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.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF SIXTEEN MEMBERS OF CONGRESS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules and Regulations

Other Authorities

INTEREST OF AMICI CURIAE[1]

Amici curiae are sixteen Members of Congress—nine Senators and seven Members of the House of Representatives. *Amici* have a special interest both in protecting and promoting the critical purposes of the Act and in safeguarding the physical health and wellbeing of their constituents. *Amici* are also uniquely positioned to speak to the history and intent of the Act.

Amici are:

- Sen. Richard J. Durbin
- Rep. Frank Pallone, Jr.
- Sen. Jeffrey A. Merkley
- Sen. Ron Wyden
- Sen. Richard Blumenthal
- Sen. Tammy Baldwin
- Sen. Jack Reed
- Sen. Elizabeth Warren
- Sen. Jeanne Shaheen
- Sen. Edward J. Markey
- Rep. Raja Krishnamoorthi
- Rep. Diana DeGette
- Rep. Rosa L. DeLauro
- Rep Kim Schrier, M.D.
- Rep. Debbie Wasserman Schultz
- Reb. Barbara Lee

[1] No counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* or their counsel made a monetary contribution to the preparation or submission of this brief.

Amici believe that the Fifth Circuit's decision setting aside the Food and Drug Administration's marketing denial orders of Respondents' Premarket Tobacco Product Applications (PMTAs) threatens to undermine both the past public health successes of the 2009 Family Smoking Prevention and Tobacco Control Act ("The Act") and its future efficacy. Accordingly, *amici* respectfully urge the Court to reverse the Fifth Circuit and reinstate the marketing denial orders.

SUMMARY OF ARGUMENT

In 2009, Congress recognized that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults."[2] Recognizing the danger, Congress took overwhelmingly bipartisan action, passing the Act and bringing about sweeping changes in the federal oversight of the tobacco market. In the fifteen years since the passage of the Act, the authority of the Food and Drug Administration (FDA) "to address issues of particular concern . . . especially the use of tobacco by young people"[3] has remained "flexible,"[4] allowing FDA to respond to evolving challenges in the marketplace. Nevertheless, youth tobacco use persists at epidemic levels, in large part due to major shifts in the tobacco industry. The advent and widespread adoption of e-

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[2] Family Smoking Prevention and Tobacco Control Act, Public L. No. 111-31 §2(1), 123 Stat. 1776, 1777 (2009).

[3] Family Smoking Prevention and Tobacco Control Act §3(2).

[4] Family Smoking Prevention and Tobacco Control Act §3(4).

cigarettes has been by far the most notable change, especially with regard to youth tobacco use.[5]

FDA has utilized its regulatory and enforcement authorities to address the health threat posed by e-cigarettes, and has done so in a manner consistent with Congressional intent as expressed in the Act: by accepting and reviewing, on a scientific basis, applications for authorization to sell e-cigarettes. Guided by Congress' chief directive—to deny such authorization unless a product under review would be "appropriate for the protection of the public health," determined by whether the product is more likely to help tobacco users quit than to encourage non-tobacco-users to start using tobacco products[6]—FDA has been appropriately mindful of children and teenagers, the most vulnerable pool of non-tobacco-users. Judicial oversight of FDA's decisions on these applications has been generally consistent and has allowed FDA to exercise its statutory authority efficiently and correctly.

But now the Fifth Circuit has set aside FDA's carefully reasoned conclusion that certain sweet and fruity flavored tobacco products—with names like "Milk and Cookies," "Rainbow Road," and "Strawberry Astronaut"—are not appropriate to protect the public health because they are more likely to appeal to youth consumers than they are to help current adult tobacco users quit. The Fifth Circuit does not suggest that FDA's conclusion was incorrect. Nor could it—FDA's

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[5] The e-cigarette market comprises a wide range of products: unless specified otherwise, *amici* use the phrase to refer to devices which "deliver nicotine to their users by vaporizing a liquid derived from tobacco," *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 13 (D.C. Cir. 2022), and, as applicable, the liquids themselves.

[6] 21 U.S.C.A. §§387j(c)(2)(A) (West 2009); 387j(c)(4)(A) (West 2009); 387j(c)(4)(B) (West 2009).

decision on Respondents' PMTAs was substantively correct. Instead, the Fifth Circuit has set aside FDA's marketing orders and would require FDA to unnecessarily re-evaluate Respondents' PMTAs in a less efficient, more resource-intensive manner before reaching the same result and once again denying the applications. This will not only divert FDA resources to completing that exercise, but will invite countless other unsuccessful applicants to challenge their own denial orders, diverting even more scarce FDA resources. While those applications are once again pending FDA review, the tobacco products they cover would continue to be sold, despite the law's clear premarket authorization regime. Simply put, applicants have a powerful financial incentive to challenge a denial order, even if they, like the Fifth Circuit and FDA, know that they will still be unable to meet their burden to make a "a showing that permitting such tobacco product to be marketed would be appropriate for the public health,"[7] and that their applications will, therefore, ultimately still be denied. And the implications of such challenges are not merely procedural; tobacco manufacturers' efforts to keep their products on the market mean that youth tobacco users will be unnecessarily exposed to products that uniquely appeal to them and, in many cases, hook them on tobacco for life.

The key to reducing tobacco related deaths is preventing youth tobacco use, and FDA's authority to oversee e-cigarette products, including by denying authorization to sell specific products, is a foundational intervention in doing so. The Fifth Circuit's decision flies directly in the face of that authority, and threatens to undermine both the Act's success to date and

[7] 21 U.S.C.A. §387j(c)(2)(A).

future federal oversight of tobacco, dragging federal regulation of e-cigarettes backwards and imperiling countless American youth. This Court should reverse the Fifth Circuit; if it were instead to affirm the Fifth Circuit on any basis, the result would be diametrically opposed to the intent of Congress in passing the Act and would have devastating consequences for the American health system and individual Americans.

