No. 12-521

In the Supreme Court of the United States

AMERICAN SNUFF COMPANY, LLC, ET AL.,
PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the court of appeals correctly upheld against a facial First Amendment challenge warning-label requirements in the Family Smoking Prevention and Tobacco Control Act (Act) for the packaging of and advertisements for cigarettes, 15 U.S.C. 1333 note (Supp. V 2011), and smokeless tobacco, 15 U.S.C. 4402 (Supp. V 2011).

2. Whether the court of appeals correctly upheld against a facial First Amendment challenge the Act's requirement that a manufacturer establish the health benefits of a tobacco product before marketing it as a modified-risk tobacco product, 21 U.S.C. 387k (Supp. V 2011).

3. Whether the court of appeals correctly upheld against a facial First Amendment challenge regulations that—

a. prohibit using the brand name of a cigarette or smokeless-tobacco brand on merchandise or to sponsor certain public events, 21 C.F.R. 1140.34(a) and (c), and

b. generally prohibit the distribution of free samples of tobacco products, 21 C.F.R. 1140.16(d); see 21 U.S.C. 387a-1(a)(2)(G) (Supp. V 2011).

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-116a) is reported at 674 F.3d 509. The district court's opinions (Pet. App. 117a-165a,[1] 166a-195a) are, respectively, reported at 678 F. Supp. 2d 512 and not published in the *Federal Supplement* but available at 2009 WL 3754273.

JURISDICTION

The judgment of the court of appeals was entered on March 19, 2012. A petition for rehearing was denied on May 31, 2012. On July 26, 2012, Justice Kagan extended the time within which to file a petition for a writ of certiorari to and including September 28, 2012. On August

[1] The petition appendix (at 165a) does not reflect the district court's amendments (Doc. 103) to its January 2010 opinion.

31, 2012, Justice Kagan further extended the time to October 26, 2012, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. Congress's statutory findings, *id.* § 2, 123 Stat. 1776-1781 (21 U.S.C. 387 note (Supp. V 2011)) (*Legislative Findings*), build upon substantial evidence gathered over decades by each Branch of the Government about the serious health risks posed by, and the tobacco industry's marketing of, tobacco products. Four aspects of that evidence are especially relevant here.

First, tobacco products are deadly and cause significant human suffering. "Each year, 440,000 people die of diseases caused by smoking or other form[s] of tobacco use—that is about 20 percent of all deaths in our nation." 155 Cong. Rec. 13,655 (2009) (statement of Surgeon General Richard H. Carmona). The Food and Drug Administration (FDA) has "quite exhaustively documented" tobacco products' "extraordinary health risks": Tobacco use is the "single leading cause of preventable death in the United States," causing more deaths than "[AIDS], car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134-135 (2000) (citation omitted). Individuals with tobacco-related illnesses "often suffer[] long and painful deaths." *Ibid.* Congress accordingly determined that the scientific "consensus" shows that "tobacco products are inherently dangerous" and "cause cancer, heart disease,

and other serious adverse health effects." *Legislative Finding* 2.

Second, tobacco products are "highly addictive because they contain nicotine, one of the most addictive substances used by humans." Institute of Medicine (IOM), *Ending the Tobacco Problem: A Blueprint for the Nation* 5 (2007) (*2007 IOM Report*). The IOM—in one of the "[m]ajor scientific reports" on which Congress based its *Legislative Findings*, see H.R. Rep. No. 58, 111th Cong., 1st Sess., Pt. 1, at 33 (2009) (*House Report*)—illustrated that fact: Although 40% of smokers attempted to quit in 2004, only 3-5% were successful. *2007 IOM Report* 82. That failure rate is not by chance. Tobacco companies, Congress determined, have specifically "designed" their products to "precisely control nicotine delivery levels" to "create and sustain addiction." *Legislative Findings* 3 and 49. The combination of that addiction and tobacco products' serious adverse health effects presents a unique health crisis for the Nation.

Third, children are at the center of that crisis. Congress found that tobacco use "by the Nation's children is a pediatric disease of considerable proportions" that "results in new generations of tobacco-dependent children and adults." *Legislative Finding* 1. Notwithstanding laws prohibiting minors from purchasing tobacco products, the "overwhelming majority of Americans who use tobacco products" begin as "minors and become addicted to the nicotine in those products before reaching the age of 18." *Legislative Finding* 31; see, *e.g.*, President's Cancer Panel, *Promoting Healthy Lifestyles* 64 (2007) (*2007 President's Cancer Panel Report*) ("Over 80 percent" become addicted by age 18). The scale of the problem is immense. "Every day, approximately

4,000 children under age 18 experiment with cigarettes for the first time." *Ibid.* "[A]nother 1,500 [children] become regular smokers" daily, "about half [of whom] eventually will die from a disease caused by tobacco use." *Ibid.*

Minors are particularly vulnerable. Adolescents systematically "underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose." *2007 President's Cancer Panel Report* 64. One survey revealed that "nearly 60 percent of adolescents believed that they could smoke for a few years and then quit." *2007 IOM Report* 91. Another showed that, although only 3% of twelfth-grade smokers estimated that they would still be smoking in five years, 63% were still smoking seven to nine years later. *Ibid.*

Fourth, the tobacco industry's products and marketing have been tailored to each of the foregoing realities as the industry aggressively pursued profits.

Internal documents show that the industry has long understood that "tobacco company profits" ultimately "depend on creating and sustaining [nicotine] addiction." *United States* v. *Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 308 (D.D.C. 2006), aff'd in part and vacated in part on other grounds, 566 F.3d 1095 (D.C. Cir. 2009), cert. denied, 130 S. Ct. 3501 (2010); *id.* at 28, 910; see, *e.g.*, 146 Cong. Rec. 4571 (2000) (discussing petitioner Reynolds' 1972 internal memorandum's statement that "the tobacco industry" is a variant of the "pharmaceutical industry" that markets "attractive forms" of "a potent drug"—nicotine). The industry has conducted sophisticated nicotine research "decades" ahead of that in the scientific community and used its "intimate[] understanding" to tailor "nicotine delivery levels" to "create and sustain addiction," while "conceal[ing] much of their

nicotine-related research" and "publicly den[ying] and distort[ing] the truth as to the addictive nature of their products for several decades." 566 F.3d at 1107, 1124; see *Legislative Finding* 49. "Every aspect of a cigarette," for example, "is precisely tailored" to deliver the "optimum amount of nicotine" to "create and sustain addiction." *Philip Morris*, 449 F. Supp. 2d at 309, 383-384.[2]

Despite knowing the grave health effects of tobacco use, the industry countered growing scientific evidence thereof with a multi-pronged campaign over many decades that "repeatedly, consistently, vigorously—and falsely—denied the existence of any adverse health effects," to create the impression of scientific uncertainty, thereby "'giv[ing] smokers a psychological crutch and a self-rationale to continue smoking.'" *Philip Morris*, 449 F. Supp. 2d at 174, 208, 855 (quoting internal memorandum).

