No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF GLOBAL ACTION TO END SMOKING, INC. AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*[*]

Global Action to End Smoking, Inc. is an independent nonprofit dedicated to ending the smoking epidemic. In furtherance of its charitable mission, Global Action funds research around the world to advance public-health knowledge, empower smokers to quit, and help tobacco farmers in the developing world to identify new livelihoods. Through September 2023, Global Action received charitable gifts from PMI Global Services, Inc. In October 2023, the organization received a final grant from PMI and adopted a policy not to seek or accept funding from companies that produce tobacco or nonmedicinal nicotine products.

This case matters to Global Action because tobacco-control thought leadership is at a crossroads. All responsible stakeholders in this arena share the goal of ending the needless suffering and premature death caused by cigarette smoking. And all agree that children and youth must not fall prey to nicotine addiction in any form, particularly to the uniquely deadly harms of smoking. But neither can we ignore the tens of millions of existing adult smokers in the United States who continue to suffer from cigarette addiction. To balance those public-health concerns, tobacco-control efforts should involve harm reduction: minimizing to the greatest extent possible the morbidity and mortality resulting from the widespread use of conventional, combustible cigarettes. Instead of fighting an all-or-nothing crusade, we must help those adults who are unable or unwilling to cease

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[*] No counsel for any party authored this brief in whole or in part, and no person or entity aside from *amicus* and its counsel funded the brief's preparation or submission.

nicotine use by (i) substantially reducing their exposure to harmful chemicals and (ii) supporting alternatives that would allow them to switch away from smoking and toward lower-risk, less-harmful products. To date, science has shown electronic cigarettes to be the best-positioned alternative to allow adults to make that potentially life-saving change.

Global Action offers this brief to explain how e-cigarettes fit within the harm-reduction framework that Congress adopted in the Family Smoking Prevention and Tobacco Control Act. That statute tasked the Food and Drug Administration with fostering the development of less-harmful tobacco products, with the goal of reducing harms from combustible tobacco use. The Fifth Circuit's decision vacating FDA's current regulatory approach to e-cigarettes provides an opportunity to refocus on that mandate.

SUMMARY OF ARGUMENT

Every year, smoking cigarettes and similar combustible tobacco products kills nearly half a million adult Americans. Tens of millions more are currently addicted to cigarettes. If these adult smokers cannot or will not stop using nicotine, they need effective tools to substantially reduce the harms caused by smoking. The Family Smoking Prevention and Tobacco Control Act lays out a pragmatic strategy for tackling that problem. But the Food and Drug Administration strayed from that sensible, science-based harm-reduction approach, adopting an all-or-nothing stance that exalts outright cessation and all but ignores the harm-reduction strategy that Congress mandated. Beyond departing from Congress's intent, FDA's position ignores overwhelming scientific evidence that e-cigarettes containing flavor additives have an im-

portant role to play in moving adult smokers down the continuum of risk. The Court should take this opportunity to ensure that FDA's scorched-earth regulatory approach does not deprive adult smokers of that important tool.

I. The Tobacco Control Act grew out of a robust debate over the best way to regulate the use of tobacco. In *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), this Court held that Congress had not authorized FDA to regulate and ban tobacco under its power to regulate drugs and devices. That decision sparked a national conversation about the principles that should govern tobacco policy. Eventually a consensus developed in the public-health community around a strategy of harm reduction. The Tobacco Control Act embodies that consensus—calling on FDA to "reduce the risk of harm," Pub. L. No. 111-31, sec. 2(44), 123 Stat. 1776, 1780 (2009), and oversee the development of "less harmful tobacco products," *id.* sec. 3(4), 123 Stat. at 1782.

II. E-cigarettes have proven to be a powerful harm-reduction tool. When a traditional cigarette burns, it releases nicotine, the primary reason that many people continue smoking in the face of great risk. Although nicotine is addictive, it does not itself cause the diseases and death resulting from combustible tobacco use. Instead, those harms come from the over 7,000 other chemicals—including at least 70 known carcinogens—that are released when tobacco burns. These compounds lodge in the lungs, increasing the risk of cancer, heart disease, and respiratory illnesses not only for the smoker but also for those nearby.

E-cigarettes use a fundamentally different means of delivering nicotine to smokers. Instead of burning tobacco, e-cigarettes use a heating coil and a liquid res-

ervoir, and they emit aerosolized water vapor, not deadly particulate matter known as "tar." That makes them far less dangerous than cigarettes. It also makes them a powerful, lower-risk alternative for adult smokers who are not ready to quit nicotine outright. Indeed, dozens of peer-reviewed studies show that e-cigarettes may be better than patches, gums, and other cessation therapies at reducing the long-term risks and harms of smoking tobacco.

E-cigarettes with flavors not associated with traditional cigarettes (that is, flavors other than tobacco or menthol) can boost that potential even further. A growing body of evidence demonstrates convincingly that such flavors play an important role in adults' decisions about stopping cigarette use. On the one hand, studies suggest that adult smokers who have flavor options are more likely to move from cigarettes to e-cigarettes. Conversely, restricting flavor options for adults makes adult smokers less likely to switch—and more likely to relapse if they do. In short: extensive experience, combined with mounting scientific evidence, shows that flavored e-cigarettes are exactly the sort of tool that Congress envisioned when it told FDA to identify and encourage the use of less-harmful alternatives.

