (Proposed Rule).

out of the thirty-six for use in the cigarette warnings when it published its Final Rule in June 2011.[4]

The district court's summary-judgment decision in January 2010 was issued over ten months before the FDA proposed any specific graphic images and over seventeen months before the FDA settled on the final nine images. The district court did not—indeed, could not—evaluate the constitutionality of the specific images the FDA chose because those images did not yet exist. Indeed, they did not even exist when the last appellate brief was filed in this Court in October 2010. Without any specific graphic images to challenge, Plaintiffs' argument is and must necessarily be that the graphic-warning requirement on its face violates the First Amendment.

As an appellate court with jurisdiction to *review* a district court decision, *see* 28 U.S.C. § 1291, this record provides nothing to review on the issue of warnings save what the statute itself requires. Moreover, federal courts "should act cautiously" when asked to overturn democratically enacted statutes because "a ruling of unconstitutionality frustrates the intent of the elected representatives of the people." *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984) (plurality opinion); *accord id.* at 653. Courts have created several doctrines imposing restraint in this area (e.g. constitutional avoidance, severability, etc.). Addressing the specific images would require us to reach a constitutional question that was neither briefed[5] nor argued and that turns on facts not available, litigated, or considered by the district court, all of which would fly in the face of the restraint we should exercise during judicial review.

Second, the district court's decision reinforces this point. In finding that the new warnings were permissible under the First Amendment, the court stated that it "does not believe that the addition of *a* graphic image will alter the substance of [the new

---

[4] *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628, 36636 (June 22, 2011) (Final Rule).

[5] The dissent is simply incorrect in suggesting otherwise in Section III.B.2. Briefing that logically could not address specific images and that did not do so cannot constitute adequate briefing by both parties.

warnings], at least *as a general rule*. Accordingly, . . . the Court finds that the *warning requirement* is [constitutional]." *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 532 (W.D. Ky. 2010) (emphasis added). Both the use of the indefinite pronoun *a* and the phrases *as a general rule* and *warning requirement* show that the district court was considering the graphic-warning requirement on its face instead of considering any specific graphic images, which did not even exist when the district court ruled on the case.

Third, three plaintiffs in this case—R.J. Reynolds Tobacco, Lorillard, and Commonwealth Brands—admit that this case challenges the Act's required warnings only facially. They have brought another case to challenge the specific graphic warnings selected by the FDA. *See R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Admin.*, — F. Supp. 2d —, 2011 WL 5307391 (D.D.C. Nov. 7, 2011). The *R.J. Reynolds* plaintiffs expressly assert in their complaint that the case before us challenges the Act's warning requirements only facially:

> Plaintiffs R.J. Reynolds Tobacco, Lorillard, and Commonwealth Brands, together with other tobacco product manufacturers and retailers, have challenged various speech restrictions mandated by the Tobacco Control Act, *including a facial challenge to the warnings as mandated by the Act itself*. . . . Both sides have appealed [the district court's rulings] to the . . . Sixth Circuit.
>
> . . . . .
>
> The plaintiffs in [*Discount Tobacco*] have argued that the Act's general graphic warnings requirement is facially unconstitutional. The [*Discount Tobacco*] plaintiffs, however, did not raise the claim brought by Plaintiffs in this action—that the particular warnings required by the Rule are unconstitutional—because the Rule had not yet been promulgated at the time that case was filed. . . . The present lawsuit challenges the specific warnings promulgated by the Rule in 'its exact form.' Accordingly, it turns primarily on facts not available, litigated, or considered in the [*Discount Tobacco*] case.

Id., DE1, Compl. 8 n.3 (emphasis added). Litigation strategy is unquestionably the domain of Plaintiffs and they aver that their litigation strategy in this case is to challenge

the warnings only facially. Reading an as-applied challenge into Plaintiffs' briefs is not tenable.

Fourth, Supreme Court precedent dictates that we review Plaintiffs' challenge to the Act's warnings as a facial one. The Court has held if the "plaintiffs' claim and the relief that would follow . . . reach beyond the particular circumstances of these plaintiffs," then the challenge is a facial challenge, even if the plaintiffs bringing the claim label it otherwise. *John Doe #1 v. Reed*, 130 S. Ct. 2811, 2817 (2011). The tobacco-product manufacturers and retailers in this case argue that the warnings violate the First Amendment. The relief flowing from this claim, should they prevail, would render the warnings unconstitutional with respect to any tobacco-product manufacturer, retailer, distributor, or importer, not just the specific entities that are a party to this lawsuit. Their claims are therefore properly reviewed under *Reed* as facial challenges to the Act's required warnings.

We now turn to Plaintiffs' facial challenge to the required warnings. "To succeed in a typical facial attack, [a plaintiff] would have to establish that no set of circumstances exists under which [the statute] would be valid, or that the statute lacks any plainly legitimate sweep." *United States v. Stevens*, 130 S. Ct. 1577, 1587 (2010) (internal citations and quotation marks omitted). In addition to scaling this steep standard of review, Plaintiffs must also contend with the fact that "[f]acial challenges are disfavored for several reasons. Claims of facial invalidity often rest on speculation. As a consequence, they raise the risk of premature interpretation of statutes on the basis of factually barebones records." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (internal quotation marks omitted).

B. The level of scrutiny

If a commercial-speech disclosure requirement fits within the framework of *Zauderer* and its progeny, then we apply a rational-basis standard. *Zauderer*, 471 U.S. at 651. If it does not, then we treat the disclosure as compelled speech under *Wooley v. Maynard*, 430 U.S. 705 (1977), and its ilk and apply strict scrutiny. *Entm't Software*

Ass'n v. Blagojevich, 469 F.3d 641, 651-52 (7th Cir. 2006) (applying strict scrutiny after determining that the disclosure did not fit within *Zauderer*).

1. Zauderer *and its progeny*

"*Zauderer* addressed the validity of a[n Ohio] rule of professional conduct that required attorneys who advertised contingency-fee services to disclose in their advertisements that a losing client might still be responsible for certain litigation fees and costs." *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010). Zauderer had advertised that he would represent clients on certain kinds of cases for a contingent fee, defined by his ad as meaning that no legal fees would be owed if the client recovered no money. *Zauderer*, 471 U.S. at 631. But because the ad did not tell potential clients that they might be liable for litigation costs even if their lawsuits were unsuccessful, Zauderer violated a professional-conduct rule and was ultimately disciplined by the state supreme court. *Id.* at 636.

