No. 13-14590

In the United States Court of Appeals for the Eleventh Circuit

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EARL GRAHAM,
as personal representative of the estate of Faye Dale Graham,
Plaintiff-Appellee,

v.

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Florida, Jacksonville Division

EN BANC BRIEF OF *AMICI CURIAE* AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN LUNG ASSOCIATION, AMERICANS FOR NONSMOKERS' RIGHTS, CAMPAIGN FOR TOBACCO-FREE KIDS, NAATPN, INC., NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS, TOBACCO CONTROL LEGAL CONSORTIUM, AND TRUTH INITIATIVE IN SUPPORT OF PLAINTIFF AND AFFIRMANCE

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In compliance with Local Rule 26.1-1 and Local Rule 29(c), the undersigned certifies that no counsel to a party authored this brief in whole or in part nor contributed any funds directly or indirectly for this brief's preparation, and that no person other than the amici curiae contributed any funding for the preparation of this brief.

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No other person, firm, partnership, or corporation has an interest in this outcome.

CORPORATE DISCLOSURE STATEMENT

No publicly held corporation owns 10% or more of the stock in any amici curiae. Nor is any amicus curiae a subsidiary of any parent company.

/s/ Rachel Bloomekatz
Rachel Bloomekatz
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INTEREST OF AMICI

Amici curiae are nonprofit public health organizations committed to supporting policies that educate the public about, and protect the public from, the devastating health consequences of tobacco.[1] Tobacco use is the leading preventable cause of death, killing more than 480,000 Americans annually. U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, Executive Summary* 17 (2014). "More than 10 times as many U.S. citizens have died prematurely from cigarette smoking than have died in all the wars fought by the United States during its history." *Id.* at 1. Despite the decline in smoking rates since the 1960s, the Surgeon General has cautioned that "much more needs to be done to end the tobacco epidemic," because, at current rates, 5.6 million children alive today are projected to die prematurely from a smoking-related illness. *Id.* Amici have a strong interest in this matter because the Court's decision could affect the existing power of states to enact public health policies.

Specifically, amici file this brief to address the second en banc issue—whether Congress preempted Florida's common law products liability and negligence claims as adjudicated in *Engle* and its progeny. Amici understand that the parties dispute whether the *Engle* cases amount to a prohibition on the sale of

[1] A further description of each amicus is included as an addendum to this brief.

cigarettes during the class period (i.e., persons injured before November 21, 1996). But, even if *Engle* and its progeny amounted to a prohibition on cigarette sales during the class period, amici demonstrate that such a prohibition would not have been preempted by then-existing federal law. As explained below, such a prohibition would fall squarely within state authority.

STATEMENT OF ISSUES

Assuming that the Florida Supreme Court's holding in *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246 (Fla. 2006), constituted a prohibition on the sale of cigarettes, is it impliedly preempted by federal law?

SUMMARY OF ARGUMENT

Defendants' preemption arguments all rest on a key flaw. They improperly conflate (1) Congress's decision to refrain from prohibiting cigarettes on a nationwide basis, as described in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134-162 (2000) ("*B&W*"), with (2) Congress's intent as to whether *states* may prohibit cigarette sales. But the former does not control the latter. Instead, a review of the relevant tobacco-related enactments reveals that, even though Congress decided not to prohibit cigarettes at the national level, it did not prohibit states or local governments from doing so within their borders. To the contrary, Congress has maintained a regulatory scheme that allows for state "innovation and

experimentation" in curbing the deleterious effects of tobacco use. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

With the passage of the 1965 Federal Cigarette Labeling and Advertising Act ("Labeling Act") and subsequent laws, Congress did not prohibit cigarettes but instead decided to inform the public about smoking dangers through uniform warnings on cigarette labels and advertising. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 513-14 (1992). At the time, multiple states and federal agencies were considering different cigarette warnings. *Id.* In response, Congress preempted states from imposing additional warning requirements. *See id.* That way tobacco users could be informed of the safety hazards, while sparing the tobacco industry the costs of "diverse, nonuniform, and confusing cigarette labeling and advertising regulations." Pub. L. No 89-92, § 2 (1965).

Defendants argue that this "distinct regulatory scheme" struck a perfect balance between "the risks of smoking" and "the economic importance of the tobacco industry." Defs' Br. at 45-46. And they try to bootstrap the Labeling Act's mention of protecting "the national economy . . . to the maximum extent" into preemption of "*any* state law that would upset this balance." *Id.* (emphasis added). But that is not the law. Congress carefully circumscribed the Labeling Act's preemptive scope to "advertising or promotion." Pub. L. No. 91-222, § 5(b) (1970). If this Court were to expand that scope, and adopt defendants' rule, it would

jeopardize local cigarette taxes, flavored-product restrictions, retail-licensing restrictions, youth-access restrictions, and other time-tested measures to protect public health.

This Court should reject defendants' preemption argument for three reasons. *First*, although defendants place great weight on the six statutes cited in *B&W*, 529 U.S. at 137, none of them evince congressional intent to restrict state or local governments from prohibiting cigarette sales. Notably, defendants' principal brief does not even describe these statutes, discuss their legislative history, or cite their preemption provisions—they are merely listed in a footnote. Defs' Br. at 45 n.5. But any preemption inquiry must begin with an analysis of the federal statutes that are claimed to block state authority. As experts in tobacco-related legislation, amici provide the Court with that analysis, which demonstrates the lack of congressional intent to block local laws prohibiting the sale of tobacco products.