III. FDA's approach in recent years has given short shrift to that evidence—and to the adult smokers who need effective harm-reduction tools. The Tobacco Control Act does not narrowly task FDA with deciding whether the benefits of a new tobacco product outweigh its risks. A positive benefit-risk ratio is how FDA has always defined "safety," and *Brown & Williamson* rightly observed that non-medicinal tobacco products could never be "safe" in that sense. Instead, the Act created an entirely new standard, which asks

whether the introduction of a new tobacco product will be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). The Act specifies that answering this question requires balancing (i) the odds that the new tobacco product would help current tobacco users against (ii) the risk that it might lead individuals to newly take up or return to tobacco products. *See id.* § 387j(c)(4)(A)–(B).

Unfortunately, FDA has not faithfully balanced those factors. It has generally ignored the first prong, brushing past the benefits that e-cigarettes—and especially flavored e-cigarettes—offer adult smokers. Instead, it has focused single-mindedly on the risk that youth might begin using these products. At the same time, FDA has also refused to consider creative proposals to address the risk of youth uptake (e.g., technological advances in device design that allow for e-cigarettes to be "locked," novel age-verification techniques at the point of sale, and marketing restrictions), *without* depriving adult smokers of access to an important harm-reduction tool. The result is a *de facto* ban on flavored e-cigarettes.

That approach strays from FDA's harm-reduction mandate, and it disserves the millions of Americans who face extremely high risks from smoking. Smoking prematurely kills one in two long-term smokers, and its harms fall hardest on Americans with lower education and income levels, those living in rural areas, Native Americans, members of the LGBTQIA+ community, military servicemembers, and people with mental-health conditions and substance-use disorders. While these Americans urgently need support from our Nation's public-health authorities, a very real consequence of FDA's ban on flavored e-cigarettes is that more people are likely to die from

smoking cigarettes and other combustible tobacco products. That is not what Congress intended when it told FDA to authorize the sale and distribution of new tobacco products that are appropriate for the protection of the public health.

ARGUMENT

I. The Tobacco Control Act reflects a historic consensus around the public-health benefits of a harm-reduction strategy.

A. *Brown & Williamson* rejected FDA's bid to ban tobacco products.

The story of the Tobacco Control Act begins with this Court's decision in *Brown & Williamson*. For most of its history, FDA "repeatedly informed Congress that cigarettes [we]re beyond" its jurisdiction. 529 U.S. at 146. But that changed in the late 1990s, when the agency declared that its "authority over 'drugs' and 'devices' included the power to regulate, and even ban, tobacco product[s]," *West Virginia* v. *EPA*, 597 U.S. 697, 721 (2022) (citation omitted). FDA then used its new power to issue regulations "concerning tobacco products' promotion, labeling, and accessibility to children and adolescents"—with the promise of more regulatory efforts to come. *Brown & Williamson*, 529 U.S. at 128, 136. Industry groups challenged the regulations, arguing that Congress had not authorized the agency to regulate tobacco. See *id.* at 129.

This Court agreed. In its zeal to regulate tobacco, the agency had created a "dilemma." *Id.* at 139. The Food, Drug, and Cosmetic Act "generally requires the FDA to prevent the marketing" of drugs or devices whose "potential for inflicting death or physical injury is not offset by the possibility of therapeutic bene-

fit." *Id.* at 134 (quoting *United States* v. *Rutherford*, 442 U.S. 544 , 556 (1979)). Here, the challenged regulation "quite exhaustively documented that 'tobacco products are unsafe,' 'dangerous,' and 'cause great pain and suffering from illness.'" *Id.* (quoting 61 Fed. Reg. 44,412 (1996)). So if cigarettes fell within FDA's jurisdiction, the statute by its plain terms "would require the agency to ban them." *Id.* at 137. Yet Congress had "foreclosed the removal of tobacco products from the market"—creating a "regulatory scheme" that was "incompatible with FDA jurisdiction." *Id.* at 137, 156.

The Court also doubted that Congress would have "delegate[d] a decision of such economic and political significance" in "so cryptic a fashion." *Id.* at 160. While an agency's "power to regulate in the public interest must always be grounded in a valid grant of authority from Congress," *id.* at 161, that is especially true in "extraordinary cases." *Id.* at 159, 161. And this was "hardly an ordinary case." *Id.* at 159. Given tobacco's "unique place in American history and society," the Court found it "highly unlikely" that Congress would "implicit[ly] delegat[e]" a decision of such "magnitude." *Id.* at 121, 159.

The Court thus sent the question of tobacco regulation back "where Article I of the Constitution says it belongs—with the people's elected representatives." *Nat'l Fed'n of Indep. Bus.* v. *Dep't of Lab.*, 595 U.S. 109, 124 (2022) (Gorsuch, J., concurring). Eight years of robust debate followed—culminating in the Tobacco Control Act.