Zauderer challenged the rule on First Amendment grounds, arguing that the required disclosure was valid only if it passed the test for restricting commercial speech under *Central Hudson*, which is that the speech must either be deceptive absent the disclosure, or the government must show that the disclosure serves some substantial interest and directly advances that interest through the least restrictive available means.[6] *Zauderer*, 471 U.S. at 650. The Supreme Court rejected the *Central Hudson* test based on the "material differences between disclosure requirements and outright prohibitions on speech." *Id.*

Protecting commercial speech under the First Amendment is principally justified by protecting the flow of accurate information, and requiring factual disclosures furthers that goal. *Id.* at 650-51; *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-14 (2d Cir. 2001). Thus, a commercial speaker's "constitutionally protected interest in *not*

[6]The precise language *Zauderer* used in setting forth the *Central Hudson* test is slightly different than the language in *Central Hudson*, but the import is the same. *Compare id.* at 638, 647, *with Central Hudson*, 447 U.S. at 566.

providing any particular factual information in his advertising is minimal." *Zauderer*, 471 U.S. at 651 (emphasis in original). "[B]ecause disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, warnings or disclaimers might be appropriately required in order to dissipate the possibility of consumer confusion or deception." *Id*. (internal quotation marks omitted). In sum, "First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed."[7] *Id.*

Disclosure requirements, to be sure, do "implicate the advertiser's First Amendment rights." *Id.* The Court "recognize[d] that unjustified or unduly burdensome disclosure requirements *might* offend the First Amendment by chilling protected commercial speech. *But* we hold that *an advertiser's rights are* adequately *protected as long as disclosure requirements are reasonably related* to the State's interest in preventing deception of consumers." *Id.* (emphasis added).

Zauderer relied on the distinction between a fact and a personal or political opinion to distinguish factual, commercial-speech disclosure requirements, to which courts apply a rational-basis rule, from the type of compelled speech on matters of opinion that is "as violative of the First Amendment as prohibitions on speech." *Id.* at 650. The Court reasoned that the disclosure required by the Ohio professional-conduct rule did not fall within the latter category because the rule did not compel Zauderer to adopt or proclaim a state-sanctioned opinion on an issue: "Ohio has not attempted to prescribe what shall be orthodox in politics, nationalism, religion, *or other matters of opinion* or force citizens to confess by word or act their faith therein." *Id.* at 651 (emphasis added and internal quotation marks omitted). Ohio instead had required that Zauderer include in his advertising only factual information—not an opinion—about the terms of his contingency fee. *Id.*

[7]The dissent fails to recognize (1) the distinction *Zauderer* draws between restricting speech and requiring disclosures, and (2) the significant interests supporting the different legal treatment required by that distinction.

In 2010, the Court reaffirmed the central principles of *Zauderer* in *Milavetz*. *Milavetz*, 130 S. Ct. at 1339-40. The Milavetz law firm and others brought a First Amendment challenge to changes to the Bankruptcy Code that required professionals who assist consumers with bankruptcy to disclose in their ads this statement: "We are a debt relief agency. We help people file for bankruptcy relief under the Bankruptcy Code." *Id.* at 1330 (quoting 11 U.S.C. § 528(a)(4)). Like Zauderer, Milavetz argued that the *Central Hudson* test governed whether the disclosure requirements were constitutional. *Id.* at 1339. But the Court again rejected this test in favor of the test set forth in *Zauderer*, determining that "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 1339-40 (quoting *Zauderer*, 471 U.S. at 651).

Milavetz applied this test for three reasons. First, the statute's disclosure requirements targeted marketing claims that inherently tended to deceive by promising "debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." *Id.* at 1340. Second, "the disclosures entail[ed] *only an accurate statement* identifying the advertiser's legal status" and providing "pertinent information about the advertiser's services." *Id.* at 1340-41 (emphasis added). Third, the disclosures did not prevent debt-relief agencies from communicating any additional information. *Id*. at 1340.

Milavetz held that the required disclosures were constitutional under *Zauderer* because the facts that the debt-relief agencies had to disclose were pertinent to a consumer in deciding whether to use the agencies' services. *See id.* at 1340-41. In other words, the disclosures were reasonably related to preventing consumer deception. *Id.* at 1341. Significantly, the Court upheld the required disclosures without separately analyzing whether they were unjustified or unduly burdensome. *Id.* at 1339-41. This makes sense because the *Zauderer* rule is that when disclosure requirements are "reasonably related to the State's interest in preventing deception of consumers," the rights of an advertiser are adequately protected. *Id.* at 1339-40 (quoting *Zauderer*, 471 U.S. at 651)).

The Second Circuit case of *Sorrell* reinforces the principles (1) that distinguishing between a fact and a personal or political opinion controls whether a required disclosure is reviewed under *Zauderer*'s rational-basis rule or the more exacting compelled-speech doctrine, (2) that deciding whether the required disclosure satisfies the *reasonably related* requirement is all that is necessary to determine the disclosure's constitutionality, and (3) that satisfying this requirement is a simple task. In addition, *Sorrell* shows that *Zauderer*'s framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception. *Sorrell* addressed a statute requiring manufacturers of mercury-containing lamps to disclose this fact on their products and packaging and to disclose that consumers should dispose of the products as hazardous waste. 272 F.3d at 107. NEMA, an association representing lamp manufacturers, sued and the district court preliminary enjoined the State of Vermont from enforcing the statute on the grounds that the statute violated NEMA's First Amendment rights. *Id.* at 107-08.