Indeed, Congress's most recent tobacco-related enactment—the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009)—explicitly reserves a state's right to prohibit tobacco sales in its "preservation clause." 21 U.S.C. § 387p(a)(1). True, as defendants now emphasize (Defs' Br. at 51-52), the TCA was not enacted until after the *Engle* class period, so it is not controlling here. But, as the panel itself explained, the TCA makes "textually explicit what was already evident" in the

prior congressional scheme, *Graham v. R.J. Reynolds*, 782 F.3d 1261, 1279 (11th Cir. 2015): It bars the FDA from prohibiting tobacco, but allows the states to do so. Defendants argued before the panel that the TCA should be viewed as a proxy for prior congressional intent, but overlooked the "preservation clause." Defs' Panel Br. at 18-19. Now, having apparently acknowledged that clause, they have reversed course, no longer arguing that the TCA "reinforces the [existing] federal policy." *Id.* at 18. They were right the first time. The TCA reflects Congress's longstanding intent not to stop tobacco sales nationwide, but to preserve a locality's power to make that decision within its own borders.

Second, defendants' reliance on *B&W* is misplaced. Defendants rest their entire preemption argument on this case, as if the Supreme Court's analysis of the FDA's authority to prohibit tobacco sales applies similarly to a state's authority to do so. The two are not the same. To regulate tobacco, the FDA needed a delegation of authority from Congress, a delegation that the Court reasoned would have resulted in a prohibition on tobacco products under then-existing FDA law. Because other congressional enactments demonstrated that Congress did not want to prohibit tobacco across the country, the Supreme Court decided that the FDA—which had long disclaimed its authority over tobacco—did not have the requisite authority. *B&W*, 529 U.S. at 135. But states do not need permission from Congress to exercise regulatory authority to protect public health. Thus, to find a

state law preempted, it is immaterial that Congress decided not to ban a product; Congress must additionally intend to prevent states from banning that product too. This Court should reject defendants' invitation to confuse one with the other.

Lastly, adopting defendants' preemption argument would disrupt the critical balance of power between states and the federal government. In a federalist system, states play an important role in experimenting and developing public health policies—on issues ranging from lead paint, to trans-fat bans, to nutritional labeling on fast-food menus. States' innovative public health strategies often serve as the model for later nationwide policies. Concluding that state laws are preempted simply because Congress has regulated (but not prohibited) a product would threaten public health and wreak havoc on the balance that federalism protects.

ARGUMENT

I. Congress never intended to remove state authority to prohibit tobacco sales.

Defendants' preemption claim rests on the assertion that a state's decision to prohibit tobacco sales would create an unacceptable "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), because Congress wanted states to allow tobacco product sales. That assertion rests on "broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law." *Wyeth v. Levine*, 555 U.S. 555, 594 (2009) (Thomas, J., concurring). Therefore,

defendants cannot satisfy the "high threshold" needed for obstacle preemption. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring).

Derived from the Supremacy Clause, preemption is a question of federal law that requires courts to review the relevant statutes for Congress's intent to block state authority. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). "Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id.* at 486. The historic police powers of the states—including the inherent state authority to prohibit tobacco sales, *Austin v. Tennessee*, 179 U.S. 343, 362 (1900)—are "'not to be superseded'" unless that was "'the clear and manifest purpose of Congress,'" *Wyeth*, 555 U.S. at 565 (quoting *Lohr,* 518 U.S. at 485). This "requirement that Congress speak clearly" when exercising preemptive power is an important "structural safeguard[] . . . to defend state interests from undue infringement." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting). Otherwise, courts improperly thwart state innovation and experimentation that is at the heart of federalism. *See infra* Part III.

In particular, claims of "obstacle preemption," like those made by defendants here, should not be an opportunity for "[a] free wheeling judicial inquiry into whether a state statute is in tension with federal objectives," as that

analysis "would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Gade*, 505 U.S. at 111 (1992) (Kennedy, J., concurring); 1 Laurence Tribe, *American Constitutional Law* §6-28, p. 1177 (3d ed. 2000) ("[P]reemption analysis is, or at least should be, a matter of precise statutory construction rather than an exercise in free-form judicial policymaking.").

A review of the relevant statutes upon which defendants rely demonstrates that it was not the "clear and manifest" purpose of Congress to displace the states' inherent authority to prohibit tobacco sales. *Wyeth*, 555 U.S. at 565. Specifically, defendants rely on six statutes—those cited in *B&W*, 529 U.S. at 137, including the Labeling Act of 1965, its 1970 amendment, and four other tobacco-related statutes—to demonstrate congressional intent. None of these statutes individually, or together, impliedly displaces a state-imposed prohibition on tobacco sales.

A. With the Labeling Act, Congress sought only to preclude state laws addressing cigarette warnings or advertising—not to command each state to allow cigarette sales within its borders.