ARGUMENT

I. CONGRESS PASSED THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT IN AN EFFORT TO ADDRESS A SUBSTANTIAL AND PREVENTABLE PUBLIC HEALTH CRISIS.

In 2009, an estimated 23.9% of high school students and an estimated 8.2% of middle school students used tobacco products.[8] These underage tobacco users also likely represented the vast majority of new users: as of 2014, "[a]lmost 90 percent of adult daily smokers started smoking by the age of 18."[9] And tobacco companies were capitalizing on this: "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth."[10] Although the 1998 Master Settlement Agreement between major tobacco manufacturers and state

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[8] *Tobacco Use Among Middle and High School Students—United States, 2000-2009*, 59 Morbidity & Mortality Wkly. Rep. 1063, 1063 (2010), https://tinyurl.com/wksckt79.

[9] *Youth and Tobacco*, FDA, https://tinyurl.com/eetpx8ck (last updated June 29, 2022).

[10] Family Smoking Prevention and Tobacco Control Act §2(15).

attorneys general had included some limitations on marketing that targeted youth, those limitations had "not been successful in preventing . . . increased use."[11]

Faced with the dire need for sweeping action to address the epidemic of youth tobacco use, Congress responded with the Act, a major piece of legislation combatting the problem from multiple angles. First, and most importantly, it provided clear "authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act. . . recognizing it as the primary Federal regulatory authority with respect to . . . tobacco products."[12] As part of that authority, the Act aimed to ensure that FDA was empowered specifically to address both dependence on tobacco and youth tobacco use,[13] including through the regulation of marketing.[14] The Act also aimed to increase public and consumer information about tobacco products, including information about ingredients and research about health effects of tobacco use.[15] Both houses of Congress passed the Act by overwhelming bipartisan majorities: 79-17 in the Senate[16] and 307-97 in the House of Representatives.[17]

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[11] *Id.*

[12] Family Smoking Prevention and Tobacco Control Act §3(1).

[13] Family Smoking Prevention and Tobacco Control Act §3(2).

[14] 21 U.S.C.A. § 387f(d)(1) (West 2009).

[15] 21 U.S.C.A. §§ 387j(b)(1)(B); 387o(b)(2) (West 2009).

[16] *Roll Call Vote 111th Congress - 1st Session*, U.S. Senate, https://tinyurl.com/4hjpbkzf (last visited Aug. 23, 2024).

[17] *Roll Call 335 | Bill Number: H. R. 1256*, U. S. House of Representatives, https://tinyurl.com/yu7dvmze (last visited Aug. 23, 2024).

a. FDA's exercise of jurisdiction over e-cigarettes effectively furthered the Act's goals with regard to emerging tobacco products.

Despite numerous legal challenges to the Act and FDA's implementation of it,[18] youth use of traditional tobacco products decreased sharply in the years following its passage. From 2011 to 2015, cigarette use among high school students fell from 15.8% to 9.3%, and from 4.3% to 2.3% among middle school students.[19] The Act was working. But even as cigarette and other traditional tobacco use fell among youth, the nascent e-cigarette market was emerging outside the reach of FDA.

Essentially left unchecked, the e-cigarette market exploded, counteracting the Act's substantial progress in reducing youth smoking. In 2011, only 1.5% of high school students used e-cigarettes.[20] But just three years later, by 2014, youth e-cigarette use already exceeded youth cigarette smoking.[21] By 2015, that number had grown to 16%—a more than ten-fold increase

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[18] *See, e.g., Family Smoking Prevention and Tobacco Control Act Litigation Update*, Tobacco Control Legal Consortium (Nov. 20, 2013), https://tinyurl.com/yc35b4f2 (non-exhaustively cataloging "multiple lawsuits challenging the constitutionality of the Act and of the FDA's regulations, the composition of the FDA's Tobacco Products Scientific Advisory Committee, and the preemptive scope of the Tobacco Control Act").

[19] Tushar Singh et al., *Tobacco Use Among Middle and High School Students — United States, 2011–2015*, 65 Morbidity & Mortality Wkly. Rep. 361, 363 (2016), https://tinyurl.com/8mzp4hrr.

[20] *Id.*

[21] *Id.* at 364.

over four years[22]—and was rapidly approaching the proportion of high school students who used *any* tobacco product only six years before. Considered in real terms, the reach and prevalence of e-cigarettes among youth were staggering: 2.39 million high school students and 620,000 middle school students used e-cigarettes in 2015.[23] This explosion was fueled, in large part, by marketing that specifically and purposefully targeted youth: concocting and distributing kid-friendly flavors, offering college scholarships, relying on social media marketing, and sponsoring youth-friendly events.[24]

As youth e-cigarette usage skyrocketed, FDA took action in 2016, promulgating the "Deeming Rule" and asserting jurisdiction over e-cigarette products.[25] FDA did not take action concerning products identified by that Rule until 2020.[26] During the delay, e-cigarettes' hold on youth only continued to grow. In 2018, President Trump's Surgeon General, Dr. Jerome Adams, and FDA Commissioner, Dr. Scott Gottlieb, both declared e-cigarette use among youth to be an "epidemic."[27] By 2019, an estimated 27.5% of

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[22] *Id.* at 363.

[23] *Id.* at 364.

[24] *4 marketing tactics e-cigarette companies use to target youth*, Truth Initiative (Aug. 9, 2018), https://tinyurl.com/23z58hsd.

[25] 21 C.F.R. Pts. 1100, 1140, and 1143 (2016).

[26] "Although the Deeming Rule was set to go into effect in August 2016, various events pushed out its final deadline until September 2020," Pet. App. 69a; *see also* J.A. 126.