B. Public consensus developed around a harm-reduction model.

1. In the early 2000s, two important developments in the public-health sphere marked a growing consensus over the best way to regulate tobacco use.

a. The first came just a year after *Brown & Williamson*. In 2001, the National Academy of Sciences published a landmark report proposing a new strategy for regulating tobacco. The heart of that strategy was harm reduction: minimizing the "adverse consequences" of tobacco products. Inst. of Med., *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* 38–39 (2001) (*Clearing the Smoke*). Recognizing that "a significant proportion of individuals will continue to use tobacco for the foreseeable future," the report "focuse[d] on substituting conventional tobacco use" with "less harmful tobacco products or with pharmaceutical preparations." *Id.* at 25. These included nicotine-replacement products like gums, patches, and inhalers, as well as smokeless-tobacco products. *Id.* at 92–93, 96. The report also predicted "an explosion" of new "cigarette-like products," *id.* at 28—the precursors to today's e-cigarettes. See *id.* at 93–94 (describing a "prototype" device consisting of "flavor beads," a "heat source" to "vaporize" liquid, and a "system that condenses the vapor into an aerosol").

At the same time, the report also called for careful guardrails. Since the 1960s and 1970s, tobacco companies had falsely touted "low tar" cigarettes as "less harmful than conventional cigarettes." *United States* v. *Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 430 (D.D.C. 2006). These claims "impl[ied] a benefit when none ha[d] been proven to exist"—misleading con-

sumers and yielding "no reduction in harm." *Clearing the Smoke* at 121, 218. To avoid similar pitfalls, the report recommended "federal regulation" that "encouraged [manufacturers] to develop and introduce new products that will reduce the burden of tobacco-related disease." *Id.* at 8.

b. The second development came four years later, when a group of researchers, public-health leaders, and tobacco-control advocates launched a "forum for discussion, debate and strategic planning" about "tobacco harm reduction." Mitchell Zeller, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 Tobacco Control 324, 325 (2009) (*Strategic Dialogue*) (cleaned up). Mirroring the "fractured and sometimes divisive debate" playing out in public, those experts approached the question of tobacco regulation from "diverse perspectives." *Id.* at 325–26. Over the course of two years, participants in this "Strategic Dialogue" "reach[ed] a consensus on one long-term vision." *Id.* at 326. The group declined to "embrace a policy of prohibition" that would "ban cigarettes" outright. *Id.* Instead, it echoed the National Academy's call for "harm reduction"—reducing "morbidity and mortality from tobacco" by reducing "the number of people who use cigarettes." *Id.* That, in turn, led the experts to propose two specific "policy objectives." *Id.*

First, all agreed that Congress should pass "effective legislation for tobacco product regulation." *Id.* at 331. Absent "public health-based regulation," the group explained, "there is no way to know" whether "new or existing products will actually reduce exposure and risk." *Id.* at 325. The solution: an "infrastructure and network for product testing and scientific inquiry." *Id.* at 331. Regulators could then "re-

duce the harmfulness of tobacco products" through "evidence-based policy"—from monitoring "access, marketing and promotion," to vetting "risk reduction claims." *Id.* at 324, 329.

Second, the group believed that public policy should focus on a "continuum of risk." *Id.* at 327. Cigarettes are "undoubtedly … more hazardous" than "non-combustible tobacco products," which in turn are "more hazardous than pharmaceutical nicotine products," which are not themselves "absolutely safe." *Id.* at 325, 328. Because outright "cessation" (the safest outcome) is often not a realistic goal, public-health efforts should focus on reducing harm by moving current smokers down the continuum of risk from cigarettes to less-dangerous options. *Id.* at 326, 328. Even then, e-cigarettes were known to be among the most promising options for such harm reduction. While these products were still new, studies had already found that early e-cigarettes produced "significantly lower levels" of "carcinogen-related toxicants" than "conventional combustible" tobacco. *Id.* at 327. As a result, shifting to "the long term and exclusive use" of such products could "create less harm" for "current tobacco users" who were "unable or unwilling" to quit. *Id.* at 326, 328. Cf. CDC, *Current Cigarette Smoking Among Adults in the United States* (2023) bit.ly/CDC_Statistics (estimating 28.3 million adult smokers).

2. Meanwhile, ordinary Americans and their representatives were reaching the same conclusion. A bill "giving the FDA the authority to regulate tobacco" passed the Senate in 2004, but stalled in the House. Inst. of Med., *Ending the Tobacco Problem: A Blueprint for the Nation* 126 (2007). Three years later, "[c]omprehensive" legislation was introduced in both Houses of Congress. *Id.* Spurred by "widespread pop-

ular consensus in favor of aggressive policy initiatives," these bills found "support across most of the political spectrum." *Id.* at 8. Hearings began in late 2007, guided in large part by ideas laid out in the National Academy's report and the Strategic Dialogue. E.g., *The Family Smoking Prevention and Tobacco Control Act: Hearing on H.R. 1108 Before the Subcomm. on Health of the H. Comm. on Energy and Com.*, 110th Cong. 37 (2007) (citing National Academy report).