Defendants' preemption argument (like the panel decision) largely relies on the Labeling Act, in which Congress set uniform warning labels for cigarettes. Pub. L. No. 89-92, 79 Stat. 282 (1965). In passing and amending the Labeling Act, Congress knew "that smoking can cause serious physical harm, even death," but it chose not to prohibit cigarettes. *Graham*, 782 F.3d at 1277. The panel found this decision *not to prohibit cigarettes* significant. *Id.* It concluded, per defendants'

contentions, that the Labeling Act balanced the harm of cigarettes against the role of cigarettes in the national economy, and decided that Congress intended for consumers to have a "free but informed choice" to purchase tobacco products. *Id.* A state prohibition would be antithetical to these so-called balanced goals. *Id.*

The problem with this argument is that it contravenes the text, purpose, and legislative history of the Labeling Act and its subsequent amendments, and extends the congressional concerns about addressing the tobacco industry's costs related to labeling well beyond the scope of the statute. The text of the Labeling Act preempts some state regulations and requirements relating to cigarette warnings and advertisements, but unmistakably does *not* preclude state laws prohibiting tobacco sales.

1. Congress intended only to preempt states from enacting "diverse, nonuniform, and confusing cigarette and advertising regulations."

"When a federal law contains an express preemption clause," as does the Labeling Act, a court must "'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1977 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). When Congress enacted the Labeling Act in 1965 it included a section titled "Preemption" that provided in relevant part: "No statement relating to smoking and health, other than the statement required by . . .

this Act, shall be required on any cigarette package" or "in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Pub. L. No. 89-92, § 5 (1965). The plain language of this provision preempts state laws that require additional warnings on cigarette packages or advertisements, but does not preempt state laws that otherwise restrict or even prohibit tobacco sales. That is, the Labeling Act's preemption clause is limited—as the Act's title indicates—to labels or advertising.

This plain language reading of the Labeling Act's original preemption provision is consistent with the Act's purpose and legislative history. The Labeling Act has two declared purposes: (1) "adequately informing the public that cigarette smoking may be hazardous to health, and (2) protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations." *Cipollone,* 505 U.S. at 514; *see* Pub. L. No 89-92, § 2 (1965) (preemption provision enacted to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations"). As explained by the Supreme Court, Congress passed the Labeling Act "in the face of impending regulation by federal agencies and the States" to regulate cigarette packaging and advertising following the Surgeon General's 1964 report emphasizing the adverse health consequences of cigarettes. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542 (2001). New York State had already adopted its own warning label requirement, and the

FTC was considering a separate requirement. *Cipollone*, 505 U.S. at 513-14; *B&W*, 529 U.S. at 145. In hearings before Congress, R.J. Reynolds argued that such "conflicting regulations" would be "intolerable." Hearings before the H. Comm. on Interstate and Foreign Commerce, 88th Cong., 2d Sess., 140 (June 25, 1964) (statement of Bowman Gray).

Accordingly, the text and legislative history make clear that Congress passed the Labeling Act to create a uniform warning requirement, but it did not go any further in preempting state action. *See* H.R. Rep. No. 195, 89th Cong., 1st Sess., 4 (1965) ("There was general agreement among the witnesses . . . that if the Committee took any action in this field, such a requirement as to labeling should be uniform; otherwise, a multiplicity of State and local regulations pertaining to labeling of cigarette packages could create chaotic marketing conditions and consumer confusion."); *Cipollone*, 505 U.S. at 519 ("[A] warning requirement promulgated by the FTC and other requirements under consideration by the States were the catalyst for passage of the 1965 Act."). There is no support in the text or the legislative history to read the Labeling Act's preemptive sweep beyond the context of labeling. "That Congress requires a particular warning label does not automatically pre-empt a regulatory field." *Cipollone*, 505 U.S. at 518.

2. Congress's 1969 amendments to the Labeling Act did not preempt state or local laws prohibiting tobacco sales.

When Congress amended the Labeling Act five years later, its essential purpose did not change. *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970). As the warnings from the 1965 law were about to expire, state governments and federal agencies again prepared their own, potentially conflicting, advertising regulations. *Cipollone*, 505 U.S. at 515. In renewing the Labeling Act, Congress was still focused on uniform labels on cigarette packages and advertisements. *Id*. The 1969 Act rewrote the warning label, prohibited broadcast advertising, and allowed the FTC to regulate print advertising. *Id*. at 520.

Congress also expanded the Labeling Act's preemptive reach, but not in any way that suggested intent to preempt localities from restricting or prohibiting tobacco sales. *See* S. Rep. No. 91-566, 91st Cong., 1st Sess., 12 (1969) (revised preemption provision was "narrowly phrased" so as to only "avoid the chaos created by a multiplicity of conflicting regulations" mandating warnings). Whereas the 1965 preemption clause "merely prohibited state and federal rulemaking bodies from mandating particular cautionary *statements* . . . in cigarette advertisements," *Cipollone*, 505 U.S. at 518, the 1969 version prohibited any "*requirement or prohibition* . . . with respect to the advertising or promotion" of cigarettes, Pub. L. No. 91-222,

§ 5(b) (1970) (emphasis added). The Supreme Court held that the 1969 provision swept more broadly because it "suggests no distinction between positive enactments and common law." *Cipollone*, 505 U.S. at 521. States could not pass a law mandating a particular statement (per the 1965 preemption provision), nor could they impose other warning obligations through common-law rules or other less direct enactments (per the 1969 amendments). *Id.* Accordingly, like the original enactment, the Labeling Act's 1969 renewal does not reveal congressional intent to block state laws outside the realm of tobacco warnings and advertising.