The circuit court reviewed the mercury disclosures under *Zauderer*'s rational-basis rule because they were factual disclosures as opposed to compelled opinions: "[o]ur decision reaches only required disclosure of *factual* commercial information. Requiring actors in the marketplace to espouse particular *opinions* would likely raise issues not presented here." *Id.* at 114 n.5 (emphasis added). Moreover, the court reasoned that requiring "disclosure of accurate, factual commercial information presents little risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions, suppressing dissent, confounding the speaker's attempts to participate in self-governance, or interfering with an individual's right to define and express his or her own personality." *Id.* at 114. Thus, the "individual liberty interests guarded by the First Amendment" were not implicated. *Id.* "Moreover, requiring disclosure of truthful information" protects the "robust and free flow of accurate information, [which] is the primary First Amendment justification for protecting commercial speech." *Id.*

Having concluded that *Zauderer*'s rational-basis rule applies, the *Sorrell* court reversed the district court, determining that the required disclosures were constitutional

without analyzing whether the disclosures were unjustified or unduly burdensome. *See id.* at 115-16. Relying on *Zauderer*'s principles, *Sorrell* instead held that the First Amendment is satisfied "by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose." *Id.* at 115. The court explained that the disclosure's purpose was not to prevent consumer deception per se, but rather to protect "human health and the environment" by reducing the amount of mercury released, a purpose that is "inextricably intertwined" with "better inform[ing] consumers about the products they purchase" and that is achieved by requiring the manufacturers to disclose whether those products contain mercury. *Id.* *Sorrell* concluded that a reasonable relationship between the purpose and means was "plain" because of the probability that some mercury lamp purchasers, once informed, "will properly dispose of [the lamps] and thereby reduce mercury pollution. By encouraging such changes in consumer behavior the labeling requirement is rationally related to the state's goal of reducing mercury contamination." *Id.* This was so even though the "statute may ultimately fail to eliminate all *or even most* mercury pollution in the state." *Id.* (emphasis added).

Sorrell relied on common sense rather than evidence to conclude that the disclosures would lead some consumers to change their behavior, thereby showing that constitutionality does not hinge upon some quantum of proof that a disclosure will realize the underlying purpose. A common-sense analysis will do. And the disclosure has to advance the purpose only slightly. *See id.* (upholding the statute even though it "may ultimately fail to eliminate all or even most mercury pollution in the state"). The district court had gone astray by requiring the means to be more effective in producing the desired ends. *See id.* at 115-16. It found as fact that lamps are not the largest source of environmental mercury and therefore determined that the solution had an insufficient impact on the stated problem. *See id.* But although the fact was correct, "[t]his analysis misses the mark." *Id.* at 116. States need not address the largest source of a problem provided that their

> response does not trench on fundamental rights. *See* [*Zauderer*, 471 U.S. at 652 n.14]. The Supreme Court has held that "the right of a commercial speaker not to divulge accurate information regarding his services is not such a fundamental right." *Id.* Absent interference with such a fundamental right, a state may choose to tackle a subsidiary cause of a problem rather than its primary cause . . . .

Id. (brackets in original omitted).

This Court has also opined on *Zauderer*'s reach and import. We have held that *Zauderer* applies not only when the required disclosure "targets speech that is *inherently* misleading," but also "where, as here, the speech is *potentially* misleading." *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 641 (6th Cir. 2010). In so holding, we relied on the principal justification for protecting commercial speech under the First Amendment: protecting the flow of accurate information, which is furthered by factual disclosures. *Id*. "The speech rights of advertisers, in contrast, are of less value; specifically, their 'constitutionally protected interest in *not* providing the required factual information is minimal.'" *Id*. (quoting *Milavetz*, 130 S. Ct. at 1339) (emphasis in original). In analyzing the constitutionality of the required disclosure, this Court examined whether there was a rational connection between the purpose served by the disclosure and the disclosure itself. *Id.* at 642-43. *International Dairy* affirmed a disclosure requirement concerning a claim about producing milk because the requirement was reasonably related to the government's interest in preventing consumer deception but invalidated a rule requiring that the disclosure be contiguous to the claim because that rule lacked a rational basis. *Id.*

2. Proper level of scrutiny

With these principles in mind, we now turn to whether the *Zauderer* framework governs the constitutionality of disclosure requirements in this case. The Act mandates nine new textual and graphic warnings for packaging and advertising of cigarettes and four new textual warnings for packaging and advertising of smokeless-tobacco products. Act §§ 201(a), 204(a). The Act requires that the warnings comprise the top 50% of the front and back of cigarette packaging, 30% of the front and back of smokeless-tobacco-

products packaging, and 20% of the advertising for cigarettes and smokeless-tobacco products. *Id.* §§ 201(a), 203(a). All of the warnings address the negative health consequences of using tobacco. *See id*. The factual content of the textual warnings is undisputed. It is beyond cavil that smoking presents the serious health risks described in the warnings, and Plaintiffs do not contend otherwise: "Again, it is undisputed that no tobacco product is riskless and reducing youth use is an important concern." (Third Br. at 2) Because the textual warnings require disclosing factual information rather than opinions, *Zauderer*'s rational-basis rule applies.

The Act's graphic-warnings provision mandates that the FDA "require color graphics depicting the negative health consequences of smoking" to accompany the textual warnings on cigarette packaging and advertising. Act § 201(a). Because Plaintiffs bring a facial challenge to the warning requirements, our concern is not the specific images the FDA chose—those are under review elsewhere—but rather whether Plaintiffs can show that " no set of circumstances exists under which [the statute] would be valid, or that the statute lacks any plainly legitimate sweep." *Stevens*, 130 S. Ct. at 1587 (internal citations and quotation marks omitted). To satisfy this burden, Plaintiffs would have to establish that a graphic warning cannot convey the negative health consequences of smoking accurately, a position tantamount to concluding that pictures can never be factually accurate, only written statements can be. Though that position stands at odds with reason, even it does not go far enough for Plaintiffs to prevail. There is nothing in the graphics-warning provision that forbids the graphics from merely being words. For example, a graphic could consist of one of the required textual warnings—"WARNING: Tobacco smoke can harm your children."—written in what appears to be a child's handwriting. Such a graphic would clearly be a factual and accurate disclosure that therefore would be scrutinized for a rational basis.

That is not to say that the graphic warnings would have to be of this form to fall within the ambit of *Zauderer*. We can envision many graphic warnings that would constitute factual disclosures under *Zauderer*. A nonexhaustive list of some that would include a picture or drawing of a nonsmoker's and smoker's lungs displayed side by

side; a picture of a doctor looking at an x-ray of either a smoker's cancerous lungs or some other part of the body presenting a smoking-related condition; a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition; a picture or drawing of a person suffering from a smoking-related medical condition; and any number of pictures consisting of text and simple graphic images.