Tobacco companies simultaneously "conducted extensive research" to "help them identify and understand potential quitters" in order to "design marketing that would dissuade them from quitting." *Philip Morris*, 449 F. Supp. 2d at 475. Manufacturers thus developed "health reassurance" products (*e.g.*, light, mild, or low-tar cigarettes) that consumers would believe pose lower health risks, provide an alternative to quitting, or repre-

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[2] *Philip Morris*'s unchallenged factual findings about the industry's practices, based on an immense evidentiary record and volumes of internal tobacco-industry documents, have been previously summarized. See, *e.g.*, Br. in Opp. at 3-11, 50-51, *Philip Morris, supra* (No. 09-976), http://www.justice.gov/osg/briefs/2009/0responses/2009-0976.resp.pdf; *id.* at 10-11 (no factual findings were challenged on appeal); Pet. at 2-6, *Philip Morris*, *supra* (No. 09-978), http://www.justice.gov/osg/briefs/2009/2pet/7pet/2009-0978.pet.aa.pdf.

sent a step in decreasing the smoker's level of dependence. 566 F.3d at 1107. The manufacturers determined, however, that those purportedly reduced-risk products "d[id] not actually deliver the low levels of tar and nicotine advertised" and provided no health benefit. *Ibid.* The manufacturers nevertheless "marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful," "either lacking evidence to substantiate their claims or knowing them to be false." *Ibid.*; *id.* at 1124; see 449 F. Supp. 2d at 430-431, 507-508, 560-561, 860. That misleading marketing "sustained corporate revenues in the face of mounting evidence about the health dangers of smoking," "assuaged the fears of smokers," and "dramatically increased" sales of low tar/light products from 2% of cigarette sales in 1967 to 92.7% in 2006. *Id.* at 508, 561; see Federal Trade Commission (FTC), *Cigarette Report for 2006*, at 7 (2009). Those products did not decrease disease risk and may have "contributed to an actual increase in death and disease among smokers." 155 Cong. Rec. 13,655 (2009) (Surgeon General Carmona); see 150 Cong. Rec. 10,527 (2004) (quoting 2001 National Cancer Institute report).

Finally, tobacco companies have a powerful incentive to capture underage customers. The industry has long recognized that "smokers are remarkably brand-loyal," that "brand switching rates are low and falling," and that the "only way [they] can sustain themselves is by bringing in large numbers of replacement smokers each year." *Philip Morris*, 449 F. Supp. 2d at 561-562. Because "[t]he majority of people who become addicted smokers start smoking before the age of eighteen," tobacco manufacturers "realize that they need to get

people smoking their brands as young as possible in order to secure them as lifelong loyal smokers." *Id.* at 562.

The industry has "intensively researched and tracked young people's attitudes, preferences, and habits" and used that research "to create highly sophisticated and appealing marketing campaigns targeted to lure [young people] into starting smoking and later becoming nicotine addicts." *Philip Morris*, 449 F. Supp. 2d at 691. That marketing has targeted "young people, including those under twenty-one, as well as those under eighteen." *Ibid.* Respondents have "spent billions of dollars" annually on such marketing, which is a "substantial contributing factor to youth smoking initiation and continuation," while "consistently, publicly, and falsely, denying they do so." *Id.* at 691-692.

Congress accordingly found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products"; that the industry "continue[s] to target and market to youth" and "dramatically increased" those efforts after its Master Settlement Agreement with the States; and that those "efforts have resulted in increased use of such products by youth" notwithstanding the government's "[p]ast efforts to oversee these activities." *Legislative Findings* 15, 47-49. Judicial findings in 2006 similarly show that the evidence "clearly establishe[d]" that the practices above were continuing and that tobacco manufacturers were "reasonably likely" to continue them. 449 F. Supp. 2d at 910-913. In 2012, such conduct remained reasonably likely. *United States* v. *Philip Morris USA Inc.*, 686 F.3d 832, 836-837 (D.C. Cir. 2012).

2. In light of such evidence, Congress enacted the Tobacco Control Act, with three provisions relevant here.

a. First, the Act establishes warning requirements for packaging and advertising of cigarettes, 15 U.S.C. 1333 note (Supp. V 2011), and smokeless tobacco, 15 U.S.C. 4402 (Supp. V 2011).[3] Each package or advertisement must include one of several statutory textual warnings, disclosing tobacco products' health risks. 15 U.S.C. 1333(a)(1) and (b)(1) note, 4402(a)(1) and (b)(1). Petitioners have not challenged the factual content of those warnings. Pet. App. 92a. The Act further specifies that the warning area must comprise 50% of cigarette packaging's front and rear panels and at least 30% of smokeless-tobacco packaging's two principal panels. 15 U.S.C. 1333(a)(2) note, 4402(a)(2). Warnings for "press and poster advertisements" must comprise at least 20% of each advertisement. 15 U.S.C. 1333(b)(2) note, 4402(b)(2). Congress authorized FDA to modify through rulemaking, *inter alia*, the "format, type size, * * * and text" of those requirements. 15 U.S.C. 1333(d) note, 4402(d).

Although the Act does not directly impose graphic warnings, it requires FDA to issue "regulations that [would] require color graphics depicting the negative health consequences of smoking" to accompany the textual warnings for cigarettes in the warning area described above. 15 U.S.C. 1333(d) note; cf. 15 U.S.C. 4402(d) (authorizing regulation requiring smokeless-tobacco graphic warnings). FDA issued such regulations after the district court entered final judgment in this case, 76 Fed. Reg. 36,628 (2011), but the graphic-

[3] All citations to the United States Code in this brief are to the 2006 edition as supplemented by its 2011 Supplement.

warning requirements in that rulemaking—which is not at issue here—have since been vacated by the D.C. Circuit. *R.J. Reynolds Tobacco Co.* v. *FDA*, 696 F.3d 1205, 1222 (2012) (*Reynolds*).

b. The Act separately requires a manufacturer to demonstrate the health benefits of a "modified risk tobacco product" to FDA before marketing that product. 21 U.S.C. 387k(a), (d) and (g). A modified-risk tobacco product is one "sold or distributed for use to reduce harm or the risk of tobacco-related disease." 15 U.S.C. 387k(b)(1). A product is so sold or distributed if (1) its labeling or advertising uses "light," "mild," "low," or "similar descriptors," or (2) its labeling or advertising explicitly or implicitly represents—or its manufacturer takes "action directed to consumers * * * respecting the product" that "would be reasonably expected to result in consumers believing"—that the product or its smoke (a) presents a lower risk of disease or is less harmful than other commercially marketed tobacco products, or (b) contains a reduced level of, presents reduced exposure to, does not contain, or is free of a substance. 15 U.S.C. 387k(b)(2)(A).

c. Finally, the Act builds upon FDA's past regulatory efforts. In 1996, FDA issued regulations to regulate tobacco and significantly reduce adolescent tobacco use. 61 Fed. Reg. 44,396, 44,615-44,618 (1996) (21 C.F.R. Pt. 897 (1997)). This Court, in reviewing those regulations, concluded that FDA had "exhaustively documented" the underlying problem and shown that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 134, 161. The Court, however, concluded that FDA lacked

statutory authority to regulate tobacco products. *Id.* at 135-139, 156, 161.