C. Congress enacted legislation embodying that consensus.

In 2009, Congress passed the landmark Family Smoking Prevention and Tobacco Control Act. The Act authorizes FDA to regulate "tobacco products" that the agency "by regulation deems" subject to the statute. 21 U.S.C. § 387a(b). Echoing the National Academy and Strategic Dialogue, Congress found that FDA has the "scientific expertise" to "reduce the risk of harm" by "evaluat[ing] scientific studies supporting claims about the safety of products." Pub. L. No. 111-31, sec. 2(44), 123 Stat. at 1780. It then called on FDA to ensure "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." *Id.* sec. 3(4), 123 Stat. at 1782.

Congress gave FDA detailed instructions on how to implement its harm-reduction mandate. Unlike the rule this Court reviewed in *Brown & Williamson*, the Act did not leave FDA with "the authority to ban cigarettes … entirely." 529 U.S. at 159. Instead, products already on the market could generally stay on the market. See 21 U.S.C. § 387g(d)(3)(A) (forbidding FDA to "ba[n] all cigarettes"). At the same time, Congress ordered FDA to reissue a modified version of its

previous rule, see *id.* § 387a-1(a)(2), with additional restrictions on the sales and marketing of existing tobacco products, see *id.* § 387a-1(a)(2)(G).

Congress applied a different framework to "new tobacco products." *Id.* § 387j(a)(1). As relevant here, products that were not "commercially marketed in the United States as of February 15, 2007" must go through "[p]remarket review" before they can be sold. *Id.* § 387j(a)(2)(A) (cleaned up). Much like new drugs or medical devices, new tobacco products require premarket review from FDA through a premarket tobacco application or "PMTA." But unlike applications for therapeutic products, a PMTA is not intended to show that the tobacco product will be safe or effective, which makes sense given that it would be impossible for a nonmedicinal tobacco product to provide benefits that outweigh its risks. Cf. *Brown & Williamson*, 529 U.S. at 134–35. Instead, a PMTA must show that marketing the new tobacco product "would be appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), considering the "risks and benefits to the population as a whole," *id.* § 387j(c)(4). And that inquiry turns on an assessment of the "increased or decreased likelihood" that (i) "existing users of tobacco will stop using such products" and (ii) "those who do not use tobacco products will start" doing so. *Id.* § 387j(c)(4)(A)–(B).

II. Flavored e-cigarettes are an important harm-reduction tool.

Smoking kills. It "remains the leading preventable cause of premature death in the United States," U.S. Dep't of Health & Hum. Servs., *The Health Consequences of Smoking—50 Years of Progress* 11 (2014) (*Health Consequences of Smoking*), and it has claimed more than 24 million lives in the last 60 years, com-

pare *id.*, with T. Thuy et al., *New Estimates of Smoking-Attributable Mortality in the U.S. from 2020 through 2035*, 66 Am. J. Preventative Med. 877, 879 (2024). E-cigarettes are a powerful tool for reducing that harm. As dozens of peer-reviewed studies have now shown, e-cigarettes are not only less dangerous than traditional cigarettes but also clearly help adult smokers switch to lower-risk alternative sources of nicotine. And appropriately regulated flavor options boost their potential health benefits, by making smokers more likely to step down the "continuum of risk" and stay there. FDA, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (June 28, 2017), bit.ly/Comprehensive_Approach (*Comprehensive Approach*).

A. E-cigarettes reduce harm by helping adult smokers move down the continuum of risk.

By the early 2000s, public-health researchers recognized that e-cigarettes held significant promise as a harm-reduction tool. The idea is simple. If e-cigarettes are less dangerous than traditional cigarettes, and if "individuals who would otherwise be using conventional cigarettes" would be willing to switch, then e-cigarettes would have "value in reducing exposure and disease." *Strategic Dialogue* at 327–28. While there may not have been "sufficient studies" at that time to be confident in that conclusion, *id.* at 327, the science is now in. E-cigarettes *are* less harmful than traditional cigarettes, and they *are* effective at helping smokers move to lower-risk alternatives.

1. E-cigarettes are less dangerous than traditional cigarettes.

a. Traditional cigarettes are made from shredded tobacco wrapped in paper. When a smoker lights up, the tobacco catches fire and smolders at around 1,100 degrees Fahrenheit. *Clearing the Smoke* at 284. That fire produces smoke, which contains nicotine. See *id.* at 288. With each puff, the smoke passes through a filter at the back of the cigarette, enters the smoker's airways, and is drawn into the lungs. From there, a dose of nicotine is absorbed through the alveoli and enters the bloodstream, reaching the brain ten to fifteen seconds later. See *id.* at 248, 285–87. The nicotine then binds to specialized receptors, "culminating in release of a number of different neurotransmitters." *Id.* at 244. Those chemicals account for nicotine's "pleasurable" and "rewarding" effects. See *id.* at 29, 244. (In other words: the smoker's "high.")