Students in biology, human-anatomy, and medical-school courses look at pictures or drawings in textbooks of both healthy and damaged cells, tissues, organs, organ systems, and humans because those pictures convey factual information about medical conditions and biological systems. The argument that a picture of a specific person or part of a person is opinion because not every person or part of a person with that condition would appear the same way is unpersuasive. By virtue of our genes and environment, every person is different. And yet medical students learn valuable factual information in part by examining pictures and images of the human body and the various illnesses that may befall it. So arguing that a representation of a medical condition becomes an opinion when people could have that medical condition in ways that deviate from the representation would lead to the insupportable conclusion that textual or pictorial descriptions of standard medical conditions must be opinions as well. People with the same illness can and often will suffer a variety of differing symptoms. But one wouldn't say that a list of symptoms characterizing a particular medical condition is nonfactual and opinion-based as a result.[8] So too with graphic images.

Zauderer itself eviscerates the argument that a picture or drawing cannot be accurate and factual. Zauderer also challenged the professional-conduct rule forbidding

---

[8]Plaintiffs' argument that *Zauderer* applies to only "purely factual and noncontroversial" disclosures is unpersuasive. (First Br. at 20 (citing *Zauderer*, 471 U.S. at 651)) This language appears in *Zauderer* once and the context does not suggest that the Court is describing the characteristics that a disclosure must possess for a court to apply *Zauderer*'s rational-basis rule. That language instead merely describes the disclosure the Court faced in that specific instance. *See Zauderer*, 471 U.S. at 651. This reading is buttressed by the fact that elsewhere *Zauderer* refers to a commercial speaker disclosing "factual information" and "accurate information." *Id.* at 651, 651 n.14. In the 2010 *Milavetz* case, the Supreme Court clearly showed that a disclosure need not be *purely factual and noncontroversial* to apply the rational-basis rule because the phrase never appears in that case. The Court instead uses the language *required factual information* and *only an accurate statement* when describing the characteristics of a disclosure that is scrutinized for a rational basis. *Milavetz*, 130 S. Ct. at 1339-40.

the use of illustrations in attorney ads. *Zauderer*, 471 U.S. at 647. One of his ads featured a drawing of a intrauterine device (IUD), and the Ohio Supreme Court punished him for violating the rule prohibiting illustrations. *Id.* at 636. The state defended the rule on appeal by arguing that the "use of illustrations in advertising by attorneys . . . creates unacceptable risks that the public will be misled, manipulated, or confused." *Id.* at 648. These unacceptable risks stemmed from the alleged "subtle uses of illustrations to play on the emotions . . . and convey false impressions." *Id.* This is essentially the argument that the dissent adopts with respect to the graphic warnings.[9] But *Zauderer* foreclosed this argument—"the use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly. Accordingly, commercial illustrations are entitled to the First Amendment protections afforded verbal commercial speech." *Id.* at 647. Because the IUD drawing for which Zauderer was disciplined was an "accurate representation" of the IUD, the Court rejected the State's argument that it needed to be able to ban all illustrations in attorney ads. *Id.* at 647-49. Although this section of *Zauderer* dealt with whether the government could restrict commercial speech rather than whether it could require disclosures (the issue in the present case), the Court's reasoning demonstrates that a picture can be accurate and factual. If a picture can accurately represent an IUD, then there is no reason why a picture could not also accurately represent a negative health consequence of smoking, such as a cancerous lung.

---

[9]For example, the dissent writes that "the graphic warning labels *are intended to create* a visceral reaction in the consumer, in order to make a consumer less emotionally likely to use or purchase a tobacco product"; and that "colorful graphic images *can* evoke a visceral response that subsumes rationale decision-making." (Dissent at 19-20 (emphasis added)) The italicized phrases underscore a fundamental flaw in the dissent: it acts as if the specific graphic warnings are before us, when in fact they are not and could not be, as explained earlier.

Indeed, the word *can* highlights the fact that if the dissent were properly reviewing Plaintiffs' challenge to the warnings as a facial challenge, then it would uphold the warnings facially. Setting aside for the moment our disagreement with the premise that a disclosure that provokes a visceral response must fall outside *Zauderer*'s ambit, if a graphic warning *can* evoke a visceral response, then obviously some graphic warnings will not. And if there are some graphic warnings that the dissent would find acceptable, then it should affirm the facial validity of the graphic-warnings requirement.

Plaintiffs' arguments premised on *Blagojevich* fare no better. That disclosure requirement mandated that a four-square-inch sticker labeled "18" be placed on any video game meeting the statutory definition of "sexually explicit." *Blagojevich*, 469 F.3d at 643, 651-52. A game could be considered sexually explicit "solely on the basis of 'contemporary community standards' with regard to the lasciviousness of any depiction of 'post-pubescent female breasts.'" *See id.* at 650 (quoting 720 Ill. Comp. Stat. § 5/12B-10(e) (defining "sexually explicit")). In other words, a game could be deemed sexually explicit "solely on the basis of widely divergent local standards." *See id.* The court reasoned that the very definition was opinion based, even if the State's definition could be made precise. *Id.* at 652. The State could have one opinion of what sexually explicit was, the video-game manufacturer another. *Id*. There was no fact for parties to agree on, rendering the entire enterprise subjective. *Id.* Thus, the disclosure amounted to nonfactual information and was reviewed using strict scrutiny as provided for in the compelled-speech line of cases.[10] *Id.* at 651-52.