The Act granted FDA the authority to regulate tobacco products, 21 U.S.C. 387a, and directed FDA to repromulgate its 1996 regulations under that authority, 21 U.S.C. 387a-1(a). See 75 Fed. Reg. 13,225 (2010) (21 C.F.R. Pt. 1140). Two regulations targeting promotional practices particularly attractive to children and adolescents are relevant here.

Section 1140.34 prohibits a manufacturer from using the "brand name" or logo of a cigarette or smokeless-tobacco brand (*e.g.*, "Camel") on merchandise or to sponsor certain public events. 21 C.F.R. 1140.34(a) and (c). The manufacturer may sponsor events in "the name of the corporation which manufactures the tobacco product" (*e.g.*, "Reynolds"). 21 C.F.R. 1140.34(c).

Section 1140.16(d) generally prohibits the distribution of "free samples" of tobacco products. 21 C.F.R. 1140.16(d)(1); see 21 U.S.C. 387a-1(a)(2)(G). Free samples of smokeless tobacco generally are permitted, however, in certain adult-only facilities. 21 C.F.R. 1140.16(d)(2).

3. Petitioners brought this action alleging, *inter alia*, that the provisions described above violate the First Amendment. At summary judgment, the government filed an immense volume of evidentiary material, including 30 binders (and an associated DVD) of reports and scientific studies, as well as a DVD containing the opinion in *Philip Morris*, 449 F. Supp. 2d 1, and all the evidentiary material cited therein. Doc. 73; see Gov't C.A. Br. App. i-x (listing materials).[4] As relevant here, the

[4] The *Philip Morris* decision, which occupies most of one volume of the *Federal Supplement*, reflects an immense record accumulated during a nine-month bench trial involving almost 14,000 admitted

district court upheld each of the provisions now at issue. Pet. App. 117a-165a.

4. The court of appeals affirmed in relevant part. Pet. App. 1a-116a. The court upheld each of the provisions still at issue, *id.* at 32a-46a, 46a-61a, 77a-116a, and explained that its decision was supported by thousands of pages of scientific and governmental reports and extensive documentation of tobacco-industry marketing practices, *id.* at 6a-7a.

a. The court of appeals rejected petitioners' claim that the Act's health-warning requirements for tobacco packaging and advertising (15 U.S.C. 1333 note, 4402) are facially invalid under the First Amendment. Pet. App. 79a-116a. The court repeatedly emphasized that, because petitioners presented only a facial challenge to the Act itself, it would not consider any particular images at issue in or other aspects of FDA's graphic-warning rulemaking. *Id.* at 79a-83a, 93a, 95a n.9, 114a-115a.

The court also determined that *Zauderer* v. *Office of Disciplinary Counsel*, 471 U. S. 626 (1985), should govern its analysis of petitioners' facial challenge. Pet. App. 84a-99a. The court explained that *Zauderer* governs challenges to "factual, commercial-speech disclosure requirements" not involving "compelled speech on matters of opinion"; that the "factual content of the [Act's] textual warnings is undisputed"; and that the Act's direction to adopt graphic-warning regulations "depicting the negative health consequences of smoking," 15 U.S.C. 1333(d) note, could be implemented with

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exhibits and testimony from nearly 250 witnesses. 566 F.3d at 1106. A DVD filed in this case (Doc. 73) includes an embedded hyperlink at each record citation in the decision, enabling the reader to display immediately the relevant page of the record associated with the court's more than 4000 factual findings.

warnings "fall[ing] within *Zauderer*'s ambit" because at least some "graphic warnings *can* convey factual information." Pet. App. 86a, 92a, 99a; see *id.* at 84a-99a. The court ultimately held that, under *Zauderer*, the Act's provisions for warnings are on their face reasonably related to the government's interest in preventing consumer deception. *Id.* at 99a-115a. Judge Clay dissented on the ground that graphic warnings did not pass the *Zauderer* test (*id.* at 23a-30a), explaining that, in his view, the district court addressed that issue "both facially and as-applied," *id.* at 23a-24a, 30a n.6.

b. The court of appeals unanimously upheld Section 387k's requirement that a manufacturer establish the health benefits of a modified-risk tobacco product to FDA before marketing that product. Pet. App. 32a-46a, 78a. The court explained that the provision does not "infringe significantly on noncommercial speech" and leaves "untouched" petitioners' "ability to make 'direct comments on public issues'" because it restricts only (1) labeling or advertising that makes certain unproven health claims about (or uses certain descriptors for) a tobacco product, and (2) certain unproven consumer-directed claims by tobacco manufacturers about such a product. *Id.* at 35a-37a (citation omitted). That restriction on commercial speech, the court concluded (*id.* at 37a-46a), is constitutional under *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980): It advances a "substantial" government interest in preventing inaccurate and harmful health claims about tobacco products of the sort that the industry has made for many decades, and it is sufficiently tailored because it concerns only consumer-targeted speech about tobacco products' heath effects or contents

and is no more extensive than warranted. Pet. App. 39a-45a.

c. Finally, the court of appeals unanimously upheld the regulatory bans on using the "brand name" of a cigarette or smokeless-tobacco brand on merchandise or to sponsor certain public events (21 C.F.R. 1140.34(a) and (c)), and distributing free samples of tobacco products (21 C.F.R. 1140.16(d)). Pet. App. 46a-59a, 78a. Those provisions, the court concluded, are sufficiently justified in light of the tobacco industry's youth-targeting marketing efforts and the deleterious impact of the banned activities on children. *Id.* at 50a-59a.

ARGUMENT

The court of appeals correctly rejected petitioners' pre-enforcement facial challenge to two provisions of the Tobacco Control Act and two regulations promulgated thereunder. The court's decision does not reflect a division of authority warranting further review. The petition should be denied.

A. Warning Labels

Petitioners contend (Pet. 22-23, 25-31) that the court of appeals' rejection of their facial challenge to the Act's health-warning provisions (15 U.S.C. 1333 note, 4402) conflicts with decisions of other courts of appeals and that their certiorari petition should be held pending rehearing in *R.J. Reynolds Tobacco Co.* v. *FDA*, 696 F.3d 1205 (D.C. Cir. 2012). The court of appeals' decision is correct and does not conflict with that of any other court of appeals. This case, moreover, would be a poor vehicle for review. Further review would not alter any existing graphic-warning requirements because *Reynolds* vacated the only legal source imposing such requirements (FDA's regulations), the D.C. Circuit has

denied rehearing in *Reynolds*, and the government has decided not to petition for certiorari in *Reynolds*.