But cigarette smoke contains a lot more than just nicotine. See *id.* at 288. Burning tobacco releases a "complex chemical mixture of more than 7,000 compounds that cause a wide range of diseases." *Health Consequences of Smoking* at 1. In addition, tiny particulates known as "tar" travel easily through the cigarette's filter and into the lungs. See *id.* at 87. Some are exhaled. But the lion's share—"from 50 to 95%"—lodge in the respiratory tract, causing a host of health problems. *Id.* at 285. Cancer is one risk: "there are many carcinogens in tobacco smoke," *id.* at 164, and "20% of all cancers worldwide are attributable to smoking," *id.* at 367. As U.S. data reflect, heart disease is another: "Each year, about 150,000 cardiovascular deaths are attributable to cigarette smoke." *Id.* at 470. And then there are smoking-related respiratory diseases, which cause around 90,000 deaths

in the U.S. annually. See *id.* at 500. All told, cigarettes killed nearly 450,000 Americans smokers last year (to say nothing of the tens of thousands of others harmed or even killed by secondhand smoke). See Thuy, *supra*, at 879 (accounting for current and former smokers).

b. E-cigarettes are different. They provide nicotine for those who cannot or will not stop using it—*without* the tar and with many fewer harmful compounds. The simplest e-cigarettes consist of a battery-powered heating coil and a liquid-nicotine reservoir, all packaged together in a cigarette-like tube. See Inst. of Med., *Public Health Consequences of E-Cigarettes* 55 (2018) (*Public Health Consequences*). When the user inhales through the mouthpiece, the heating coil engages, turning the liquid into a vapor. See *id.* Like the smoke from a cigarette, the vapor from an e-cigarette is drawn into the lungs, where nicotine is absorbed into the bloodstream and then delivered to the brain. But unlike cigarettes, e-cigarettes don't involve burning tobacco or the by-products of combustion.

That difference makes e-cigarettes inherently and significantly less dangerous than combusted products. Cigarette smoke contains "toxic combustion products associated with cancers." *Id.* at 32. By contrast, e-cigarette vapor is mostly aerosolized water and "carrier liquid," *id.* at 75, 155—making e-cigarettes "likely to be far less harmful than combustible tobacco cigarettes," *id.* at 1 (cleaned up). As for nicotine, its health risks are "far fewer and less serious than those of other tobacco constituents." *Clearing the Smoke* at 28–29. In fact, FDA itself has approved numerous nicotine-based products as safe and effective drugs and has approved or cleared others as

medical devices. See FDA, *Want to Quit Smoking? FDA-Approved and FDA-Cleared Cessation Products Can Help* (July 21, 2022), bit.ly/FDA_Nicotine.

c. None of that is to say that e-cigarettes are risk-free. While e-cigarettes are significantly safer than traditional cigarettes, they *do* "emit potentially toxic substances," including "fine particulate matter" and metals. *Public Health Consequences* at 32. "These substances are known to cause adverse health consequences such as cardiovascular and respiratory illnesses." *Id.* For that reason, "[t]he safest nicotine-based products are likely to be therapeutic nicotine products such as the gum, patch and lozenge." *Strategic Dialogue* at 328. Still, after reviewing "more than 800 peer-reviewed scientific studies," the National Academy of Sciences found "conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens"—a meaningful step down the continuum of health risks. *Public Health Consequences* at 604 (cleaned up). And (as we explain next) e-cigarettes may even offer significant benefits over the cessation products that FDA regulates as drugs or devices.

2. E-cigarettes are likely better than FDA-approved cessation aids at helping adult smokers reduce harm.

Recent science suggests that e-cigarettes containing nicotine are not just far less dangerous than traditional cigarettes: "Evidence shows they work better than nicotine replacement therapy" to help smokers switch away from cigarettes. N. Lindson et al., *Electronic Cigarettes for Smoking Cessation (Review)*, Cochrane Database of Systematic Revs. 2023, at 4.

a. Smokers who are trying to stop consuming combustible tobacco products turn to e-cigarettes more often than other tools. After following 15,000 smokers over a two-year period, researchers affiliated with the Centers for Disease Control and Prevention found that more smokers turned to e-cigarettes than to "the nicotine patch, nicotine gum, or other … cessation aids." Ralph S. Caraballo et al., *Quit Methods Used by US Adult Cigarette Smokers, 2014–2016*, 14 Preventing Chronic Disease, at 1–2 (2017). Another group of scientists found the same result among smokers with substance-use disorders. See Olufemi Erinoso et al., *Choice of Smoking Cessation Products Among People with Substance Use Problems in the US*, 158 Addictive Behaviors, at *5 (2024). This all makes perfect sense. Unlike patches and gums, e-cigarettes offer an immediate nicotine dose like that provided by cigarettes. At the same time, e-cigarettes evoke the "combination of pleasant stimuli associated with the [smoking] ritual"—from the "sensations of inhaling and exhaling" to the familiar "hand-to-mouth movements" of smoking a cigarette. *Public Health Consequences* at 257.

b. Perhaps more importantly, dozens of studies have shown that e-cigarettes can help smokers stop using cigarettes more effectively than patches, gums, and other nicotine-replacement options. In a recent meta-analysis, researchers reviewed 88 smoking-cessation studies, involving more than 27,000 participants. See Lindson, *supra*, at *17. Over half of the studies were randomized controlled trials. *Id.* at *18. After analyzing for "risk of bias"—and using "sensitivity analyses" to "remov[e] studies with tobacco or vaping industry funding"—the researchers found "high-certainty evidence" that e-cigarettes "increas[e] quit rates" compared to nicotine-replacement thera-

pies. *Id.* at *37–38. Specifically, "[f]or every 100 people using nicotine e-cigarettes to stop smoking, 8 to 10 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy." *Id.* at *3. Meanwhile, "[n]one" of the studies "detected serious adverse events" from e-cigarette use. *Id.* at *39. In fact, there was "no clear difference" on that score among participants using e-cigarettes, nicotine-replacement therapy, or no treatment. *Id.* at *36.