[27] Rob Stein, *Surgeon General Warns Youth Vaping Is Now An 'Epidemic*,' Nat'l Pub. Radio (Dec. 18, 2018), https://tinyurl.com/4hws8hk8; *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, FDA (Sept. 11, 2018), https://tinyurl.com/347vy59n.

high school students and 10.5% of middle school students were using e-cigarettes.[28]

Faced with this epidemic, in early 2020, FDA announced prioritized enforcement against e-cigarettes that particularly appealed to youth,[29] including flavored products.[30] The results were astonishing: after e-cigarettes' meteoric rise among youth to that point, usage suddenly began to decrease, with 19.6% of high school students and 4.7% of middle school students using e-cigarettes in 2020.[31] As FDA began issuing its first marketing denial orders to the millions of e-cigarette applications it received,[32] youth usage continued to decline in 2021, with usage rates of 11.3% among high school students and 2.8% among middle school

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[28] Teresa W. Wang, et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA Network Open 1, 2 (June 7, 2021), https://tinyurl.com/u535rk7b.

[29] J.A. 130.

[30] J.A. 129. In describing "flavored" products, FDA excluded "tobacco- or menthol- flavored product[s]." *Id.* *Amici* use the same definition in this brief—unless indicated otherwise, references to "flavored" tobacco products include all flavored products *except* those that are menthol-flavored or tobacco-flavored.

[31] Wang, *supra* note 28, at 1.

[32] FDA issued its first e-cigarette marketing denial orders to about 55,000 flavored products on August 26, 2021. *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health,* FDA (Aug. 26, 2021), https://tinyurl.com/5n93cfb2. Several months later, on October 12, 2021, FDA issued its first authorizations to e-cigarettes. *FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency,* FDA (Oct. 12, 2021), https://tinyurl.com/mrypc927.

students.[33] By 2023, 10% of high school students were using e-cigarettes, though usage among middle school students had increased to 4.6%.[34]

While the decline in youth e-cigarette use since the beginning of FDA regulation of the market has not been perfectly linear, it has been unmistakable: from 27.5% of high school students and 10.5% of middle school students in 2019 to 10% of high school students and 4.6% of middle school students in 2023. FDA's assertion of jurisdiction over the e-cigarette market, and its subsequent exercise of its authority to deny access to the market to those e-cigarettes which are not "appropriate for the protection of the public health,"[35] is among the Act's greatest success stories.

b. FDA's general approach to the Premarket Tobacco Product Application system protects public health.

In exercising its authority, FDA must answer a basic question: does the "likelihood that [a new product will lead] existing users of tobacco products [to] stop using such products"[36] outweigh the "likelihood that [a product will lead] those who do not use tobacco

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[33] Eunice Park-Lee et al., *Notes from the Field: E-Cigarette Use Among Middle and high School Students—National Youth Tobacco Survey, United States, 2021*, 70 Morbidity & Mortality Wkly. Rep. 1387, 1387 (2021), https://tinyurl.com/ywzjmxuk.

[34] Jan Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, 72 Morbidity & Mortality Wkly. Rep. 1173, 1175 (2023), https://tinyurl.com/43r2xcr6.

[35] 21 § U.S.C.A. 387j(c)(2)(A).

[36] 21 § U.S.C.A. 387j(c)(4)(A).

products [to] start using such products?"[37] If a product's likely contribution to tobacco cessation is greater than the harm it will likely cause by enticing new tobacco users, FDA, unsurprisingly, will determine that it is "appropriate for the protection of the public health" and grant authorization. On the other hand, if a product is more likely to attract new tobacco users—who are overwhelmingly young—than it is to aid in cessation, FDA will, unsurprisingly, determine that it is *not* "appropriate for the protection of the public health" and deny marketing authorization. FDA bases its determination on a PMTA submitted by an applicant who wishes to introduce a given product to market.[38] An applicant must demonstrate that its product would be appropriate for the protection of the public health; if FDA finds that there is a "lack"[39] of such a showing, it must deny the application.

FDA has taken this work seriously, issuing authorization orders on applications for 34 different e-cigarette products after determining that their availability would be appropriate for the protection of the public health,[40] while denying applications for a wide variety of flavored e-cigarette products, in no small part because "[y]outh users are more likely to use flavored ENDS [electronic nicotine delivery systems, or e-cigarettes] than adult ENDS users. Flavors are associated with ENDS initiation and progression among youth . . . evidence demonstrates that flavored ENDS

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[37] 21 § U.S.C.A. 387j(c)(4)(B).

[38] 21 § U.S.C.A. 387j.

[39] 21 U.S.C.A. § 387j(c)(2)(A).

[40] *E-Cigarettes Authorized by the FDA*, FDA (July 2024), https://tinyurl.com/ye5xzsnv.

pose a significant risk to youth."[41] This conclusion is inescapable in light of the fact that "non-tobacco flavors were associated with more curiosity, less perceived danger, and greater perceived ease-of-use among high school students, compared to tobacco flavor."[42] Indeed, nine in ten middle and high school students who use e-cigarettes use flavored products.[43]

II. FDA'S CONDUCT IN REVIEWING INDIVIDUAL APPLICATIONS IS LAWFUL AND CONSISTENT WITH BOTH CONGRESSIONAL INTENT AND THE TEXT OF THE ACT.

FDA correctly did the job Congress laid out for it when it reviewed—and denied—Respondents' applications. The Fifth Circuit's conclusions to the contrary rely on a misunderstanding of FDA's role as an expert agency.

a. The Fifth Circuit failed to recognize that FDA is meant to—and does—use its scientific expertise to evaluate evidence in applications.

FDA's review of applications relies on information submitted by applicants—and FDA has given effect to Congress' clear instruction that its determination on whether a product is appropriate for the protection of the public health must be based on "well-controlled

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[41] Pet. App. 304a-305a.

[42] *Technical Project Lead (TPL) Review of Logic Technology PMTAs* 28-29, FDA (Mar. 23, 2022), https://tinyurl.com/4e2erkwj.