3. Congress's expressed desire to protect the economy does not broaden the Labeling Act's preemptive scope.

Defendants emphasize that the existence of the express preemption provision in the Labeling Act "does *not* bar the ordinary working of conflict pre-emption principles," *Geier*, 529 U.S. at 869, and that Congress impliedly preempted any state from preventing tobacco sales due to its concern for protecting the economy. Defs' Br. at 45-46. This argument has multiple flaws.

First, even when evaluating obstacle preemption, express preemption clauses are nonetheless the best evidence of Congress's preemptive intent. Following an *expressio unius* logic, the Supreme Court has often found it "powerful evidence" that Congress decided to expressly preempt some state laws, but not the challenged law. *Wyeth*, 555 U.S. at 574-75 ("despite its 1976 enactment of an express pre-emption

provision . . . Congress has not enacted such a provision for [the challenged state law]"); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) ("Congress could have applied the preemption clause [more broadly]. It did not do so."). Similarly, the Labeling Act's express preemption clauses, combined with their legislative history, demonstrate that Congress meant only to preempt state laws that added warning or advertising requirements, but *not* state restrictions or prohibitions on tobacco sales.

Second, the Labeling Act's reference to protecting the economy cannot be bootstrapped into an argument for obstacle preemption. Defs' Br. at 45-46. The purpose section reads:

> It is the policy of the Congress . . . to establish a *comprehensive Federal program to deal with cigarette labeling and advertising* with respect to any relationship between smoking and health, whereby--
> **(1)** the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
> **(2)** commerce and the national economy may be *(A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations* with respect to any relationship between smoking and health.

15 U.S.C. § 1331 (emphasis added). From this section, defendants argue that Congress intended to protect the economy "'to the maximum extent' consistent with [the labeling requirements]," and that "[f]ederal law thus impliedly preempts *any state law that would upset this balance."* Defs' Br. at 45-46 (emphasis added).

Instead, this language shows only that Congress meant to preempt laws concerning tobacco warnings and advertising. Critically, the key language the defendants cite regarding Congress's intent to protect the economy "to the maximum extent" is preceded by Congress's explanation that the whole Act seeks to establish a "comprehensive Federal program to deal with *cigarette labeling and advertising.*" 15 U.S.C. § 1331 (emphasis added); *Altria Group, Inc. v. Good*, 555 U.S. 70, 78 (2008). The Labeling Act protects tobacco manufacturers from "diverse, nonuniform, and confusing cigarette labeling and advertising regulations," not from all economic threats. 15 U.S.C. § 1331. This Court should not "assume that Congress wanted to pursue [its stated] policies 'at all costs.'" *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring in the judgment). Read in context, Congress's economic concerns were limited to labeling and advertising.

Lastly, defendants' "balance" argument proves too much, and, if accepted, would wreck havoc on tobacco control measures nationwide. If, as defendants contend, it were Congress's intent to protect the national economy by protecting cigarette sales—and consumer safety could only be protected with warnings—"any" other law affecting tobacco sales would be preempted. Defs' Br. at 46. By this account, myriad local laws existing during the *Engle* class period taxing tobacco products, imposing tobacco-retailer licensing requirements, raising the age of persons who can purchase cigarettes, limiting the areas where tobacco can be used

("smokefree" laws), and prohibiting sales of particular flavors of cigarettes would all be invalid because they all (as the tobacco industry has long argued) would impact tobacco sales and the economy.[2] The implications would be grave.

The panel opinion, in adopting defendants' "economic balance" argument, did not also adopt defendants' argument that "*any* state law that upsets this balance" is preempted. It concluded only that total restrictions on cigarette sales were preempted. *Graham*, 782 F.3d at 1285. But how did it draw the line there based on Congress's general statement that it wanted to protect the economy? Why only prohibitions on cigarette sales and not prohibitions on purchasing flavored tobacco products, prohibitions on those under 21 buying cigarettes, or any other restriction (or tax)? All could impact the economy. This speculation is precisely the "free wheeling inquiry" of whether state law undermines supposed federal purposes and objectives that the Supreme Court has rejected in recognition that "Congress rather than the courts" gets to displace state law. *Gade*, 505 U.S. at 111 (1992) (Kennedy, J. concurring). And it is exactly why the Supreme Court has rejected

[2] Most of these laws are now (since 2009) explicitly allowed by the TCA, as described below. But according to defendants' argument they would have been preempted prior to that 2009 enactment. For example, the first locality to increase the smoking age to 21 was Needham, Massachusetts, in 2005. Shari Kessel Schneider, et al., *Community reductions in youth smoking after raising the minimum tobacco sales age to 21*, TOBACCO CONTROL, 25:355 (2015). Even after 1965, every state has maintained a tobacco tax. Orzechowski & Walker, *The Tax Burden on Tobacco: Historical Compilation* 10-11 (2014).

obstacle preemption arguments—like this Court should here—based on the contention that a state law "upsets the balance that Congress sought to strike" in enacting a statute. *Whiting*, 131 S. Ct. at 1983.