1. This Court in *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 650-653 (1985), upheld a state requirement that a lawyer's advertisement disclose certain "purely factual and uncontroversial information" about costs a client might incur in litigation. *Id.* at 651. The Court explained that commercial speech enjoys First Amendment protection principally because of its "information[al]" "value to consumers" and that a person engaging in such speech will possess only a "minimal" protected interest "in *not* providing any particular information in his advertising." *Ibid.* Informational "disclosure requirements," the Court reasoned, are thus analytically distinct from "suppression of [commercial] speech." *Id.* at 650-652 & n.14. *Zauderer* observed that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech," but "h[e]ld that [commercial-speech] rights are adequately protected as long as the [challenged] disclosure requirements are reasonably related to the [government's] interest in preventing deception of consumers." *Id.* at 651. Such requirements can satisfy *Zauderer*'s "reasonabl[e] relat[ionship]" test even though they are not the "least restrictive means" available and "other means" could achieve the government's interests. *Id.* at 651 n.14.

The court of appeals correctly concluded that petitioners' facial challenge to the Act's warning provisions is properly analyzed under and satisfies *Zauderer*'s standard for mandatory commercial-speech disclosures. Pet. App. 79a-116a; pp. 11-12, *supra*. The certiorari petition does not develop a contrary argument on the merits. See Pet. 25-31. Petitioners instead argue (*ibid.*)

that review is warranted because the court of appeals' decision conflicts with decisions of other courts of appeals. That is incorrect.

2. First, petitioners assert (Pet. 25-26) that the court of appeals' decision conflicts with *Reynolds*. But the "only question" in *Reynolds* was whether the particular graphic-warning images required by FDA's 2011 regulations violated the First Amendment. 696 F.3d at 1211. *Reynolds* determined that the warnings FDA adopted should be subject to intermediate-scrutiny under *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980), rather than *Zauderer*'s reasonable-relationship test, because, *inter alia*, the court understood those particular images in FDA's rulemaking to be "primarily intended to evoke an emotional response" rather than convey the type of factual information permitted under *Zauderer*. 696 F.3d at 1216-1217. The D.C. Circuit observed that the *Reynolds* plaintiffs (many of whom are petitioners or corporate affiliates of petitioners here) "concede[d]" that "new disclosure requirements" with "less shocking graphics" would be acceptable. *Id.* at 1215. Cf. *id.* at 1215-1216 (rulemaking in *Reynolds* did not justify the graphic warnings with the rationale—made here—that warnings address the industry's "years of deception"); *id.* at 1218. The Sixth Circuit declined to consider the particular graphic warnings adopted by FDA and applied *Zauderer*'s test because the Act could be implemented with at least some graphic warnings that appropriately convey factual health-risk information. See pp. 11-12, *supra*. *Reynolds* is thus compatible with the Sixth Cir-

cuit's rejection of petitioners' facial challenge to the Act itself.[5]

Petitioners contend (Pet. 26) that a "disparate geographic result" in the Sixth and D.C. Circuits "alone warrants" review. But the Act does not directly impose any graphic-warning requirement; such warnings would be required for cigarettes only if FDA's regulations require them. See 15 U.S.C. 1333(d) note. *Reynolds* vacated FDA's graphic-warning requirements before they became effective and remanded the matter to FDA, 696 F.3d at 1211, 1222; the D.C. Circuit has now denied rehearing, and the government has decided not to seek further review. Instead, FDA has advised this Office that it will undertake research necessary to support a new rulemaking consistent with the Act and the First Amendment. Review of the court of appeals' rejection of petitioners' facial challenge to the Act's graphic-warning provision in the abstract would not address any warning-label obligations that exist now or that might exist in the future, and any future regulatory obligations that might be imposed would themselves be subject to judicial review, based on a new rulemaking record.

Furthermore, as this Court has observed, facial challenges "often rest on speculation" and risk "premature interpretation of statutes." *Washington State Grange* v.

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[5] Although the Sixth Circuit here and the D.C. Circuit in *Reynolds* applied different analytical approaches, that difference does not reflect a conflict of authority warranting this Court's review because the two cases involve different operative provisions and records under review. Cf. Pet. 26 n.6; Pls. Opp. to Reh'g Pet. at 9 n.1, *Reynolds*, *supra* (No. 11-5332) (argument by several petitioners here that rehearing was unwarranted because the *Reynolds* "record was not before the Sixth Circuit, which considered only a facial challenge to the general requirements of the [Act]").

Washington State Republican Party, 552 U.S. 442, 450 (2008) (citation omitted). A plaintiff asserting a facial challenge therefore must establish that the "law is unconstitutional in all of its applications," lacks any "legitimate sweep," or is "impermissibly overbroad because a 'substantial number' of its applications are unconstitutional." *Id.* at 449 & n.6 (citations omitted). Such a showing cannot be based on "speculat[ion] about 'hypothetical' or 'imaginary' cases." *Id.* at 450 (citation omitted). Yet until FDA completes a new graphic-warning rulemaking, the First Amendment implications of such warnings will necessarily be speculative. Any review by this Court should thus wait until any new FDA warning regulations have been adopted.

3. Petitioners suggest (Pet. 27-28) that the Sixth Circuit, unlike other courts, has refused to consider whether the Act's warning requirements are "unjustified" or "unduly burdensome." That contention is misplaced. The court appears to have recognized that *Zauderer*'s "reasonable relationship" standard may take such matters into account: It quoted *Zauderer*'s observation that "unjustified or unduly burdensome disclosure requirements *might* offend the First Amendment by chilling protected commercial speech," Pet. App. 110a, thereby indicating that an impermissible chilling effect could show that a particular disclosure requirement was not "reasonably related" to advancing the government's legitimate interests. Judge Clay similarly explained, in "reasoning" with which the majority agreed (*id.* at 77a-78a), that *Zauderer* permits disclosure requirements when they are "not 'unjustified or unduly burdensome,'" *id.* at 16a-17a (citation omitted). That agreement reflects the Sixth Circuit's conclusion in a prior decision—which was binding on and cited by the panel here (*e.g.*,

id. at 91a, 97a n.10)—that under the "reasonable relationship" inquiry, disclosure requirements "cannot be 'unjustified or unduly burdensome.'" *International Dairy Foods Ass'n* v. *Boggs*, 622 F.3d 628, 640-643 (2010) (quoting *Zauderer*, 471 U.S. at 651).