[43] *E-Cigarette Use Among Youth*, CDC (May 15, 2024), https://tinyurl.com/4vrb2w5s.

investigations"[44] or, if other "valid scientific evidence"[45] exists, on the basis of that evidence. Specifically, in guidance on submitting a PMTA, FDA advised potential applicants that FDA would "review" information submitted, such as "information on other products . . . with appropriate bridging studies . . . to determine whether it is valid scientific evidence sufficient to demonstrate that the marketing of a product would be"[46] appropriate for the protection of the public health. The burden is on manufacturers to bring forth sufficient information to demonstrate that a tobacco product meets the statutory standard for authorization, which Congress intentionally set as a high bar for the introduction of new products that hold such risk of hazard.[47]

In denying Respondents' applications, FDA noted that the applications lacked "robust and reliable evidence"[48] of the products' potential benefits to public health. FDA went on to list various types of evidence that could have satisfied that requirement: "This evidence could have been provided using a randomized control trial and/or longitudinal cohort study . . . [a]lternatively, FDA would consider other evidence."[49] Far from arbitrarily and capriciously changing its mind *ex post* about the types of evidence it would require, FDA merely provided illustrative examples of types of evidence that could satisfy its requirements.

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[44] 21 U.S.C.A. § 387j(c)(5)(A) (West 2009).

[45] 21 U.S.C.A. § 387j(c)(5)(B) (West 2009).

[46] J.A. 28.

[47] *See supra* notes 38-39 and accompanying text.

[48] *See, e.g.*, Pet. App. 227a.

[49] *Id*.

The Fifth Circuit noted that Respondents had submitted "robust, reliable, and peer-reviewed scientific studies involving *unflavored* products to draw inferences about *flavored* products,"[50] and apparently concluded that simply having *submitted* those studies, among others, constituted adequate scientific evidence of their products' appropriateness to the protection of the public health.[51] This logic ignores FDA's critical role in the application process: to review and *evaluate* applications on a case-by-case basis. Reaching determinations on applications is not a perfunctory box-checking exercise. It requires FDA's "scientific expertise . . . to evaluate scientific studies supporting claims about the safety of products."[52] The obvious reading of FDA's denials is not that the *form* of the evidence Respondents submitted was deficient, but rather that, in the course of its rigorous review of the materials submitted, the agency concluded that the evidence was insufficient to justify a finding that Respondents' products were appropriate for the protection of the public health.[53] Nowhere has FDA indicated that material that purports to constitute information on another product and an accompanying

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[50] Pet. App. 17a.

[51] Pet. App. 32a (characterizing FDA as having denied the applications "because" of the failure to submit the specific studies FDA identified as potentially satisfying the evidence requirement).

[52] Family Smoking Prevention and Tobacco Control Act, §2(44).

[53] *See, e.g.*, *Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 629 (2d Cir. 2023), *pet. for cert. filed*, No. 23-799 (U.S. Jan. 24, 2024) ("FDA never changed its position: that it might accept evidence other than long-term studies to demonstrate that an ENDS product was Appropriate *if* that evidence had sufficient scientific underpinnings. Consistent with its position, FDA considered [applicant's] weak scientific evidence and found it insufficient to support an Appropriate finding.").

bridging study automatically qualifies as "valid scientific evidence." And such a standard would be flatly inconsistent with the plain Congressional instruction that evidence other than well-controlled investigations can justify a finding that a product is appropriate for the protection of public health only "[i]f the Secretary determines that there exists valid scientific evidence . . . which is sufficient to evaluate the tobacco product."[54]

The Fifth Circuit's conclusion that FDA has "imposed an across-the-board ban on *all* flavored products"[55] suffers from a similar logical fallacy. FDA's uniform denial to date of all applications for flavored products does not indicate a determination by FDA that all such products are inherently inappropriate for the protection of the public health. Rather, it indicates only that no evidence sufficient to demonstrate otherwise has been submitted in connection with a PMTA. The only "categorical ban" FDA has enforced is a categorical ban on products subject to applications that fail to meet the statutory requirements for authorization.[56] Indeed, FDA has made clear its

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[54] 21 U.S.C.A. § 387j(c)(5)(B).

[55] Pet. App. 47a.

[56] Indeed, despite having proposed a ban on menthol as a characterizing flavor in conventional cigarettes, Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt 1162) because menthol's "flavor and sensory effects increase appeal and make menthol cigarettes easier to use, particularly among youth and young adults," *id.*, FDA nevertheless recently approved PMTAs for four menthol-flavored e-cigarette products. *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review*, FDA (June 21, 2024), https://tinyurl.com/bdtvhwje. FDA has previously recognized that menthol poses a substantial and unique danger, especially to youth,

openness to the existence of such evidence by identifying potential types of evidence that could demonstrate the appropriateness of such products. Respondents, or any other manufacturer of flavored e-cigarettes, could submit such evidence.[57] The fact that they have not done so suggests that no such evidence is *currently* available; neither *amici* nor the Fifth Circuit are competent to predict whether such evidence could be produced with longer periods of study.

The Fifth Circuit also characterized FDA as having "changed its position on cartridge-versus-open systems"[58] after the 2020 Enforcement Priorities as a prerequisite to imposing the non-existent flavor ban. This ignores both the reason for the evolution in FDA's position and the nature of the 2020 Enforcement Priorities. The 2020 Enforcement Priorities were merely guidance about FDA's intended approach to enforcement actions against illegal e-cigarettes.[59] While that document indicated FDA's intent to prioritize enforcement against cartridge-based systems,[60] it made clear that that enforcement prioritization was based on contemporary data "that youth overwhelmingly use cartridge-based" e-cigarettes, and that FDA

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but still determined that these four products were appropriate for the protection of the public health. It is difficult to imagine clearer evidence that FDA considers each application on its own contents and merits, rather than enforcing an imagined *de facto* position on flavored products.

[57] *See* Pet. App. 167a (providing instructions "[i]f you choose to submit new applications for these products").

[58] Pet. App. 46a.