B. Congress's other tobacco laws enacted during the *Engle* class period fail to demonstrate Congress's intent to preempt states from prohibiting tobacco sales.

The remaining four laws that defendants cite do not strengthen defendants' argument. Defendants do not even describe these laws, and for good reason. Even the brief descriptions below demonstrate that none provides the "clear and manifest" evidence of Congress's preemptive intent.

First, the Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175 (1983), as related to tobacco issues, only required the Secretary of HHS to report every three years to Congress on "current research findings made with respect to . . . the addictive property of tobacco." There is no regulation of tobacco sales and no mention of preemption.

Second, the Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984), mainly updated some of the cigarette warnings and required the Secretary of HHS to conduct additional research and outreach on tobacco-related health dangers. *Id.* Rather than preempt state tobacco laws, it acknowledged their robust presence: the law required the Secretary to "compile and make available

information on State and local laws relating to the use and consumption of cigarettes." *Id.*

Third, the Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (1986), largely extended existing cigarette-related laws to "smokeless" tobacco (e.g., chew tobacco). Like the Labeling Act, this law established a uniform label for smokeless tobacco and preempted state and local governments from requiring any "statement relating to the use of smokeless tobacco products and health . . . on any package or in any advertisement" (except billboards). But, at the same time, the Act "preserved state-law damages actions based on those products." *Cipollone*, 505 U.S. at 518; 15 U.S.C. § 4406 ("Nothing in this [Act] shall relieve any person from liability at common law or under State statutory law to any other person."). *See also* S. Rep. No. 99-209, 99th Cong., 1st Sess., 14 (1985) ("[T]he Committee [on Labor and Human Resources] wants to emphasize that . . . it does not intend to preempt . . . product liability suits in State or Federal courts.")

Lastly, the ADAMHA Reorganization Act, Pub. L. No. 102-321, § 202, 106 Stat. 394 (1992), established federal block grants to fund programs targeted at reducing youth tobacco use. Grants were contingent on states making tobacco sales illegal to those under 18 years old. *Id.* Therefore, none of these laws individually, or

considered together with the Labeling Act, preempts state or local governments from prohibiting tobacco sales.

C. The Tobacco Control Act explicitly preserves states' ability to prohibit tobacco sales, demonstrating Congress's intent to maintain state power to prohibit tobacco sales even as the federal government further regulated tobacco.

Though enacted after the *Engle* class period, the TCA reflects Congress's longstanding decision not to step on states' authority to prohibit tobacco sales. The TCA gave the FDA authority to regulate tobacco products for the first time, but specifically stated that the FDA "is prohibited from" "banning all cigarettes." 21 U.S.C. § 387g(d)(3). Because Congress prevented the FDA from banning cigarettes, defendants assumed (as did the panel) that the TCA also prevented states from doing so, and they cited the TCA as "reinforc[ing]" their preemption argument. Defs' Panel Br. at 18.

In the TCA, however, Congress explicitly preserved a state's power to prohibit the sale of tobacco products. The TCA's "preservation clause" saves for states the power to create laws "*prohibiting the sale*, distribution, possession, exposure to, . . . or use of tobacco products." 21 U.S.C. § 387p(a)(1) (emphasis added); *see also U.S. Smokeless Tobacco Mfg. Co. v. New York*, 708 F.3d 428, 436 (2d Cir. 2013). Even as Congress prohibited the FDA from banning certain categories of tobacco products, it ensured that states retained the power they always had to prohibit tobacco sales. 21 U.S.C. § 387; *Austin*, 179 U.S. at 362. Thus, while the panel

correctly concluded that the TCA makes "textually explicit what was already evident" in prior tobacco-related legislation, *Graham*, 782 F.3d at 1279, it misunderstood the congressional scheme: Congress never intended to ban cigarettes as a national matter, but neither did it block states from acting within their own borders.

Defendants have changed tune in their en banc briefing, emphasizing only that the TCA was not operative during the class period, and thus is irrelevant. Defs' Br. at 45. But they cannot have it both ways. They already acknowledged (and the panel agreed) that the TCA did not change course with respect to preempting state sales prohibitions. Indeed, the TCA legislative history demonstrates that Congress considered eliminating state authority to prohibit tobacco sales, but decided not to, instead opting to maintain the existing scheme. *See U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 433 n.1 (explaining that earlier drafts of the TCA "would have expressly reserved to the federal government authority to ban the sale of entire categories of tobacco products" but as passed "does not forbid such bans by state and local governments"). The TCA simply made explicit that states continue to retain their inherent authority to prohibit tobacco sales.

II. *Brown & Williamson* does not demonstrate Congress's intent to preempt state governments from prohibiting tobacco sales.

Rather than analyze the relevant statutes, defendants rest their preemption argument entirely on the Supreme Court's decision in *B&W*. Defs' Br. at 44-46.

But *B&W* is not a preemption case; it demonstrates only that Congress did not want the *FDA* to enact a national prohibition on tobacco sales—it says nothing about Congress's intent as to whether *states* may do so. Thus, *B&W* cannot make defendants' case for them.