The big-picture results are just as striking. Every year, public-health researchers track the "smoking cessation rate"—the percentage of survey respondents who (i) smoked a year ago but (ii) have not smoked for the last three months. Shu-Hong Zhu et al., *E-Cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys*, 358 BMJ 3262, at *2 (2017). For decades, "one of the most vexing results in the smoking cessation literature" was that the cessation rate "show[ed] no discernible trend," even as more and more smokers tried FDA-approved quitting aids. *Id.* at *6. But the 2014–15 survey—which "coincided with … [a] dramatic increase in e-cigarette use"—brought a surprise: "the first statistically significant increase in the population cessation rate." *Id.* at *5–6. What changed? "The cessation rate for those who did not use e-cigarettes in 2014–15" was "statistically indistinguishable from those of the previous years." *Id.* at *6. But e-cigarette users "succeeded in quitting at higher rates," and their "increased smoking cessation rate … translated into a higher overall population cessation rate." *Id.* at *5–6. In other words: e-cigarette users appeared to pull the laboring oar.

B. Flavor options boost e-cigarettes' harm-reducing potential.

"There are many reasons to think" that adult smokers benefit from a range of e-cigarette flavor options. Nicola Lindson et al., *An Exploration of Flavours in Studies of E-Cigarettes for Smoking Cessation*, 118 Addiction 634, 635 (2023). For some smokers, "[s]imply having a choice" among flavors could make e-cigarettes a "more desirable quitting aid." *Id.* At the same time, those who find flavors they enjoy might "continue to use" e-cigarettes, "reduc[ing] the risk of relapse to smoking combustible cigarettes." *Id.* Unsurprisingly, studies confirmed the importance of flavor options in helping adults switch—and stay—away from cigarettes.

1. A growing body of evidence suggests that flavor options increase smokers' odds of switching away from cigarettes.

One longitudinal study compared adult smokers who used tobacco-flavored e-cigarettes with those who used other flavors. See Abigail S. Friedman et al., *Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation*, 3 JAMA Network Open (2020). The researchers found that smokers in the second group were 2.3 times more likely to give up cigarettes—a statistically significant difference. *Id.* at *1, *8. Other longitudinal studies show a similar relationship between flavor options and reduced cigarette use. See Anne Buu et al., *The Association Between E-Cigarette Use Characteristics and Combustible Cigarette Consumption and Dependence Symptoms: Results from a National Longitudinal Study*, 84 Addictive Behaviors 69 (2018) (flavor linked to reduced smoking); Julia Cen Chen, *Flavored E-Cigarette Use and Cigarette Smoking Re-*

duction and Cessation—A Large National Study Among Young Adult Smokers, 53 Substance Use & Misuse 2017 (2018) (similar).

Surveys show comparable results. In one study, researchers asked adult e-cigarette users about their flavor preferences and history of smoking. See Alayna P. Tackett et al., *Biochemically Verified Smoking Cessation and Vaping Beliefs among Vape Store Customers*, 110 Addiction 868 (2015). Those who used "fruity, candy or bakery flavors" were 2.5 times more likely to have stopped smoking cigarettes than those who used "traditional" tobacco or menthol flavors. *Id.* at 873. The upshot: "access to a variety" of flavor options is "important for encouraging and assisting" adult smokers to "use e-cigarettes in place of conventional cigarettes." Christopher Russell, *Changing Patterns of First E-Cigarette Flavor Used and Current Flavors Used by 20,836 Adult Frequent E-Cigarette Users in the USA*, 15 Harm Reduction J., at *13 (2018).

2. Conversely, when flavor options are limited, adult smokers are less likely to switch away from cigarettes and, if they do make the switch, are more likely to relapse and return to smoking cigarettes—greatly increasing the risk of harm.

Smokers with fewer flavor options show "reduc[ed] … interest in switching to e-cigarettes." *Id.* Asked how flavor restrictions would have impacted their decision to stop smoking cigarettes, 39.7% of e-cigarette users told researchers that they would have been "[l]ess likely to reduce or quit." See Konstantinos E. Farsalinos et al., *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, 10 Int'l J. of Env't Res. & Pub. H. 7272, 7277 (2013).

Flavor restrictions also make it easier to "rationalize a return to cigarette smoking." Russell, *supra*, at *13. According to a survey, 48.5% of e-cigarette users would experience "increase[d] … cravings for [tobacco] cigarettes" if flavor options were restricted. Farsalinos, *supra*, at 7277. And experimenters found similar results when they simulated the effects of a flavor ban. See John Buckell, *Should Flavours Be Banned in Cigarettes and E-Cigarettes? Evidence on Adult Smokers and Recent Quitters from a Discrete Choice Experiment*, 28 J. Tobacco Control 168 (2019). When researchers "banned" all but tobacco-flavored e-cigarettes, current and former smokers participating in the study were more likely to prefer cigarettes and less likely to choose e-cigarettes. *Id.* at 172.