Petitioners' criticism focuses at best on a semantic distinction that has not produced different results. All members of the panel below agreed that the Act's non-graphic-warning requirements were constitutional, Pet. App. 30a-31a, 112a (size and location of warning area), after rejecting petitioners' contention that the Act's warnings were "unjustified" and "unduly burdensome." Congress required larger, updated warnings in the wake of, *inter alia*, the Surgeon General's conclusion that existing warnings were "given little attention or consideration by viewers" and IOM's analysis showing that those warnings "'fail[ed] to convey relevant information in an effective way.'" *Id.* at 102a (citations omitted). Petitioners urged the court of appeals to rely on the opinion of their expert (W. Kip Viscusi) that "consumers already know the health risks of using tobacco." *Id.* at 110a. But the court explained, *inter alia*, that "myriad independent studies contradict Viscusi's position" and that even Viscusi admitted that "his conclusions"—which were rejected in *Philip Morris*—"are largely based on research commissioned by tobacco industry law firms specifically for use in litigation." *Id.* at 110a-111a (citing illustrative studies); see *id.* at 21a n.4 (Clay, J.).

The court of appeals likewise rejected petitioners' argument that the size of the warnings was unduly burdensome. The court found "[a]mple evidence support[ing] the size requirement for the new warnings" and explained that petitioners failed to show that "the

remaining portions of their packaging are insufficient for them to market their products." Pet. App. 112a; *id.* at 31a (Clay, J.). The Act leaves "half of cigarette packs, 70% of smokeless tobacco packages, and 80% of advertisements" for manufacturers' commercial speech. *Id.* at 20a (Clay, J.) (citations omitted). And despite a decade of experience in Canada with warnings covering 50% of cigarette packaging (*id.* at 107a), petitioners failed to produce evidence that that requirement would unduly limit their commercial speech. Moreover, the new warning-label requirements for smokeless tobacco (which do not involve graphic warnings) have been implemented for almost three years. See 15 U.S.C. 4402 note. The industry's continuing advertising reflects no impermissible chill. See, *e.g.*, Duff Wilson, *New Bold Warnings on Tobacco Ads* (May 3, 2010), http://well.blogs.nytimes.com/2010/05/03/new-bold-warnings-on-tobacco-ads (pictorial comparison of old and new 20% warnings for advertisements).

4. Petitioners contend (Pet. 29-30) that other courts have indicated that *Zauderer* applies only to "purely factual and uncontroversial" disclosures. In a footnote, the court of appeals here noted that this Court in *Zauderer* described the mandated litigation-cost disclosure before it as "purely factual and uncontroversial" and that *Zauderer*'s analysis ultimately turned on whether the disclosure conveyed "accurate" and "factual information." Pet. App. 94a n.8 (citations omitted). But that observation does not appear to reflect any meaningful analytical difference from the decisions petitioners cite, and petitioners identify none.

The outcome of this case does not turn on the linguistic description of the "accurate" and "factual" disclosures properly analyzed under *Zauderer*. Petitioners'

facial challenge necessarily concerns only the Act's unelaborated instruction that FDA promulgate regulations requiring "color graphics depicting the negative health consequences of smoking." 15 U.S.C. 1333(d) note. The court of appeals correctly concluded that no "specific graphic warnings" are at issue and that at least *some* graphic warnings could accurately convey factual information. Pet. App. 96a & n.9. Because even petitioners fail to argue that *no* graphic warning could *ever* be "purely factual and uncontroversial," applying petitioners' formulation would not alter the judgment below. And as explained above, review would in any event be unwarranted here, because no graphic warnings for tobacco products can be required unless and until specific graphics are adopted in a new FDA rulemaking that itself would be subject to judicial review.

B. Modified-Risk Tobacco Products

Petitioners seek (Pet. 31-38) review of the court of appeals' rejection of their facial challenge to 21 U.S.C. 387k's requirement that a manufacturer demonstrate the health benefits of a "modified risk tobacco product" to FDA before marketing the product. But they no longer contend that pre-market review restricts "intertwined political and commercial speech" or dispute that the government has a substantial (indeed, compelling) interest in ensuring that such products will actually reduce risks. See Pet. App. 34a, 41a-42a. Petitioners instead argue that the court of appeals' application of *Central Hudson*'s "narrow-tailoring prong" (Pet. 31-34) and its recognition of *Central Hudson*'s statement that the "traditional" prior-restraint doctrine may not apply in commercial-speech contexts (Pet. 34-35) reflect divisions of authority warranting review. Petitioners are wrong.

Section 387k was enacted against the tobacco industry's history of false and misleading marketing to consumers about the health effects of their products. See pp. 4-6, *supra*. Although petitioners assert that they no longer use misleading modified-risk descriptors such as "'light', 'mild,' or 'low,'" Pet. 9 n.4, Congress's authority is not limited to protecting public health from the particular types of false and misleading commercial speech previously used by the industry. Congress's authority to regulate tobacco products as products delivering a highly addictive drug carrying significant health risks includes authority to require pre-market review of tobacco products that would be labeled or promoted as presenting a reduced risk.

1. Congress concluded that the health dangers of tobacco products marketed as "modified risk tobacco products" that "do not in fact reduce risk" are "so high" that FDA's pre-market review is necessary to ensure that they will actually reduce health risks. *Legislative Findings* 39-40, 43. Citing the FTC's determination 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," Congress concluded that simply requiring disclaimers would not sufficiently protect the public health in this context, given the "inherently dangerous" and "addictive" nature of tobacco products. *Legislative Findings* 2-3, 37, 41-42. Petitioners contend (Pet. 31-34) that the court of appeals erred and created a division of authority by not "cit[ing]" evidence (Pet. 31) to support Congress's conclusions. Petitioners are incorrect.

Potentially misleading commercial speech may sometimes be sufficiently addressed through disclaimers. Pet. 31-32. But that principle does not uniformly extend

to all contexts, particularly where the public health is at stake. Congress's health-focused approach to modified-risk tobacco products parallels pre-market review of drug products. Both are constitutional.

Congress has long defined new "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" that are not generally recognized by experts as safe and effective for such use. 21 U.S.C. 321(g)(1)(B) and (p). No such drug may be marketed until FDA determines that it is safe and effective for the uses proposed in its labeling, 21 U.S.C. 355(a) and (d), which includes the product's promotional materials. *Kordel* v. *United States*, 335 U.S. 345, 349-351 (1948); see 21 U.S.C. 321(m). A manufacturer's "promotional claims" thus reflect evidence of a product's intended use as a drug, which requires FDA pre-market approval. *United States* v. *Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (citing cases).