Blagojevich is distinguishable from this case. The textual warnings in this case provide undisputed factual information about the health risks of using tobacco products. Similarly, for the reasons outlined above, there are myriad graphic images that would also provide such factual information. The health risks of smoking tobacco have been uncovered through scientific study. They are facts. Warnings about these risks—whether textual or graphic—can communicate these facts. In contrast, what constitutes a sexually explicit video game is a matter of personal taste and sexual morals that is necessarily based on opinion, as enshrined in the very definition of "sexually explicit" that *Blagojevich* examined. A required disclosure announcing that the game

[10]The court's conclusion that the sticker failed to be narrowly tailored because of its size compared to the size of a video-game box followed the court's decision to employ strict scrutiny. *Id*. at 652. This is therefore irrelevant to the size of the warnings under *Zauderer*, which requires only a reasonable relationship between purpose and ends, rather than a narrow tailoring. *Int'l Dairy*, 622 F.3d at 643; *Sorrell*, 272 F.3d at 115-16.

is sexually explicit communicates the government's *opinion* that the game is sexually explicit. *Blagojevich* and the standards it articulates are inapplicable here.[11]

Under Supreme Court precedent and our application of it, *Zauderer* governs. The next step in the analysis is to determine whether the Act's required warnings survive *Zauderer*'s rational-basis rule.

C. Evaluating the disclosure requirement under *Zauderer*'s rational-basis rule

The Act's required textual and graphic warnings are constitutional if there is a rational connection between the warnings' purpose and the means used to achieve that purpose. *Sorrell*, 272 F.3d at 115. The warnings' purpose is to prevent consumers from being misled about the health risks of using tobacco. Accordingly, the warnings are designed to "promote greater public understanding of [those] risks." *See* Act § 202(b) (authorizing the FDA to adjust the warnings if the change would help consumers better understand the health risks).

Before undertaking the rational-basis analysis itself, a brief reminder. In Part B we concluded that graphic warnings *can* convey factual information, just as textual warnings can, and that because this case constitutes a facial challenge, it falls within *Zauderer*'s ambit rather than within the compelled-speech doctrine. The question we are thus faced with is whether graphic and textual warnings that convey factual information about the health risks of tobacco use are reasonably related to the purpose of preventing consumer deception. We find they are. To explain why, we begin with the Act's purpose and then turn to how the warnings provisions established by Congress are reasonably related to that purpose.

---

[11] Although *Blagojevich* is distinguishable from the present case, the dissent errs in arguing that *Blagojevich* is distinguishable because it involved restrictions on speech in addition to requiring disclosures. (Dissent at 16) The Act in the present case includes both restrictions and disclosures as well. *Compare* Act § 201(a) (requiring disclosures), *with* Act § 103(b)(13) (prohibiting the tobacco companies from making certain statements regarding their products). *Blagojevich* was careful to separate its analysis of the law restricting the sale of sexually explicit video games (the speech restriction) from its analysis of the law requiring the sticker labeled "18" (the speech disclosure). *See Blagojevich*, 469 F.3d at 643, 645-53 (analyzing the speech restriction in Section C and the required disclosure in Section D). The dissent fails to grapple with the *Blagojevich* analysis that is potentially relevant to our case, but ultimately distinguishable—the required disclosure analyzed in Section D.

The genesis of the stated purpose is self-evident. Tobacco manufacturers and tobacco-related trade organizations (collectively, "Tobacco Companies") knowingly and actively conspired to deceive the public about the health risks and addictiveness of smoking for decades. *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1105-08, 1119-20, 1122-24 (D.C. Cir. 2009) (*per curiam*) (affirming the district court's finding of deception for nine tobacco manufacturers—two of whom are plaintiffs in this case—and two tobacco-related trade organizations created by tobacco manufacturers). These Tobacco Companies knew from their own research and from outside research they funded that "cigarette smoking causes disease [like lung cancer], suffering, and death"; "that nicotine is an addictive drug"; that they "designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction"; that filtered and low-tar cigarettes do not reduce the risks of smoking; and "that secondhand smoke causes disease." *Id.* at 1124; *accord id.* at 1106-08, 1119-20, 1122-23. Even though—more accurately, because—Tobacco Companies knew these facts, they

> engaged in a scheme to defraud smokers and potential smokers by (1) falsely denying the adverse health effects of smoking; (2) falsely denying that nicotine and smoking are addictive; (3) falsely denying that they manipulated cigarette design and composition so as to assure nicotine delivery levels that create and sustain addiction; (4) falsely representing that light and low tar cigarettes deliver less nicotine and tar and therefore present fewer health risks than full flavor cigarettes; (5) falsely denying that they market to youth; (6) falsely denying that secondhand smoke causes disease; and (7) suppressing documents, information, and research to prevent the public from learning the truth about these subjects and to avoid or limit liability in litigation.

Id. at 1108 (citations omitted); *accord id.* at 1106-07, 1119-20, 1122-24. The Tobacco Companies disseminated these falsehoods through advertisements, publications, press releases, and public statements. *Id.* at 1106-08. They also paid for scientific research "to produce favorable research results and witnesses specifically for use in litigation and for support of industry public statements." *Id.* at 1107; *accord id.* at 1108.

In addition to this decades-long deception by Tobacco Companies, their advertising promoting smoking deceives consumers if it does not warn consumers about tobacco's serious health risks. The Supreme Court expressly recognized this fact when it approvingly cited the Federal Trade Commission's conclusion that "[t]o avoid giving a false impression that smoking [is] innocuous, the cigarette manufacturer who represents the alleged pleasures or satisfactions of cigarette smoking in his advertising must also disclose the serious risks to life that smoking involves." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992) (quoting 29 Fed. Reg. 8356 (1964)). These disclosures may "appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 n.24 (1976).

In the face of this deception stand the existing warnings required before the Act. They have not been revised since 1984[12] and do not effectively convey the risks of smoking, primarily because the warnings are easily overlooked. The current warnings take up less than 5% of cigarette packaging and advertising, and the warnings appear on only one side panel of the cigarette pack. (Krugman Aff., DE 70-2 at 28-29); 76 Fed. Reg. at 36,678; 75 Fed. Reg. at 69,531. In 1994, the Surgeon General reported that empirical studies consistently indicate that these "warnings are given little attention or consideration by viewers." Department of Health and Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* 168 (1994) (hereafter, 1994 Surgeon General's Report). One study of adolescents found that "more than 40 percent of subjects did not even view the warning. An additional 20 percent looked at the warning but failed to actually read it." *Id.* The Institute of Medicine concluded in 2007 that the warnings are "not prominent"; that "evidence regarding the ineffectiveness of the prescribed warnings has continued to accumulate"; and that "the basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way." Institute of Medicine, *Ending the*

[12] *See* Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984).