[59] J.A. 129-131 ("This guidance document describes how we intend to prioritize our enforcement resources . . . guidances describe the Agency's current thinking on a topic").

[60] J.A. 161-167.

would "continue to evaluate new information and adjust these enforcement priorities, as warranted, in light of the best available data about these products."[61] And when those new data indicated that "there is variability in the popularity of device types among youth . . . [but] the role of flavor is consistent,"[62] FDA acted accordingly, reducing its emphasis on device type.[63] Furthermore, even if data had indicated that the factual predicates for the 2020 Enforcement Priorities were still correct, FDA need not have reconciled its enforcement priorities with its PMTA decisions. Indeed, it would not have been inconsistent for FDA to have made the same determinations it has made on every PMTA to date while still continuing to prioritize enforcement against cartridge-based e-cigarettes. Considerations which inform the allocation of limited enforcement resources do not necessarily have any bearing on science-based marketing approval decisions, and neither the Fifth Circuit nor Respondents identified a reason that device type *should* affect marketing approval decisions in this instance.[64]

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[61] J.A. 164-165.

[62] Pet. App. 191a.

[63] *See FDA Denies Marketing Applications*, *supra* note 32.

[64] *See* Pet. App. 47a ("it might very well be true that the agency has the power to impose the policy it wants to impose. . . All that matters here is that the agency . . . changed its position").

b. The Fifth Circuit's decision would slow FDA review of applications for no reason, and without changing the outcome for any given application.

"Promotion and advertising by the tobacco industry *causes* tobacco use, including its initiation among youth,"[65] so it is appropriate that FDA accounts for marketing plans in its review. FDA has noted that "none of the ENDS PMTAs that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns . . . regarding youth use."[66] Even so, FDA acknowledges that "[i]t is theoretically possible that significant mitigation efforts could reduce youth access and appeal such that the risk for youth initiation would be reduced."[67] And FDA should review marketing plans to the extent necessary to determine whether any given plan includes such efforts. But absent any specific indication that an applicant has proposed such a novel mitigation effort, it would be inefficient for FDA to fully review individual marketing plans simply to conclude that, like similar plans before them, they are insufficient to counterbalance the overarching concerns regarding the specific product's impact on youth e-cigarette use.[68] Like

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[65] *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* 508, HHS (2012), https://tinyurl.com/nhh3vh97.

[66] Pet. App. 200a-201a n. xix.

[67] *Id.*

[68] *See, e.g.*, *Liquid Labs LLC v. FDA*, 52 F.4th 533, 544 (3d Cir. 2022) ("Because [applicant] has not shown that its marketing plans differ from those previously rejected or that its plans would

a publisher checking each page of every copy of a book they print despite having no indication that the printing press has malfunctioned, doing so would serve only to delay the review of applications by drowning the agency in paperwork.

III. THE APPROACH TAKEN BY SEVEN COURTS OF APPEALS TO RESPONDENTS' ARGUMENTS IS CONSISTENT WITH THE PURPOSES OF THE ACT, AND AVOIDS THE DEVASTATING CONSEQUENCES INHERENT TO THE FIFTH CIRCUIT'S APPROACH.

Given the significant flaws in the Fifth Circuit's reasoning, it is unsurprising that seven Courts of Appeals to review similar arguments against FDA denials of authorization for flavored e-cigarettes upheld those denials, with only a single other Court of Appeals setting aside an FDA denial.[69] This near-

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have rectified the scientific deficiencies, the marketing plans would not change the result. Accordingly, even assuming the FDA erred in declining to review [applicant's] marketing plans, the error was harmless.").

[69] Pet. For Cert. at 13, 18 (listing cases); the other case of which *amici* are aware in which a Court of Appeals set aside FDA denial orders distinguished the Fifth Circuit review of Respondents' applications *by name*. *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1208 (11th Cir. 2022) ("This appeal is also different from those before our sister circuits in several ways. First, our harmless-error standard is different from the standard imposed by the Fifth Circuit . . . Second, the statements made before the Fifth Circuit at oral argument . . . were not made before this Court." (citing case below)); furthermore, *Bidi* expressly depended on FDA's failure "to consider the *novel* marketing and sales-access-restriction plans submitted by the tobacco companies." *Id*. at 1206 (emphasis added). Respondents here have never claimed that any part of their marketing plans were novel.

uniformity of judicial approach enables FDA to consistently and efficiently review an enormous number of applications, representing a sizeable share of the e-cigarette market.[70]

a. Adopting the Fifth Circuit's position regarding any of the alleged deficiencies of FDA's review would significantly slow down review of applications, and allow products to remain on the market to the detriment of public health.

Once FDA has determined that a given marketing plan does not materially differ from plans it has previously determined to be insufficient to protect public health, requiring FDA to undertake a burdensome and unnecessary full review of that plan will only slow down review of PMTAs. Prompt review of applications is critical, both to protect public health and to expedite review and potential authorization of new products that could be beneficial for public health. While applications are pending before FDA, products often remain available on the market,[71] at least

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[70] *See, e.g., FDA Marketing Denial Orders List,* https://tinyurl.com/yuak7k4f (last updated Aug. 6, 2024); *Premarket Tobacco Product Marketing Granted Orders*, FDA https://tinyurl.com/2wcebs33 (last updated Mar. 28, 2024); *see also* Def.'s Status Report and Mot. for Relief Under Rule 60(b) From Obligation to File Further Status Reports at 8, *AAP et al. v. FDA*, No. 8:18-cv-883-DLB, (D. Md., Jul 22, 2024), ECF No. 222 ("FDA has resolved more than 26 million of the approximately 27 million PMTAs received to date").