The court of appeals here concluded that pre-market approval of a product for uses reflected in promotional claims must "withstand First Amendment analysis" under *Central Hudson*. Pet. App. 38a-39a. The court then concluded that the "real and significant" risks to public health from false or misleading modified-risk claims warranted pre-market review under *Central Hudson* "in the context of a deadly and highly addictive product" for which it would be "a virtual impossibility to unring the bell of misinformation," particularly in light of the industry's history of false health claims. *Id.* at 41a-42a, 45a. Such regulatory scrutiny is constitutionally valid for products (like new drugs) having a significant potential to adversely affect public health when not

subjected to FDA's pre-market review. *Whitaker* v. *Thompson*, 353 F.3d 947, 952-953 (D.C. Cir.), cert. denied, 543 U.S. 925 (2004); cf. *United States* v. *Caronia*, 703 F.3d 149, 161 & n.8 (2d Cir. 2012) (assuming "a drug's intended use" as reflected in promotional materials may prove a violation of federal drug laws; but holding prosecution erroneously rested on theory that promotional acts were themselves unlawful).

Tobacco products are inherently dangerous and deliver a highly addictive drug (nicotine). The Tobacco Control Act requires FDA's pre-market approval of such products when "sold or distributed for use to reduce harm or the risk of tobacco-related disease" as demonstrated by a manufacturer's labeling, advertising, or other communications directed to consumers about the product. 21 U.S.C. 387k(b); see p. 9, *supra*. That regulation, like FDA pre-market approval of drug products with purported health benefits, is necessary to prevent harm to the public health from marketing such products for purported but unproven health benefits. That holds particularly true here given the tobacco industry's history of false and misleading marketing of "reduced-risk" tobacco products and the FTC's determination that consumers have misinterpreted advertising in which one product is claimed to be less harmful than another. Pet. App. 39a-45a.

Petitioners contend (Pet. 32-33) that this case is "indistinguishable" from *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999), which rejected FDA's conclusion—after FDA's pre-market review of health claims in proposed dietary-supplement labeling—that disclaimers would be insufficient to protect consumers from the potentially inaccurate claims. But *Pearson* did not question that a manufacturer could be subject to pre-market review of

health claims; it merely set aside FDA's decision *after* such review. Moreover, *Pearson* stressed that its analysis turned on the fact that FDA did not claim the dietary supplements "in any fashion *threaten[ed]* consumer's health and safety" and explained that drugs could be "in an entirely different category" because their "potential harm presumably is much greater." *Id.* at 656 & n.6. Petitioners neither dispute Congress's determination that tobacco products are "inherently dangerous" nor distinguish drugs from tobacco products sold to reduce the harm or risk of disease.

Petitioners' reliance (Pet. 32) on *Public Citizen, Inc.* v. *Louisiana Attorney Disciplinary Board*, 632 F.3d 212 (5th Cir. 2011), and *Alexander* v. *Cahill*, 598 F.3d 79 (2d Cir.), cert. denied, 131 S. Ct. 820 (2010), is even further afield. Both invalidated categorical bans on attorney advertisements portraying judges or juries, because "no argument or evidence in the record" suggested such portrayals would generally give the false, deceptive, or misleading impression that "the lawyer has the ability to influence improperly a court." *Public Citizen*, 632 F.3d at 224 (quoting *Alexander*, 598 F.3d at 93). Both likewise deemed the "blanket" bans insufficiently tailored because there was no evidence that disclaimers would be ineffective in dispelling any (minimal) potential for that misleading impression. *Ibid.*; *Alexander*, 598 F.3d at 96. Neither holding applies to this context involving inherently dangerous and addictive products, particularly in light of a long history of misleading claims.

Petitioners suggest (Pet. 34) that the government might adequately protect consumers with "post-market review." But such after-the-fact enforcement comes too late for the addicted consumer: "[I]n 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." Pet. App. 45a. Surgeon General Carmona specifically admonished Congress to heed "[o]ur [N]ation's experience with low-tar cigarettes" when deciding how to regulate smokeless tobacco products: Not only were manufacturers' promised health benefits illusory, the purportedly lower-risk products may have "contributed to an actual *increase* in death and disease among smokers." 155 Cong. Rec. 13,655-13,656 (2009) (emphasis added). Petitioners alternatively suggest (Pet. 34) that increased penalties might deter their misleading health claims. That assertion is remarkable here. The D.C. Circuit recently stressed that tobacco companies were "[un]deterred by the possibility of RICO liability" for their decades-long pattern of "false or deceptive statements" notwithstanding RICO's "sweeping" penalties and are "reasonably likely" to continue such deception in the future. *United States* v. *Philip Morris USA Inc.*, 686 F.3d 832, 834, 837 (2012).

Finally, petitioners rely (Pet. 33, 36) on *Thompson* v. *Western States Medical Center*, 535 U.S. 357 (2002). But *Thompson* dealt with a total ban on (undisputedly truthful) advertising that a pharmacy compounds particular drugs—a ban that was intended to "draw a line" between permissible, small-scale compounding and impermissible manufacturing. *Id.* at 365, 370-371. The Court identified a number of specific "non-speech-related means" of limiting the size of compounding operations and explained that the blanket advertising ban was not sufficiently tailored under *Central Hudson* because the government did "not offer[] any reason why these possibilities" would be "insufficient." *Id.* at 372-373. By contrast, reasonable pre-market review of—not

a total marketing ban on—modified-risk tobacco products is amply justified by their inherently dangerous and addictive nature; the problem of advertising directed to consumers generally (of all ages); consumers' difficulty in evaluating comparative-risk marketing even when accompanied by disclaimers; and a history of misleading modified-risk tobacco claims.[6]

2. Petitioners contend (Pet. 34-35) that "traditional" prior-restraint analysis should apply, citing inapposite decisions involving core protected speech. See *Nebraska Press Ass'n* v. *Stuart*, 427 U.S. 539 (1976) (journalism); *Southeastern Promotions, Ltd.* v. *Conrad*, 420 U.S. 546 (1975) (theater); *Freedman* v. *Maryland*, 380 U.S. 51 (1965) (film). But this case involves commercial speech, with respect to an addictive and dangerous product. This Court has indicated that "traditional" prior-restraint doctrine may not directly apply as such to commercial speech. *Central Hudson*, 447 U.S. at 571 n.13. Rather, commercial-speech restrictions have long been analyzed under *Central Hudson*'s framework.