A. The Supreme Court held that Congress did not delegate authority to the FDA to prohibit tobacco sales.

In *B&W*, the Court considered whether Congress had delegated to the FDA the authority to regulate tobacco products when it gave the FDA the authority to regulate "drugs" and "devices" in the Food, Drug, and Cosmetic Act ("FDCA"). 529 U.S. at 125. The FDA had "expressly disavowed any such authority since its inception," *id.*, a fact the Court repeatedly emphasized, *see id.* at 130-31, 144, 148, 151, 152-53, 156, 159. In the face of research linking tobacco to cancer, heart disease, and "unfavorable pregnancy outcomes," the FDA told Congress for 35 years that the agency had no authority to act. *Id.* at 153. Congress considered giving the FDA authority to regulate tobacco products, *id.* at 147, 144, but "Congress' consistent judgment [was] to deny the FDA this power," *id.* at 160. Instead, "act[ing] against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco," Congress itself passed measures regulating tobacco, namely the six statutes described above. *Id.* at 143-44.

As Congress passed the Labeling Act and other statutes described above, it created a "distinct regulatory scheme to address the problem of tobacco and health," but "stopped well short of ordering a ban." *Id.* at 144, 138. This observation was critical to the Supreme Court's decision. If the FDA regulated nicotine as a "drug" (and cigarettes as "combination products"), the Court reasoned that the FDA would be required to ban cigarettes because there is no way to make them safe. *Id.* at 137. How could Congress have simultaneously (1) delegated authority over tobacco products to the FDA, which would require a ban, and (2) passed laws mandating cigarette warnings, giving block grants to States to reduce tobacco use, and the like? This "apparent anomaly" demonstrated to the Court that Congress had not given the FDA such power. *Id.* at 130.

B. Congress's intent with respect to the FDA does not control the preemption question here.

The Supreme Court's holding in *B&W* does not govern the question here: whether *states* can prohibit sales of tobacco products. The question of agency *delegation* and state *preemption*—though both rest on congressional intent—require different showings. As the Court explained, "an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Id.* at 161. The FDCA gave the FDA power over "drugs" and "devices." *Id.* at 126. Given tobacco's "unique place in American history and society," the Court was "confident that Congress could not have intended to

delegate a decision of such economic and political importance [as prohibiting tobacco] to an agency in so cryptic a fashion." *Id.* at 159-60. The absence of a more concrete delegation was fatal to the FDA's regulatory authority.

By contrast, the absence of concrete congressional intent to preempt means that states *retain* their inherent authority to prohibit sales of tobacco products. For preemption, Congress must intend affirmatively to block state authority in an area. *Wyeth*, 555 U.S. at 565. *B&W* did not need to, and did not, reach that question, because the only issue was whether the *FDA* could prohibit tobacco products. Congress's intent with respect to the FDA has no bearing on its intent regarding state power over sales restrictions. That is especially true because states have had the authority to regulate, and even prohibit, tobacco products for over a hundred years. *Austin*, 179 U.S. at 362.[3] Just as it would be "cryptic" for Congress to have delegated the FDA power to prohibit tobacco products without a greater showing, *B&W*, 529 U.S. at 160, it would likewise be "cryptic" for Congress to usurp well-established state power without more. Cryptic silences cannot justify preemption.

Defendants emphasize that, in *B&W*, the Court concluded that Congress "foreclosed the removal of tobacco products from the market." Defs' Br. at 44. But what Congress "foreclosed" as a matter of federal policy is not the same as its intent

[3]Fifteen states prohibited the sale of cigarettes in the late nineteenth and early twentieth century. Robert N. Proctor, *Why ban the sale of cigarettes? The case for abolition*, TOBACCO CONTROL, 22:i27 (2013).

with respect to state preemption. Congress's decision not to prohibit tobacco products nationwide does not mean Congress intended to block the states from imposing tobacco sales restrictions within their own borders. The TCA's preservation clause proves that point. And, as discussed further below, the decision not to prohibit cigarettes at the federal level is fully consistent with a congressional desire to give the states autonomy to experiment with their own regulatory approaches.

Moreover, even if (as defendants argue) Congress passed tobacco-related statutes on the "collective premise . . . that cigarettes and smokeless tobacco products will continue to be sold in the United States," that does not mean that states must allow their sale. *Id.* Congress may have assumed that most, or even all, states would continue to allow tobacco sales. But that does not mean it thwarted states' freedom to make their own decisions. Background assumptions do not have preemptive effect. *B&W* does not speak to preemptive intent, and thus is not controlling here.

III. Adopting defendants' preemption arguments would disrupt federalism and block states from developing new public health measures.

Defendants have argued for (and the panel adopted) a dangerously low standard for obstacle preemption: when Congress engages in limited product regulation, states cannot do more, lest they upset some presumed "balance"

Congress intended to achieve. And defendants' amici further seek to eliminate the presumption against preemption altogether. Br. of Washington Legal Foundation at 25. Such a rule would have dangerous implications for the dynamic relationship between the states and federal government in developing public health measures.