[71] *See, e.g. Vapetasia Store Locator*, Vapetasia https://tinyurl.com/mr23e598 (last visited Aug. 27, 2024) (listing retail locations selling Respondent Vapetasia's products); *JUUL Labs Statement on the FDA's Rescission of its 2022 Marketing Denial*

arguably illegally.[72] Prompt authorization of an appropriate application eliminates any uncertainty surrounding a product's legality, and allows the manufacturer to bring it to market without the risk of FDA enforcement. Prompt denial of an inappropriate application, on the other hand, serves to remove products which are inappropriate for the protection of the public health from the market, minimizing the amount of time they may attract new youth users.

Judicial interference with, and second-guessing of, FDA's scientific judgment in evaluating evidence will similarly hinder review of applications, create delays for judicial proceedings, and risk the substitution of courts' efforts at scientific opinion in place of FDA's expertise. All of these results would be contrary to the intent and purposes of the Act, and would frustrate FDA's statutory ability to continue to take badly needed action to rein in the e-cigarettes that most endanger American youth.

Orders, JUUL Labs (June 6, 2024), https://tinyurl.com/mttp5wts (JUUL products "will remain on the market" during review of applications).

[72] Natalie Hemmerich, *A Quick Recap: What's Going on with the Premarket Review Process?*, Pub. Health L. Ctr. at Mitchell Hamline Sch. of L. (May 16, 2022), https://tinyurl.com/fep4nh9p ("products that have not received authorization . . . are being illegally sold in violation of the court's order.").

b. Resolving the current circuit split in favor of the Fifth Circuit's outlier position would create an avalanche of substantively meritless challenges to settled FDA denial orders.

FDA can only issue an "incorrect" order in one of two ways: by denying an order that should have been granted, or by granting an order that should have been denied. Respondents have not claimed, nor did the Fifth Circuit describe, any deficiency in FDA's review of their applications that could have led FDA to deny their applications when they should have been granted: it was harmless error not to review a marketing plan substantively identical to previously rejected plans, and it was not arbitrary and capricious for FDA to evaluate the strength of scientific evidence in an application. Put simply, FDA's denial of Respondents' applications was substantively correct. The products covered by those applications, like many products covered by other applications FDA has denied, are inappropriate for the protection of public health because they are more likely to attract new youth tobacco users than they are to help existing users quit; the applicants did not prove to FDA that the products met the statutory threshold for authorization.

More broadly, there is no reason to believe that *any* FDA denial order of a flavored e-cigarette application to date has been substantively incorrect. Only the Fifth Circuit in this case and the Eleventh Circuit in *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022) have ever set aside such an order. For the reasons discussed above and in Petitioners' brief, the orders at issue here were properly denied. The Eleventh Circuit expressly noted that its decision setting aside the denial orders "does not mandate a different result

on remand. We acknowledge the evidence in the record catalogued by the dissent of the serious risk to youth, and it may be that the Administration will conclude on remand that"[73] the applications should be denied as inappropriate for the protection of the public health. In at least some instances, FDA has in fact denied those applications,[74] and, at a minimum, none of the products covered by the applications at issue in *Bidi* presently appear on FDA's list of authorized products.[75]

Should this Court uphold the Fifth Circuit's decision setting aside FDA's denial orders, it would likely open a floodgate of challenges to other issued denial orders—including those previously upheld by other Courts of Appeals—with catastrophic consequences.[76] The subsequent logjam of applications for FDA review would hamper review of applications that are currently pending, of which there are several thousand,[77] likely allowing those e-cigarette products to remain on the market unreviewed. Further, lower courts would have no choice but to set aside any prior denial order challenged on a basis consistent with this Court's

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[73] *Bidi*, 47 F.4th at 1205.

[74] *See FDA Denies Marketing of Bidi E-Cigarette*, FDA (Jan. 22, 2024), https://tinyurl.com/ykj9tj3h.

[75] *E-Cigarettes Authorized by the FDA*, *supra* note 40.

[76] Indeed, the Fifth Circuit, relying entirely on its prior decision in this case, has already set aside marketing denial orders issued against flavored products from five separate companies. *SWT Global Supply, Inc. v. FDA*, 2024 WL 3595387 (5th Cir. July 31, 2024) ("for the reasons amply explained by the en banc court in *Wages*, we hold that FDA acted unlawfully here as well by denying Petitioners' PMTAs").

[77] Jeffrey S. Smith, *Menthol-Flavored Electronic Cigarette Receives Marketing Granted Order from the FDA*, R Street (June 24, 2024), https://tinyurl.com/3ve625d3.

opinion, allowing *those* products to return to the market as well. But because the orders at issue in this case were substantively correct, and the Fifth Circuit's conclusions to the contrary legally incorrect, any application reopened on such a basis would be destined to be denied again. In other words, applicants would be able to return to the market products FDA has already correctly determined to be inappropriate for the protection of the public health, reaping ill-gotten profits and endangering countless youth.

c. Products that appeal to youth remaining on shelves is literally a matter of life and death.

Flavored tobacco products are more appealing to youth than unflavored alternatives simply because they are flavored. But in many instances, the appeal does not stop there. Flashy product names that go well beyond a simple description of the flavor are often indistinguishable from, if not identical to, fixtures of youth culture.

Consider the naming similarities between just some of Respondents' products and various components of teen culture. Fifteen of the items in the following alphabetical list are names or partial names of e-cigarette products covered by Respondents' PMTAs.[78] The remaining items are a rap group

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[78] Big Granny, Blackberry Lemonade, Blueberry Parfait, Chewy Clouds, The Cookie, Jimmy the Juice Man, Killer Kustard, Mom's Pistachio, Mother's Milk and Cookies, Peachy Strawberry, Pineapple Express, Pink Lemonade, Rainbow Road (also a video game level), Strawberry Astronaut, Suicide Bunny. Rule 30.2(a) Appendix – Volume I at A3-A56, A109-A123, *Wages and White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024) (No. 21-60766).

fronted by Grammy-winning rapper Big Boi,[79] two songs by popular musician Harry Styles (over 62 million monthly listens on Spotify),[80] the name of a level in a 2020 video game for Nintendo Switch (identical to the name of one of the products),[81] a rapper with over 66 million monthly listens on Spotify,[82] an electronic music producer with over 60 million monthly listens on Spotify,[83] a particular Haribo gummy candy,[84] a top streamer on Twitch,[85] a pop musical group with over 16 million monthly listens on Spotify,[86] three songs from Taylor Swift's double platinum album *Midnights*,[87] a rapper with over 22 million monthly listens

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[79] Big Grams. Jay Balfour, *Big Grams*, Pitchfork Mag. (Oct. 1, 2015), https://tinyurl.com/yc7dvwh2.