Petitioners note (Pet. 35) that *New York Magazine* v. *Metropolitan Transp. Auth.*, 136 F.3d 123, 131-132 (2d Cir.), cert. denied, 525 U.S. 824 (1998), indicates that normal procedural safeguards for prior restraints should not be relaxed when commercial speech is restrained. But *New York Magazine* simply concludes

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[6] The context here is quite unlike others (cf. Pet. 35-37) involving bans on using drug-prescription data in direct marketing to medical doctors, who are "sophisticated and experienced" consumers of such data, see *Sorrell* v. *IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011) (citation omitted), or bans on the advertising of undisputed facts (like the price of a product) that reflect a "paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely." *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484, 497 (1996).

that *Central Hudson's* analytical commercial-speech framework should be applied, *ibid.*, as was done here (Pet. App. 37a, 39a). See also *Desert Outdoor Adver., Inc.* v. *City of Moreno Valley*, 103 F.3d 814, 819 (9th Cir. 1996) (applying *Central Hudson*), cert. denied, 522 U.S. 912 (1997). The Second Circuit thus later followed *New York Magazine* by applying *Central Hudson*'s test to uphold FDA's 540-day pre-market-approval period for dietary-supplement health claims. *Nutritional Health Alliance* v. *Shalala*, 144 F.3d 220, 228 (2d Cir.), cert. denied, 525 U.S. 1040 (1998). There, as here, pre-market review is reasonably tailored "given the need to protect consumers before any harm occurs," to "evaluate the evidence in support of labeling claims," and to develop "a record on the matter so that a court can determine whether the regulated speech is, in fact, truthful and non-misleading." *Ibid.*[7]

3. Petitioners contend (Pet. 36-38) that requiring FDA to evaluate modified-risk claims by considering, *inter alia*, the "health of the population as a whole"—including existing tobacco users and others who do not "currently" use tobacco, 21 U.S.C. 387k(g)(1)(B) and (4)—could prohibit advertising that petitioners assert might accurately inform consumers about tobacco products purportedly having fewer risks than cigarettes. But the marketing and sale of such products would not be limited to just current cigarette smokers. It therefore is appropriate to consider health effects on those

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[7] Petitioners suggest (Pet. 10) that the Act "does not ensure prompt [modified-risk-tobacco-product] decisions by FDA," notwithstanding FDA's guidance reflecting its intent to act within 360 days. But petitioners brought a facial, not an as-applied, challenge, and they may later seek to compel any particular agency action unreasonably delayed. See Pet. App. 148a.

who may be injured by the product, similar to the drug context where Congress "generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'" *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) (citation omitted).

Petitioners' assertions about smokeless tobacco underscore the need for pre-market review. Echoing claims previously made about "low tar" cigarettes, petitioners now assert (Pet. 8, 37) that their smokeless-tobacco products are less harmful than the cigarettes they sell and that lives might be saved if cigarette smokers switched to smokeless products. Petitioners have based these claims on their expert (Brad Rodu), who opined that smokeless tobacco is even more effective at helping smokers quit than FDA-approved products like nicotine gum and the nicotine patch, but whose research was financed by the tobacco companies, Doc. 72-2 ¶¶ 6, 17, 40, and has not been subject to rigorous independent review.

The very point of Section 387k's pre-market review—like pre-market review of drug products—is to ensure that they will yield the comparatively improved health effects for which they are marketed. Here, for instance, independent research indicates that tobacco companies have manipulated the nicotine levels in smokeless tobacco products so that those products reinforce, not reduce, cigarette addiction. Many smokeless tobacco products are explicitly "marketed to smokers as a way to sustain their [cigarette] addictions in places where smoking is no longer allowed." 155 Cong. Rec. 13,903 (2009) (Sen. Durbin) (discussing advertising that Reynolds' Camel-brand snus can be used to avoid "smoking bans and

restrictions"). But rather than providing a substitute for cigarettes, they appear to be designed as a nicotine bridge. For instance, Marlboro snus, which deliver less nicotine than "snus" sold in Sweden, "will leave the smoker craving for a cigarette." See Jonathan Foulds & Helena Furberg, *Is low-nicotine Marlboro snus really snus?*, 5:9 Harm Reduction Journal 3 (Feb. 2008). Such "dual use" of cigarettes and smokeless tobacco is emerging as a significant threat to public health. See, *e.g.*, Scott L. Tomar *et al.*, *Patterns of dual use of cigarettes and smokeless tobacco among US males*, 19 Tobacco Control 104, 108 (Dec. 2009).

Public health concerns are exacerbated by the evidence—including internal "tobacco company documents"—that "youth are encouraged to experiment with low-nicotine starter products and subsequently graduate to higher-level nicotine brands or switch to cigarettes as their tolerance for nicotine increases." 155 Cong. Rec. 13,656 (2009) (statement of Surgeon General Carmona); see Office of the Surgeon General, *Preventing Tobacco Use Among Youth and Young Adults* 541, 600 (2012). Modern smokeless-tobacco products do not require spitting, and they escape detection in the school environment. After "teachers in schools" began to notice round "containers [of Reynolds' Camel-brand snus] in their students' pockets," for instance, Reynolds redesigned its packaging to resemble cell phones "so that teachers can't recognize that these are smokeless tobacco products." *Id.* at 13,654 (Sen. Merkley).

Petitioners ultimately assert that Section 387k stifles "debate about the role that less-risky tobacco products, like smokeless tobacco, should play within the public-health strategy for reducing the harms from tobacco use." Pet. 23, 36. But the court of appeals explained

that the provision's application to claims "directed to consumers" about "specific products" leaves petitioners' "ability to make 'direct comments on [such] public issues'" "untouched." Pet. App. 36a-37a (emphasis omitted). By contrast, the very purpose of pre-market review is to determine, on the basis of scientific evidence, whether a *particular* tobacco product will actually provide the reduced risks for which it is marketed.

C. Branded Merchandise, Event Sponsorship, And Free Samples

Petitioners seek review (Pet. 38-40) of the court of appeals' rejection of their facial challenge to regulations prohibiting the use of a tobacco product's brand name or logo on merchandise or to sponsor public events, 21 C.F.R. 1140.34(a) and (c), and generally prohibiting free samples of tobacco products, 21 C.F.R. 1140.16(d). That issue warrants no further review.

1. A court analyzing *Central Hudson*'s requirement of a "reasonable fit between the means and ends" in this context not only must consider whether FDA's regulations advance the interest of reducing youth smoking, it also "must consider" the tobacco industry's "interest in conveying truthful information about their products to adults" and adult consumers' "interest in receiving [such] information." *Lorillard Tobacco Co.* v. *Reilly*, 533 U.S. 525, 556, 561, 564 (2001). Petitioners assert (Pet. 38-39) that the court of appeals failed to consider those speech interests. But the court articulated the very requirement that petitioners advocate, quoting *Lorillard*'s precise formulation in explaining that its *Central Hudson* tailoring analysis "must consider" those interests. Pet. App. 7a-8a, 15a, 69a (quoting *Lorillard*, 533 U.S. at 556, 564, 571); see *id.* at 77a-78a.

To the extent petitioners contend that the court of appeals misapplied a "properly stated rule of law," that fact-bound contention warrants no further review. See Sup. Ct. R. 10. It is also incorrect. This Court in *Lorillard* explained that, where "studies have identified particular advertising and promotion practices that appeal to youth, tailoring [under *Central Hudson*] would involve targeting those practices while permitting others." 533 U.S. at 563. Here, petitioners have not challenged the sufficiency of the evidence documenting the special harm that these practices have on youth. Under *Lorillard*, the focused targeting of youth-appealing practices will reflect a logical and reasonable fit when other adult-focused practices remain available such that "the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products" is not "unduly impinge[d]." *Id.* at 565. As the court of appeals concluded, the regulations here do precisely that. Pet. App. 54a-59a.