The "high threshold" required for obstacle preemption, *Whiting*, 131 S. Ct. at 1985, protects states' ability to legislate for the health of their citizens and enact innovative public health policies—measures that, once proven effective, are often adopted by Congress. States, of course, retain paramount authority to protect the health and wellbeing of their citizens. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" (quoting *Slaughter-House Cases,* 16 Wall. 36, 62 (1873)). That autonomy helps states serve a valuable role "as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring). "It is one of the happy incidents of federalism that a single courageous State may, if its citizens choose, serve as a laboratory" for the rest of the country. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

Public health scholars recognize that "[s]tates serve a vital function as laboratories of legislative ingenuity in meeting the disparate public health needs

across the nation." James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 356 (1998). "[R]esults from actual field implementations of laws and regulations . . . facilitat[e] diffusion of successful approaches to other jurisdictions, resulting in major improvements in population health." Alexander C. Wagenaar & Kelli A. Komro, *Natural Experiments: Design Elements for Optimal Causal Inference* 24 (2011); *see also* Scott Burris et al., *Making the Case for Laws that Improve Health: A Framework for Public Health Law Research*, 88 MILBANK Q. 169, 185-88 (2010) (changes in law can be used to evaluate a law's efficacy and guide further policy development).

This iterative dynamic between the states and federal government is responsible for key nationwide public health measures, including, among many others, the ban on lead paint, the ban on trans fats, and calorie labeling on restaurant menus. Lead paint is now a well-known toxin, but it was not until the 1950s that some cities began regulating its use. *See* Gerald Markowitz & David Rosner, *Lead Wars* 29 (2013). Baltimore, New York, and other major cities passed the first "ordinances that required warnings on [paint] containers and restrictions on the sale of lead paints for use on walls, woodwork, and other surfaces accessible to children." *Id.* The federal government eventually caught on. In 1971, for example, it began regulating lead paint in public housing, but did not prohibit lead paint use more generally. *See* Lead-Based Paint Poisoning Prevention Act, Pub. L.

No. 91-695, 84 Stat. 2078 (1971); Markowitz & Rosner, *Lead Wars*, at 57. Even though Congress decided not to ban lead paint at that time, other states and localities took that step, recognizing the huge dangers that lead poisoning present to children. *See, e.g.,* N.Y. Pub. H. Law § 1372 (banning use of lead paint on interior surfaces and for children's toys and furniture). Again, the federal government followed the lead of states, and later banned lead paint use more generally in 1978. *See* 16 C.F.R. § 1303 (1977).

The same is true of trans fats. In response to the dangers caused by trans fats, the FDA decided to require nutrition labels to include trans fats starting in 2006 (the rule was adopted in 2003) so that consumers could make informed choices. 21 C.F.R. 101.9(c)(2)(ii) (2003). But localities and states felt this measure was insufficient to protect public health. In 2005, New York City asked restaurants to voluntarily eliminate trans fats and mounted a public education campaign. Marc Santora, *Hold That Fat, New York Asks Its Restaurants*, N.Y. TIMES (Aug. 11, 2005). When the City found that measure lacking, it banned trans fats in December 2006. N.Y.C. Health Code §81.08. Philadelphia soon followed in 2007. Phil. Code § 6-307. In 2008, California passed a bill banning trans fats statewide. Cal. Health & Safety Code § 114377 (2008). Though the federal government had only regulated trans fats with ingredient labels, localities experimented with prohibiting the product. Given the success in these cities and states, the federal government has

now followed, and trans fats must be removed from all processed foods nationwide by 2018. *See* 80 Fed. Reg. 34650 (June 17, 2015).

Laws requiring restaurant chains to include caloric counts on their menus provide yet another example of a public health measure that developed from the ground up. In 2006, New York City passed the nation's first law requiring caloric disclosure on restaurant menus. N.Y.C. Health Code §81.50 (2006). "Momentum for similar requirements grew around the country, leading at least 20 jurisdictions to pass similar laws." Mark Pertschuk, et al., *Assessing the Impact of Federal and State Preemption in Public Health: A Framework for Decision Makers*, JOURNAL OF PUBLIC HEALTH MGMT. AND PRAC. 215 (2012). The restaurant industry challenged New York City's law, claiming it was preempted by the Nutrition Labeling and Education Act of 1990 ("NLEA"). At the time NLEA was enacted, many of that Act's supporters wanted the law's mandatory nutrition labeling provisions to apply to restaurant foods, but such coverage "was vociferously opposed by the National Restaurant Association," Laura Sims, *The Politics of Fat: Food and Nutrition Policy in America* 200 (1998), and ultimately excluded. 21 U.S.C. § 343(q)(5)(A)(i). Though Congress decided not to require restaurant menu labeling, the Second Circuit held that state and local authority remained intact. Following the jurisdictions that experimented with menu labeling, Congress later incorporated a nationwide

requirement for menu labeling into the Affordable Care Act. *See* 21 U.S.C. § 343(q)(5)(H)(i) (2012).

Under the rule defendants propose, these key public health measures may not have survived scrutiny for "obstacle" preemption. As these examples demonstrate, when Congress regulates in an area, or decides not to ban a product, state and local laws are not preempted unless Congress specifically intends to cut off state autonomy and experimentation. Given these high stakes, courts presume that Congress does not want to disrupt state autonomy and dynamic federalism. "'[P]articularly in those [instances] in which Congress has legislated . . . in a field which the States have traditionally occupied,'" courts "'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485).