[80] Sweet Creature and Watermelon Sugar. *Harry Styles*, Spotify, https://tinyurl.com/2dsvpc4j (last visited Aug. 28, 2024).

[81] Rainbow Road. *Rainbow Road (Mario Kart Live: Home Circuit)*, Super Mario Wiki, https://tinyurl.com/ac7ebpnv (last visited Aug. 28, 2024).

[82] Bad Bunny. *Bad Bunny*, Spotify, https://tinyurl.com/475va236 (last visited Aug. 28, 2024).

[83] Marshmello. *Marshmello*, Spotify, https://tinyurl.com/299nw3wm (last visited Aug. 28, 2024).

[84] Berry Clouds. *Berry Clouds*, Haribo, https://tinyurl.com/mryrwmvj (last visited Aug. 28, 2024).

[85] Sodapoppin. *Twitch Earnings Leaderboard*, Twitch, https://tinyurl.com/56wfz6k9 (last visited Aug. 28, 2024).

[86] BLACKPINK. *BLACKPINK*, Spotify, https://tinyurl.com/4n4dvchc (last visited Aug. 28, 2024).

[87] Lavender Haze, Midnight Rain, and Snow on the Beach. *Midnights*, Spotify, https://tinyurl.com/3wr5n34m (last visited Aug. 28, 2024).

on Spotify,[88] a flavor of Ben and Jerry's ice cream,[89] and a rapper with over 28 million monthly listens on Spotify:[90]

> Bad Bunny, Berry Clouds, Big Grams, Big Granny, Blackberry Lemonade, BLACKPINK, Blueberry Parfait, Chewy Clouds, The Cookie, Ice Spice, Jimmy the Juice Man, Juice WRLD, Karamel Sutra Core, Killer Kustard, Lavender Haze, Marshmello, Midnight Rain, Mom's Pistachio, Mother's Milk and Cookies, Peachy Strawberry, Pineapple Express, Pink Lemonade, Rainbow Road, Snow on the Beach, Sodapoppin, Strawberry Astronaut, Suicide Bunny, Sweet Creature, and Watermelon Sugar.

One need not conclude that Respondents intentionally designed and marketed their products to youth to conclude that underage consumers would likely be drawn to at least some of their products based on name alone. Add to these unfortunate trade names the well-established facts that flavored tobacco products are particularly appealing to young consumers[91] and that an overwhelming majority of tobacco users start young,[92] and it is easy to understand how these products pose a substantial risk of attracting underage or other young tobacco users.

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[88] Ice Spice. *Ice Spice*, Spotify, https://tinyurl.com/mr4ahs4v (last visited Aug. 28, 2024).

[89] Karamel Sutra Core. *Karamel Sutra Core*, Ben & Jerry's, https://tinyurl.com/27yc9wzu (last visited Aug. 28, 2024).

[90] Juice WRLD. *Juice WRLD*, Spotify, https://tinyurl.com/38ntpcum (last visited Aug. 28, 2024).

[91] *See supra* notes 41-43 and accompanying text.

[92] *See supra* note 9 and accompanying text.

And these represent just a selection of the products covered by Respondents' applications—FDA has issued marketing denial orders to hundreds of other applicants.[93] If this Court were to affirm the Fifth Circuit and even a fraction of those applicants were to subsequently challenge the denial orders they had previously received, they would likely flood the market with previously disapproved products, quickly returning the reality of store shelves to something resembling the height of the e-cigarette epidemic. The regulatory holiday would last only until FDA could begin completing reviews and issuing denial (or, more accurately, re-denial) orders. But in the interim, there is every reason to expect that youth adoption of the newly available and appealing products would climb back toward 2019 peaks, if not surpass that milestone.[94] It would be nearly impossible to swiftly put the genie back into the bottle without risking a new wave of youth nicotine addiction.

The science is clear: "[y]outh use of tobacco products *in any form* is unsafe" (emphasis added).[95] This is why FDA evaluates PMTAs with reference to risk of uptake by new tobacco users, rather than only focusing on potential contributions to cessation. A young person who uses tobacco for the first time after being drawn to one of these products would immediately expose themselves to a "highly addictive"[96] substance—nicotine. Nicotine is so addictive, in fact, that 63.9% of middle and high school students who use e-cigarettes want to quit, and 67.4% have attempted to

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[93] *FDA Marketing Denial Orders List*, *supra* note 70.

[94] *See supra* notes 27-28 and accompanying text.

[95] *Youth and Tobacco Use*, CDC, https://tinyurl.com/z3um5dmk (last reviewed Nov. 2, 2023).

[96] *E-Cigarette Use Among Youth*, *supra* note 43.

quit but have been unable to do so.[97] If young people are already unable to quit relatively soon after acquiring their e-cigarette habit, they are unlikely to be able to do so later in life. It is safe to assume that the vast majority of people who first use an e-cigarette during a hypothetical free-for-all would become long-term users and would suffer all the health consequences that come with prolonged tobacco use. And the earlier a person becomes addicted to tobacco, the longer they face the health risks associated with its use—and of course, the earlier in life they may develop serious tobacco-related illness or die as a result of their addiction.