The government's interest in reducing underage tobacco use is compelling, *Lorillard*, 533 U.S. at 564, and the scale of the problem is immense. See pp. 3-4, *supra*. "Virtually all" new tobacco users are underage; an "overwhelming majority" of existing users became addicted before the age of 18, *Legislative Findings* 4, 31; and "decades of experience in tracking tobacco use show that if people do not begin to use tobacco as youngsters, they are highly unlikely to initiate use as adults," IOM, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* 5 (1994). This Court concluded in 2001 that limiting youth exposure to tobacco advertising would directly advance the goal of reducing underage tobacco use. *Lorillard*, 533 U.S. at 557-561.

That conclusion has since been reinforced by further scientific evidence. See, *e.g.*, *House Report* 32.

a. The placement of "name brands" and logos of particular brands of tobacco products on merchandise has a strong effect on youth. The court of appeals cited studies of adolescent smoking showing that "obtaining tobacco branded non-tobacco products 'precedes, and *reliably predicts*, smoking initiation.'" Pet. App. 55a (emphasis added; citations omitted). Despite industry claims to distribute such merchandise only to adults, the court explained that nearly half of all adolescent smokers owned one or more tobacco-related promotional items. *Ibid.* The evidence both amply supports those conclusions and shows that there is no way to limit distribution of such branded items to adults alone. See, *e.g.*, Gov't C.A. Br. 74-76 (citing illustrative studies).

b. Similarly, although the ban on direct tobacco advertising on television, properly functions to protect children, the court of appeals explained that the evidence demonstrates that brand-name tobacco sponsorships of public events results in "substantial" advertising exposure to children (often on television) and directly affects "juvenile tobacco consumption." Pet. App. 57a. Although the 1998 Master Settlement Agreement (MSA) between States and tobacco companies purportedly limited brand-name sponsorships, tobacco companies actually "increased their sponsorship budgets [after] signing the MSA." *Philip Morris*, 449 F. Supp. 2d at 664. In 2001, for instance, tobacco sponsorship included Winston's association with NASCAR; Skoal racing teams at National Hot Rod Association events; the Players, Kool, and Marlboro teams at Championship Auto Racing; and Copenhagen booths at Professional Rodeo Cowboys Association and professional bull-riding

events. See National Cancer Institute, *Monograph 19: The Role of the Media in Promoting and Reducing Tobacco Use* 154-155 (2008). Annual viewership of tobacco-sponsored races that year swelled to 513 million, leading one study to conclude that "cigarette manufacturers have used auto racing sponsorships to successfully circumvent both the ban on televised cigarette advertising and the intent of the [MSA] not to target youth." Margaret Morrison et al., *Inhaling and Accelerating: Tobacco Motor Sports Sponsorship In Televised Auto Races, 2000-2002*, 15 Sport Marketing Q. 7, 12 (Mar. 2006). In 2002 alone, petitioner Reynolds received $1.2 billion of marketing exposure for "its cigarette brands at televised racing events." *Philip Morris*, 449 F. Supp. 2d at 666.[8]

c. The general prohibition on free samples of tobacco products (which does not apply to free smokeless tobacco in certain adult-only facilities) also directly targets a practice that appeals particularly to youth. Even assuming that such a ban on pricing and conduct could properly be regarded as a restriction on commercial *speech*,[9] the court of appeals correctly concluded that

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[8] Although petitioners argued that a brand-name-sponsorship ban could capture an adult-only blackjack tournament without "*any* media coverage," the court of appeals correctly explained that this small, "incidental effect" was insufficient to invalidate the regulation on its face. Pet. App. 58a-59a (emphasis added). Petitioners' failure to demonstrate "substantial" overbreadth in this facial challenge, *Washington State Grange*, 552 U.S. at 449 & n.6, simply means that any such idiosyncratic event-sponsorship claims must proceed as specific, as-applied challenges.

[9] In the government's view, the court of appeals erred in concluding (Pet. App. 48a) that First Amendment concerns are implicated by the ban on free tobacco samples. The ban regulates pricing conduct without any significant expressive element.

"extensive" evidence shows that free tobacco samples constitute an "easily accessible source" for youth, notwithstanding the industry's own efforts that "supposedly restrict [such] distribution" to underage persons. Pet. App. 54a (citations omitted). It is somewhat unclear whether petitioners even seek to challenge this aspect of the court's holding. See Pet. 17 n.5.

d. Petitioners have not meaningfully disputed the evidentiary foundation for the foregoing conclusions, which demonstrate that the restrictions at issue specifically target "particular advertising and promotion practices that appeal to youth." *Lorillard*, 533 U.S. at 563. Those restrictions—which simply prohibit brand-name sponsorships and merchandise and free tobacco samples—leave tobacco manufacturers with meaningful ways to communicate with adult customers. Petitioners are free to use written and oral communications to inform adults of the price, availability, and other features of their products. The regulations thus are manifestly not "blanket bans on commercial marketing to adults," Pet. 40, nor do they significantly "impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products." *Lorillard*, 533 U.S. at 565. The regulations stand in sharp contrast to the blanket restrictions in *Lorillard*, which banned all outdoor tobacco advertising within a 1000-foot radius of a playground or school, including any indoor advertising visible though store windows and even oral communications by retailers. *Id.* at 561-563. Those restrictions "constitute[d] nearly a *complete* ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers" in some geographic areas and left retailers with "*no means* of communicating to passersby on the

street that [they] sell[] tobacco products." *Id.* at 562, 565 (emphasis added). Such restrictions failed to reflect "a careful calculation of the speech interests involved," *id.* at 562, unlike the focused targeting of brand-name sponsorships, brand-name merchandise, and free samples in this case.

2. Petitioners contend (Pet. 39-40) that the court of appeals' decision conflicts with cases like *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476 (1995), which require consideration of less-restrictive alternatives. Petitioners refer (Pet. 14, 39) to only two such alternatives: "enforcing laws" prohibiting tobacco sales to minors and "designing anti-tobacco programs" targeting youth. But as the court of appeals explained (Pet. App. 44a), such efforts have been tried and found wanting.

As the district court explained, Congress has for decades "implement[ed] [such] measures" without restricting commercial speech in tobacco marketing and ultimately determined from experience that those means would be insufficient and would continue to be undermined by the tobacco industry's ongoing "use of advertising 'to stimulate underage demand.'" Pet. App. 159a (citation omitted); *id.* at 155a-159a. Because "[l]ess restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by [the] regulations," *Legislative Finding* 31, the regulations here targeting specific practices that are particularly attractive to youth are appropriately tailored under *Central Hudson*.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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