Multiple jurists have deemed obstacle preemption particularly suspect because, unlike other types of preemption, it is based neither on an express clause nor on the inability to comply with both federal and local laws. *See Hillman v. Maretta*, 133 S. Ct. 1943, 1955 (2013) (Thomas, J., concurring) (criticizing obstacle preemption, because it "looks beyond the text of the enacted federal law and thereby permits the Federal Government to displace state law without satisfying . . . the Bi-cameral and Presentment clause"); *Geier*, 529 U.S. at 907 (Stevens, J.,

dissenting) (requiring "that Congress speak clearly when exercising" preemptive power "serves as a limiting principle that prevents federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"). Accordingly, courts have limited obstacle preemption to areas where state laws "directly interfere[] with the operation" of a federal program. *Whiting*, 131 S. Ct. at 1983. "To stay experimentation in things social and economic is a grave responsibility," *New State Ice Co.*, 285 U.S. at 311 (Brandeis, J., dissenting), one not justified by the lack of Congress's preemptive intent here.

CONCLUSION

For these reasons, amici respectfully request that this Court affirm the verdict.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

I hereby certify that my word processing program, Microsoft Word, counted 6,987 words in the foregoing brief, exclusive of the portions excluded by Rule 32(a)(7)(B)(iii). This brief also complies with the typeface and type style requirements of Rules 32(a)(5) and 32(a)(6) because it appears in 14-point roman Baskerville, a proportionally spaced typeface.

/s/ Rachel Bloomekatz

May 20, 2016 Rachel Bloomekatz

CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2016, I electronically filed the foregoing Brief for American Cancer Society Cancer Action Network, American Lung Association, Americans for Nonsmokers' Rights, Campaign for Tobacco-Free Kids, NAATPN, Inc., National Association of County and City Health Officials, Tobacco Control Legal Consortium, and Truth Initiative with the Clerk of the Court of the U.S. Court of Appeals for the Eleventh Circuit by using the Appellate CM/ECF system. All participants are registered CM/ECF users, and will be served by the Appellate CM/ECF system.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

ADDENDUM: IDENTITY OF AMICI CURIAE

American Cancer Society Cancer Action Network

American Cancer Society Cancer Action Network is the nation's leading cancer advocacy organization, working every day to make cancer issues a national priority. Many of the most important decisions about cancer are made outside of the doctor's office. Instead, they are made by government officials at the federal, state, and local levels—including in courts across the nation that rule on legal cases about tobacco control. ACS CAN works with over one million volunteer advocates on effective tobacco control across the nation.

American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. Because smoking is a major cause of lung cancer and chronic obstructive pulmonary disease (COPD), the American Lung Association has long been active in research, education, and public policy advocacy regarding the adverse health effects caused by tobacco use, as well as efforts to regulate the marketing, manufacture, and sale of tobacco products.

Americans for Nonsmokers' Rights

Americans for Nonsmokers' Rights is a national advocacy organization with more than 8,000 members which promotes the protection of everyone's right to breathe smoke-free air, educates the public and policy-makers regarding the dangers of secondhand smoke, works to prevent youth tobacco addiction, and tracks and reports on the adversarial effects of the tobacco industry.

Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco. It works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit, and protect everyone from secondhand smoke.

NAATPN, Inc.

NAATPN, Inc. works to address the health impact of tobacco products on African Americans through education and advocacy. It is the parent organization of the National African American Tobacco Prevention Network, a Centers for Disease Control and Prevention-funded network that focuses on assessing the impact of tobacco within disparate populations, identifying gaps in data, crafting

interventions, and conducting research involving African Americans and tobacco use.

National Association of County and City Health Officials
The National Association of County and City Health Officials (NACCHO) is the voice of the 2,800 local health departments across the country. Local health departments develop policies and create environments that make it easier for people to be healthy and safe, including informing the public of the hazards of tobacco use, reducing youth access to tobacco, and limiting exposure to secondhand smoke.

Tobacco Control Legal Consortium
The Tobacco Control Legal Consortium is a national network of nonprofit legal centers that provides technical assistance to public officials, health professionals, and advocates concerning legal issues related to tobacco and public health. The Consortium serves as amicus curiae in cases where its experience and expertise may assist courts in resolving tobacco-related legal issues of national significance. Many of the Consortium's briefs—in the United States Supreme Court, United States Courts of Appeals, and state and federal courts around the nation—have addressed issues related to federal preemption and state and local government authority to regulate the sale of tobacco products. The Consortium exists to protect the public from the devastating health consequences of tobacco use. It has a strong interest in ensuring that state and local governments retain the authority to address tobacco use and exposure in their communities.

The Tobacco Control Legal Consortium's activities are coordinated through the Public Health Law Center, at William Mitchell College of Law in St. Paul, Minnesota. The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland School of Law, Baltimore, Maryland; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey; and the Public Health Advocacy Institute and Center for Public Health and Tobacco Policy, at Northeastern University School of Law, Boston, Massachusetts.

Truth Initiative
Truth Initiative is a national public health organization that is inspiring tobacco-free lives and building a culture where all youth and young adults reject tobacco. The truth about tobacco and the tobacco industry are at the heart of its proven-

effective and nationally recognized truth® public education campaign, its rigorous and scientific research and policy studies, and its innovative community and youth engagement programs supporting populations at high risk of using tobacco. The Washington D.C.-based organization, formerly known as the American Legacy Foundation, was established and funded through the 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories and the tobacco industry.