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All of that evidence boils down to this: Flavor options "increas[e]" the "likelihood that existing users" of cigarettes "will stop using such products." 21 U.S.C. § 387j(c)(4)(A). At the same time, flavor restrictions will "decreas[e]" the "likelihood that existing" smokers "will stop," *id.*—and "increas[e]" the "likelihood that those who do not use" cigarettes anymore will relapse, *id.* § 387j(c)(4)(B). In other words: "by banning flavors … regulators may be doing more harm than good." Tackett at 873. Thus, at a minimum in any balancing test of the best way to "reduce the harm of tobacco use," FDA must consider these data in deciding on a strategy for regulating smoking-related activities.

III. FDA's *de facto* flavor ban strays from the agency's harm-reduction mission.

FDA has given all of these considerations short shrift. To determine whether flavored products are

"appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), FDA must forthrightly assess the odds that they will help current tobacco users and the risk that they might lead youth or others to start using tobacco products. *See id.* § 387j(c)(4)(A)–(B). Unfortunately, FDA has ignored the first prong of that analysis. Here, the agency failed to consider both the available research about flavored products discussed above, as well as the "inferences" that could be drawn from "robust, reliable, and peer-reviewed scientific studies involving *unflavored* products." *Wages & White Lion Invs., L.L.C.* v. *FDA*, 90 F.4th 357, 369 (5th Cir. 2024). At the same time, FDA also overlooked the ways that removing flavor options can deter current smokers from switching away from cigarettes and lead former smokers to relapse. See 21 U.S.C. § 387j(a)–(b). Finally, after ignoring both bodies of evidence, the agency claimed that "the risks to youth" were controlling across the board. *Wages & White Lion*, 90 F.4th at 370. It has used this same logic to reject over a million flavored-product applications. See *id.*

Such a wholesale rejection is not true to FDA's statutory mission. When Congress passed the Tobacco Control Act, it envisioned the introduction of new, less-harmful tobacco products, and it tasked FDA with considering the risks and benefits that those products could bring to both users and nonusers. But instead of carrying out that mandate, FDA has all but outlawed products that could save lives by helping adults who smoke move down the "continuum of risk," *Comprehensive Approach*—even as cigarettes remain widely available. Congress has already weighed in and rejected that all-or-nothing approach. Straying from Congress's harm-reduction mandate

disserves the millions of adult Americans who need more effective and more easily accessible tools to stop smoking. See Clifford E. Douglas et al. *The American Cancer Society Public Health Statement on Eliminating Combustible Tobacco Use in the United States,* American Cancer Society Public, 68 CA: Cancer J. Clin. 240, 240–41 (2018).

A. Things were not always this way. Just seven years ago, FDA promised to "recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution." *Comprehensive Approach*. That, in turn, required the agency to "foste[r] innovation when it comes to potentially less harmful forms of nicotine delivery." *Id.* This was especially true of the "extraordinary opportunity" offered by new "technolog[y] to deliver nicotine, for those who need it, that doesn't bring with it the deadly consequences of burning tobacco and inhaling the resulting smoke." *Id.*

But FDA soon changed course. In 2018, public-health experts announced that youth had begun using e-cigarettes at alarming levels, leading to an "epidemic of e-cigarette use among teenagers." FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use* (Sept. 11, 2018), bit.ly/FDA-Statement.

Then, a year later, news broke that some users were being hospitalized with a serious, sometimes fatal, lung disease—later traced to illicit "THC vapes" laced with Vitamin E acetate. Michael F. Pesko et al., *United States Public Health Officials Need to Correct E-Cigarette Health Misinformation*, 118 Addiction 785, 785 (2023). While "no research has identified any chemicals found in nicotine e-cigarettes" as the culprit, the outbreak led to "an immediate increase in

the perceived risks of e-cigarettes." *Id.* Soon afterward, influential advocacy groups began to exploit this public alarm by calling for the "banning [of] all flavored e-cigarettes"—never mind that the incidents of lung disease had nothing to do with those products. Bloomberg Philanthropies, *Bloomberg Philanthropies Launches New $160 Million Program to End the Youth E-Cigarette Epidemic* (Sept. 10, 2019), bloombg.org/3YRYftS.

Rather than responding to this misinformation in a measured or scientific fashion, FDA allowed itself to be a captive of these advocacy efforts. See Jeffrey Weiss, *The Regulatory Capture of FDA's Tobacco Policy—and How to Reverse It*, 79 Food & Drug L.J., at *31–32 (2024). Within months, the agency vowed to "prioritize enforcement resources" against flavored e-cigarettes and issued a guidance document outlining its plans. *Wages & White Lion*, 90 F.4th at 366. Then, in 2021, it "announce[d] the *en masse* denial of 55,000 flavored e-cigarette applications." *Id.* at 370. Another 946,000 denials followed a month later. *Id.*; see also Nyah Phengsitthy, *FDA to Launch Updated Portal for Tobacco Product Applications*, Bloomberg Law (July 15, 2024), bit.ly/FDA_Applications (noting that FDA has received 27 million applications for e-cigarette products and granted only 27). Advocacy groups praised these efforts—and urged the agency to go further. In a statement supporting the President's choice for FDA Commissioner, one group "urge[d]" the nominee to "eliminate all flavored tobacco products, including flavored e-cigarettes." Campaign for Tobacco-Free Kids, *Tobacco-Free Kids Strongly Endorses Dr. Robert Califf for FDA Commissioner* (Nov. 12, 2021), bit.ly/Califf_Endorsement.