Tobacco Problem: A Blueprint for the Nation 290-91 (2007) (hereafter, 2007 IOM Report).

Another problem with the current warnings—and a strong reason for the new graphic warnings required by the Act—is that consumers must be able to read at a relatively high level to properly understand the warnings. The warnings "require a college reading level" and thus "may be inappropriate for youth and Americans with poor reading abilities" and low levels of education. *Id.* at C-3. "This is particularly important considering that, in most countries, smokers report lower levels of education than the general public." *Id*. These same concerns extend to consumers who may speak English as a second language, or suffer from reading disorders such as dyslexia. And these concerns are magnified in the context of preventing youth from using tobacco because the target audience, by definition, is expected to possess the reading comprehension level of only a schoolchild.

Given these ineffective warnings, the evidence unsurprisingly shows that most people do not understand the full dangers of tobacco use. After an extensive bench trial lasting nine months and including "live testimony from 84 witnesses, written testimony from 162 witnesses, and almost 14,000 exhibits in evidence," *Philip Morris*, 566 F.3d at 1106, a district court found that "[m]ost people do not have a complete understanding of the many serious diseases caused by smoking, the true nature of addiction, or what it would be like to experience either those diseases or addiction itself. Rather, most people have only a superficial awareness that smoking is dangerous." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 578 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009) (*per curiam*). "[S]mokers were more than twice as likely as nonsmokers to doubt that they would die from smoking, even if they were to smoke for 30 to 40 years." 2007 IOM Report at 90.

Youth—the specific target of tobacco companies' marketing campaigns[13]—especially fail to understand the danger of using tobacco. "[R]esearch suggests 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. . . . These distorted risk perceptions are associated with adolescents' decisions to initiate tobacco use . . . ." *Id.* at 93. Although youth do overestimate the risk of developing lung cancer from smoking, they "underestimate[] the degree to which smoking can shorten a smoker's life" and the chance that they personally would suffer a tobacco-related disease. *Id.* at 89-90. "In sum, 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." *Philip Morris*, 449 F. Supp. 2d at 579-80.

Faced with evidence that the current warnings ineffectively convey the risks of tobacco use and that most people do not understand the full risks, the Act's new warnings are reasonably related to promoting greater public understanding of the risks. A warning that is not noticed, read, or understood by consumers does not serve its function. The new warnings rationally address these problems by being larger and including graphics.

Sorrell establishes that the above reasoning alone is enough to satisfy the rational-basis rule. As noted, *Sorrell* held that the required mercury disclosures satisfied the rule because "*[i]t is probable* that *some* mercury lamp purchasers, newly informed by the Vermont label, will properly dispose of [the lamps] and thereby reduce mercury pollution. By encouraging such changes in consumer behavior, the labeling requirement is rationally related to the state's goal of reducing mercury contamination." *Sorrell*, 272

[13]Congress found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products" and have been successful—attracting the very group that once initiated into tobacco products is most likely to use them throughout their life. Act § 2(15); *accord id.* § 2(4), (5), (20), (23), (31).

F.3d at 115 (emphasis added). In concluding that *it was probable* that some consumers would change their behavior in response to the disclosures, *Sorrell* did not point to any evidence showing that some consumers would change; instead, it reasonably assumed they would based on common sense. *See id.* That sufficed. *Id.* We can similarly assume, based on common sense, that larger warnings incorporating graphics will better convey the risks of using tobacco to consumers. The reasonableness of this assumption is highlighted by the Plaintiffs' own argument that the Act's ban on using color or graphics in their tobacco advertising "eviscerates Plaintiffs' ability *to effectively communicate* with adult tobacco consumers *using advertising that captures their attention*." (First Br. at 4 n.2 (emphasis added)) If color and graphics are *necessary* for Plaintiffs to effectively communicate and capture the audience's attention, then warnings using color and graphics should more effectively convey risks than do purely textual warnings. Plaintiffs essentially admitted this point by stating at oral argument that "color and imagery are the *most effective way to* get your ad noticed and *communicate a message*." (Emphasis added.) *Zauderer* supports this assumption as well—"[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly." *Zauderer*, 471 U.S. at 647. The warnings are therefore reasonably related to promoting greater understanding of tobacco-related risks.

The Supreme Court's *Milavetz* decision buttresses this conclusion. *Milavetz* held that the required disclosures were constitutional because the facts that the debt-relief agencies had to disclose were pertinent to a consumer in deciding whether to use the agencies' services. *See Milavetz*, 130 S. Ct. at 1340-41. This made the disclosures reasonably related to preventing consumer deception. *Id.* at 1341. And the D.C. Circuit has concluded that industry "statements about the adverse health effects of smoking"—a category that would include facts disclosed in the Act's new warnings—"would be a matter of importance to a reasonable person deciding to purchase cigarettes." *Philip Morris*, 566 F.3d at 1122. Under *Milavetz*'s logic, the disclosures are reasonably related to preventing consumer deception.

In addition, abundant evidence establishes that larger warnings incorporating graphics promote a greater understanding of tobacco-related health risks and materially affect consumers' decisions regarding tobacco use.[14] Drawing on the available scientific evidence, the IOM concluded in its 2007 Report that "graphic warnings of the kind required in Canada, Brazil, and Thailand would promote greater public understanding of the risks of using tobacco and would help reduce consumption" in the United States. 2007 IOM Report at 295 (internal quotation marks omitted). "[S]mokers are more likely to recall larger warnings, as well as warnings that appear on the front of packages as opposed to on the sides." *Id.* at C-3. And because "there is evidence that smokers with less education are less likely to recall health information in text-based messages," warnings incorporating graphics "may be particularly important" in communicating with those who have less education. *Id.* at C-5.

In 2000, Canada implemented warnings essentially identical in form to the Act's warnings: the warnings occupied the top 50% of the front and back panels of cigarette packages and included a photograph or drawing, the word *Warning*, and a short textual warning. *Id.* at C-2 to C-3. Surveys in Canada following these new warnings show 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 C-5. And Canadian smokers were more likely to report cigarette packages as a source of information about health risks of smoking than smokers in the United States or other countries with only textual warnings. Hammond, D., et al., *Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey*, 15(III) Tobacco Control, iii19 (2006).