All the while, agency staff were clashing behind the scenes over how to handle menthol-flavored products. See *Logic Tech. Dev. LLC* v. *FDA*, 84 F.4th 537, 545–46 (3d Cir. 2023). FDA's latest guidance document "excluded menthol-flavored e-cigarettes from its definition of 'flavored' products," reasoning that menthol is "less popular with youth" than other flavors. *Wages & White Lion*, 90 F.4th at 373. Applying that guidance, FDA's Office of Science recommended granting an application for menthol-flavored e-cigarettes. See *Logic Tech.*, 84 F.4th at 545. But the Center for Tobacco Products director disagreed and decided that the same rules should apply to menthol e-cigarettes. See *id.* at 546. So FDA denied that application too. *Id.*

To date, FDA has "consistently denied *all* applications" for e-cigarettes in nontraditional flavors. Weiss, *supra*, at *38. And while it recently granted a handful of applications for menthol-flavored products, it shows no sign of budging on other flavors. See FDA, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products after Extensive Scientific Review* (June 21, 2024), bit.ly/FDA_Menthol. *Amicus* does not doubt that some applications should be denied, lest children be exposed to harm. But we cannot reconcile FDA's much wider categorical ban—and its failure to account for the needs of existing adult smokers—with the balanced approach that Congress mandated.

B. The result is that FDA has imposed a "de facto ban on flavored e-cigarettes." *Wages & White Lion*, 90 F.4th at 384 n.5. But that flies in the face of FDA's harm-reduction mission. Congress tasked FDA with "effective[ly] overs[eeing]" the development, introduction, and promotion of "less harmful tobacco products." Pub. L. No. 111-31, sec. 3(4), 123 Stat. at 1782.

In its zeal to restrict flavors, however, FDA is missing opportunities to reduce harm—and letting the perfect become the enemy of the good. While "quitting all nicotine and tobacco use is the surest way to reduce risk," smokers who are unable or unwilling to do so outright, which includes millions of people, can still "significantly reduce their risk" by "switching to a noncombustible" nicotine source. Clifford E. Douglas, *It is Time to Act with Integrity and End the Internecine Warfare over E-Cigarettes* (Mar. 2021), at 3, bit.ly/Douglas_Integrity.

That is not to diminish the very real risk of youth tobacco use. "[T]here is widespread agreement that adolescents should not use nicotine in any form, including e-cigarettes." Kenneth E. Warner et al., *A Proposed Policy Agenda for Electronic Cigarettes in the US: Product, Price, Place, and Promotion*, 41 Health Affs. 1299, 1299 (2022). That weighty interest calls for creative policymaking—like restricting flavors "favored by youth" while allowing "other flavors with clearly adult-oriented marketing." *Id.* at 1302. By the same token, e-cigarettes should be restricted to "adult-only establishments," *id.* at 1303, and promotion limited to "encourag[ing] smokers who are unable to quit by other means to try using e-cigarettes instead of combustible cigarettes," *id.* at 1304; see also *Wages & White Lion*, 90 F.4th at 369 (noting "marketing and sales-access restriction[s]" to "limit youth access"). Had FDA not "refused even to read" the marketing plans included in Respondent's applications, *id.* at 371, a productive dialogue about these (and other) ideas could have followed.

Instead, FDA swung so far in one direction that it lost sight of Congress's command to consider both "*users* and nonusers." 21 U.S.C. § 387j(c)(4) (emphasis

added). Just as FDA must protect youth from beginning to smoke in the first place, it must also consider the harms that existing American smokers are facing here and now. Those harms are not spread evenly throughout society. Smoking disproportionately affects Americans with lower education and income levels, people in rural areas, Native Americans, members of the LGBTQIA+ community, military servicemembers, and people with mental-health conditions and substance-use disorders. See Jeffrey Drope et al., *Who's Still Smoking? Disparities in Adult Cigarette Smoking Prevalence in the United States*, 68 CA: Cancer J. Clin. 106, 113 (2018). The Tobacco Control Act protects these Americans as well—and millions of other adult smokers. FDA must heed Congress's mandate to account for the harms they face too. Banning flavored e-cigarettes is not the answer Congress mandated.

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By rejecting FDA's categorical approach to dealing with flavored e-cigarettes on procedural grounds, the Fifth Circuit has given the agency a fresh opportunity to implement Congress's intent. In place of the current ban on flavored products, which perpetuates grave risks to American smokers, FDA now can evaluate each application on its merits and determine which products will reduce harm and help adult smokers switch away from cigarettes without encouraging our youth to begin using tobacco products.

CONCLUSION

The Court should make clear that the Tobacco Control Act requires FDA to take a more balanced and nuanced approach to evaluating applications for flavored e-cigarettes.

Respectfully submitted,

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