---

[14] *See, e.g.*, Borland, R., et al., *Impact of graphic and text warnings on cigarette packs: findings from four countries over five years*, 18 Tobacco Control 358 (2009); White, V., et al., *Do graphic health warning labels have an impact on adolescents' smoking-related beliefs and behaviors?* 103 Addiction 1652 (2008); Peters, E., et al., *The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers*, 9 Nicotine & Tobacco Research 4, 473-481 (2007).

Australia, which adopted graphic warnings in 2006, provides another good example of the benefits of larger warnings incorporating graphics. White, V., et mal., *Do graphic health warning labels have an impact on adolescents' smoking-related beliefs and behaviors?* 103 Addiction 1562 (2008). In the year that Australia adopted the new warnings, adolescents were more likely to cognitively process cigarette warnings, which means that they were more likely to read, think about, and discuss the warnings. *Id.* When that year in Australia is compared to the year following the UK's adoption of new warnings in early 2003, there was a larger increase in cognitive processing and foregoing cigarettes—the two strongest predictors of quitting smoking—in Australia, even after controlling for the different dates on which the warnings were introduced. Borland, R., et al., *Impact of graphic and text warnings on cigarette packs: findings from four countries over five years,* 18 Tobacco Control 358 (2009). This is especially significant because Australia's warnings incorporated graphics whereas the UK's did not. *Id.* In sum, there is more than substantial evidence to support the conclusion that larger warnings incorporating graphics would promote greater public understanding of the health risks of using tobacco.

This makes sense because psychology has established that "[g]enerally, pictures are easier to remember than words." S. David Leonard et al., *Comprehension and Memory,* in *Warnings and Risk Communication* 149, 158 (Michael S. Wogalter et al. eds. 1999). Studies of warnings generally have "found that pictorials in combination with conspicuous print facilitated recollection of warning contents," and that "the enhanced memory was directly related to the fact that the warning was noticed in the first place[]." Wendy A. Rogers et al., *Warning Research: An Integrative Perspective,* 42 Human Factors 102, 114 (Spring 2000). The same underlying truths about how humans process and remember information undergird Plaintiffs' argument that the Act's ban on using color or graphics in Plaintiffs' advertising "eviscerates Plaintiffs' ability *to effectively communicate* with adult tobacco consumers *using advertising that captures their attention*." (First Br. at 4 n.2 (emphasis added)) In crafting warnings that effectively convey the serious health risks of smoking, Congress was simply following the findings

of science, findings that Plaintiffs concede in their effort to protect their own advertising. The warnings are reasonably related to the purpose Congress sought to achieve—namely, preventing consumer deception—and are therefore constitutional.

Plaintiffs' arguments to the contrary are not persuasive. Their first argument is that the warnings cannot be justified on the basis of preventing consumer deception because consumers know—and in some cases overestimate—the health risks of using tobacco products. First, to the extent Plaintiffs argue that we must separately analyze whether the warnings are unjustified, they are mistaken. The test, as set forth in *Zauderer* and confirmed in *Milavetz* and *Sorrell*, is that the warnings (the means) be reasonably related to the purpose (here, preventing consumer deception). *Zauderer*, 471 U.S. at 651; *Milavetz*, 130 S. Ct. at 1328; *Sorrell*, 272 F.3d at 115. This is plain from how *Zauderer* articulated the test: "unjustified or unduly burdensome disclosure requirements *might* offend the First Amendment by chilling protected commercial speech. *But we hold* that *an advertiser's rights are* adequately *protected as long as disclosure requirements are reasonably related* to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 651 (emphasis added). Deciding whether a disclosure requirement is reasonably related to the purpose is all the law requires to assess constitutionality.

Second, the premise of Plaintiffs' argument—that consumers already know the health risks of using tobacco—is false. Plaintiffs rely on their expert Dr. Viscusi (an economist) to support this premise. But Viscusi admitted at trial in *Philip Morris* that his conclusions are largely based on research commissioned by tobacco-industry law firms specifically for use in litigation. (*See* Trial Tr. at 17930, *Philip Morris*, 449 F. Supp. 2d 1) And myriad independent studies contradict Viscusi's position. *See, e.g.*, 2007 IOM Report at 89-91, 93; The President's Cancer Panel, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk* 64 (2007) (hereafter, 2007 President's Cancer Panel Report). Most tellingly, in the nine-month long *Philip Morris* trial, the district court fully considered and rejected Viscusi's

opinion[15] that consumers already know the health risks and determined that "[m]ost people do not have a complete understanding of the many serious diseases caused by smoking, the true nature of addiction, or what it would be like to experience either those diseases or addiction itself. Rather, most people have only a superficial awareness that smoking is dangerous." 449 F. Supp. 2d at 578.

Plaintiffs next argue that the warnings will not reduce tobacco use, again relying on the opinions of Viscusi. But even if Plaintiffs were correct about this fact, it is irrelevant. The purpose of the warnings is to prevent consumers from being misled about the health risks of using tobacco. What matters in our review of the required warnings is not how many consumers ultimately choose to buy tobacco products, but that the warnings effectively communicate the associated health risks so that consumers possess accurate, factual information when deciding whether to buy tobacco products. As shown above, the warnings effectively convey this factual information, just as they were designed to do.

Plaintiffs' final argument that the warnings are unduly burdensome because their size drowns out their speech is unpersuasive. Again, to the extent that Plaintiffs argue that we must separately analyze whether the warnings are unduly burdensome, they are mistaken. The test is simply that the warnings be reasonably related to the government's interest in preventing consumer deception. *Zauderer*, 471 U.S. at 651; *Milavetz*, 130 S. Ct. at 1328; *Sorrell*, 272 F.3d at 115. Ample evidence supports the size requirement for the new warnings, *see, e.g.*, World Health Organization, *WHO Framework Convention on Tobacco Control* (2003), and Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to market their products. Moreover, this argument is undercut by Plaintiffs' claim that the warnings will not reduce the use of their tobacco products. If that is true, then the provision is certainly not unduly burdening Plaintiffs' speech.

---

[15]Viscusi's opinion and the data underlying it were presented in full to the district court through both oral and written testimony. (*See* Trial Tr. At 17854-18036, *Phillip Morris*, 449 F. Supp. 2d 1; Written Testimony of Viscusi, *id*.)

The dissent's arguments concerning graphic warnings are unpersuasive as well. The dissent argues that the Act's required warnings are unconstitutional because they are not a "reasonably tailored solution" that "materially advances the government's stated interest." (Dissent at 20-21) But the wisdom of requiring graphic images that depict the health risks of using tobacco products is amply supported by the evidence that the current textual warnings do not effectively convey these risks.[16] More to the point, the required warnings need not be a reasonably tailored solution that materially advances the stated interest; they need only be reasonably related to the government's interest in preventing consumer deception. *Zauderer*, 471 U.S. at 651. The dissent errs by using the wrong test: it evaluates the warnings under *Central Hudson*, relying on cases that analyze laws restricting commercial speech rather than laws requiring disclosures. (*See* Dissent at 20-21 (citing *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) (holding that a law prohibiting advertising and promoting particular compounded drugs was an unconstitutional *restriction* of commercial speech under the *Central Hudson* test); *Bell South Telecommunications, Inc. v. Farris*, 542 F.3d 499 (6th Cir. 2008) (applying the *Central Hudson* test and holding that a law preventing telecommunication providers from identifying a new tax on consumer's bills unconstitutionally *suppressed* speech)) Requiring disclosures and restricting speech are not only factually distinguishable activities, they are governed by different law.

---

[16]To prove that the graphic warnings do not materially advance the government's interest in effectively conveying health information, the dissent points out that "color graphics cannot accurately convey *all* of the health risks associated with tobacco use." (Dissent at 21 (emphasis added)) Possibly true, but so what? The list of health risks from using tobacco is so enormous that a disclosure could hardly be faulted if it could not convey all of them. Smoking causes the following cancers: oropharynx, larynx, esophagus, trachea, bronchus, lung, acute myeloid leukemia, stomach, pancreas, kidney, ureter, cervix, and bladder. World Health Organization, *Report on the Global Tobacco Epidemic* 44 (2011) (hereafter, 2011 WHO Report). It also causes the following chronic diseases: stroke, blindness, cataracts, periodontitis, aortic aneurysm, coronary heart disease, pneumonia, atherosclerotic peripheral vascular disease, hip fractures, adverse reproductive effects in women (including reduced fertility), chronic obstructive pulmonary disease, asthma, and other respiratory effects. *Id.* Moreover, tobacco use is at least a contributory agent to the following cancers: lip, nasopharynx, nasal cavity, and paranasal sinuses. 2007 President's Cancer Panel Report at vii. And this list doesn't even include the health risks of secondhand smoke. 2011 WHO Report at 44.

The dissent cites no authority supporting the proposition that a disclosure must be capable of addressing every conceivable problem to be constitutional, nor does it specify which health risks graphic warnings could not accurately convey. Moreover, the dissent's point is undercut by our unanimous determination that the textual warnings are constitutional even though they also address only a fraction of these health risks.

Moreover, the dissent's reliance on the recent D.C. district court opinion actually undercuts the dissent's conclusion that the Act's required warnings are facially unconstitutional. As the dissent acknowledges, the district court in the D.C. case examined the "government's proposed color graphic images"—namely, the final nine images the FDA settled on when it issued its Final Rule. (Dissent at 22 n.6); *see R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Admin.*, — F. Supp. 2d —, 2012 WL 653828, at *2, *4-6, *8 (D.D.C. February 29, 2012). The distinction drawn by the D.C. court between the graphic-warning requirements of the FDA's Rule and the graphic-warning requirements of the Act is a crucial one that the dissent's analysis glosses over. The flaw caused by ignoring this distinction is that the characteristic of the FDA-chosen images that the dissent finds objectionable—namely, that the images provoke a visceral response in the audience—is simply not in the statute. The dissent reads that characteristic as something required by the face of the statute when the statute on its face requires no such thing. The Act simply requires "color graphics depicting the negative health consequences of smoking."[17] Act § 201(a).

We cannot join that analysis. Moreover, we vigorously disagree with the underlying premise that a disclosure that provokes a visceral response must fall outside *Zauderer*'s ambit. Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions. As set forth above, whether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy. *See Zauderer*, 471 U.S. at 650-51; *Milavetz*, 130 S. Ct. at 1340-41; *Sorrell*, 272 F.3d at 114 n.5. Because graphics can present factual information regarding the health risks of using tobacco, and

[17]The D.C. court opinion addresses issues that are not before us—namely, the FDA Final Rule and the nine images it proposes. Although we address the statute only facially with respect to the warnings, we articulate the applicable First Amendment test and, as discussed more fully below, we disagree with the dissent and the D.C. court's underlying premises that a disclosure that provokes a visceral response or controversy cannot pass muster under *Zauderer* (the dissent's view) or is not even analyzed under *Zauderer* (the D.C. court's view).

because this information alleviates the possibility of consumer confusion, the Act's graphic-warning requirement is constitutional under *Zauderer*.

D. Conclusion

We return to where we began—the lack of consumer awareness of tobacco's serious health risks resulting from the decades-long deception by Tobacco Companies. Ample evidence establishes that current warnings do not effectively inform consumers of the health risks of tobacco use and that consumers do not understand these risks. It is beyond cavil that adolescents are a target of the marketing expertise of Tobacco Companies, a targeting that exists precisely because of intertwined advantages—or for the young, disadvantages—the coupling of immaturity of risk perception with the evidence that the vast majority of regular smokers made the decision to begin smoking as an adolescent. It bears emphasizing that the risks here include the undisputed fact that Plaintiffs' products literally kill users and, often, members of the families of users: Tobacco products kill up to one-half of the people who use them as they are intended to be used. World Health Organization, *Report on the Global Tobacco Epidemic* V, 7 (2011); 2007 President's Cancer Panel Report at 61. Against this backdrop, the Act requires graphic and textual warnings that convey the factual health risks of smoking to provide consumers with truthful information as they make decisions about purchasing and using tobacco products.

For the reasons set forth above, we hold that the Act's warnings are reasonably related to the government's interest in preventing consumer deception and are therefore constitutional.