Besides its addictive properties, nicotine exposure, whether from e-cigarettes or other products, "has more significant and durable damaging effects on adolescent brains compared to adult brains"[98] and can cause "priming for use of other addictive substances, reduced impulse control, deficits in attention and cognition, and mood disorders."[99] And the physiological impacts do not stop there. Despite e-cigarette manufacturers' claims of superior safety,[100] "the limited data available suggest that the typical cardiovascular effects exerted by nicotine are also exerted by e-

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[97] Lei Zhang et al., *Tobacco Cessation Behaviors Among U.S. Middle and High School Students, 2020*, 70 J. Adolescent Health 147, 147 (2022), https://tinyurl.com/yc6jfjw7.

[98] *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 105, HHS (2016), https://tinyurl.com/4hjk6adu.

[99] *Id*. at vii.

[100] *See, e.g,*, Howie G., *Vapetasia PMTA Submitted*, Vapetasia (Sept. 29, 2020), https://tinyurl.com/zxhpur95 (Respondent Vapetasia describes products as "safe alternatives to combustible tobacco").

cigarettes."[101] Use of e-cigarettes "risks respiratory exposure to a variety of aerosolized chemicals, including solvents and flavorants . . . adulterants . . . and other toxicants. . . several [of which] are known carcinogens."[102] Among other chemicals, users are exposed to acetaldehyde and formaldehyde,[103] which are linked to cancer, lung disease and cardiovascular disease,[104] and to acrolein,[105] which carries similar risks, and may also contribute to chronic obstructive pulmonary disease (COPD) and asthma.[106]

Additionally, while the effects appear to be less severe than those resulting from exposure to traditional tobacco products (so-called "secondhand smoke"), passive secondhand exposure to e-cigarette use leads to a similar increase in cotinine, a chemical which forms in the body after exposure to nicotine.[107] While further research is needed to assess the precise impacts of e-cigarette use on nearby non-users, secondhand

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[101] *E-Cigarette Use Among Youth and Young Adults*, *supra* note 98, at 101.

[102] *Id.* at 124.

[103] Mumiye A Ogunwale et al., *Aldehyde Detection in Electronic Cigarette Aerosols*, 2 Am. Chem. Soc. Omega 1207, 1207 (Mar. 29, 2017), https://tinyurl.com/3k34xjyz.

[104] *Id.*; *E-Cigarette Use Among Youth and Young Adults*, *supra* note 98, at 117.

[105] Ogunwale et al., *supra* note 103, at 1209.

[106] Pawel Hikisz & Damian Jacenik, *The Tobacco Smoke Component, Acrolein, as a Major Culprit in Lung Diseases and Respiratory Cancers: Molecular Mechanisms of Acrolein Cytotoxic Activity*, 12 Cells 879, 880 (2023), https://tinyurl.com/mva4tpr6; *E-Cigarette Use Among Youth and Young Adults*, *supra* note 98, at 117.

[107] A. Marsot & N. Simon, *Nicotine and Cotinine Levels With Electronic Cigarette: A Review*, 35 Int'l J. Toxicology 179, 179 (2016), https://tinyurl.com/3nbhkdwk.

exposure likely presents at least some physiological danger.

While e-cigarette usage may be "less harmful than smoking, . . . it's still not safe."[108] Due to the relative newness of the e-cigarette market, data are not yet available about the long-term health consequences of e-cigarette use, but lessons learned from traditional cigarettes may be instructive. As of 2023, cigarette smoking remained "the leading cause of preventable disease, disability, and death in the United States, accounting for . . . about 1 in 5 deaths."[109] The rate of associated morbidity may be even more alarming: smoking increases the risk of coronary heart disease and stroke by 2 to 4 times and the risk of lung cancer by about 25 times.[110] While these risks will likely prove not to be as high for e-cigarettes, the similarities between the products—particularly the chemicals to which they expose users—suggest that e-cigarettes will contribute to elevated risk for these morbidities. Tobacco-related illnesses in America currently cost more than $300 billion per year in medical costs and lost productivity, [111] borne to a significant degree by federally funded programs including Medicare,

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[108] Michael Joseph Blaha, *5 Vaping Facts You Need to Know*, Johns Hopkins Med. https://tinyurl.com/582aks5b (last visited Aug. 28, 2024).

[109] *Current Cigarette Smoking Among Adults in the United States*, CDC, https://tinyurl.com/2f9pf5c3 (last reviewed May 4, 2023).

[110] *Health Effects of Cigarette Smoking*, CDC, https://tinyurl.com/mr3dm32n (last reviewed Oct. 29, 2021).

[111] *Health Topics—Tobacco*, CDC Polaris, https://tinyurl.com/bdcwv4tf (last reviewed Sept. 30, 2021).

Medicaid, and the Veterans Health Administration.[112] The per-user financial cost of illnesses resulting from e-cigarettes will likely be lower, given the likelihood that illnesses will be less prevalent and may be less severe. Nevertheless, the total financial cost and human toll of e-cigarette illnesses will only increase as the products attract and hook more users—including during a judicially created free-for-all.

As harrowing as these statistics are, *amici* are mindful that they reflect—in staggering numbers—actual individual people. Bryan Lee Curtis, a man from Florida, started smoking at age 13.[113] That choice killed him at age 34, leaving his nine-year-old daughter and two-year-old son without their father.[114] His daughter Amber's favorite thing to do with her "dad was going walking along the pier, down by the beach. [They] did that together a lot."[115] After going to the hospital for severe abdominal pain, Bryan was diagnosed with small cell lung cancer that had spread to his liver—he died approximately two months later.[116] The image of Bryan's emaciated body as he was about to die is so unsettling that the Australian

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[112] Xin Xu et al., *Annual Healthcare Spending Attributable to Cigarette Smoking: An Update*, 48 Am. J. Preventive Med. 326, 331 (2016), https://tinyurl.com/363urh6e (as of 2010, over 60% "of smoking-attributable healthcare was financed through public health insurance programs. Each year, cigarette smoking-related diseases accounted for 9.6% of Medicare expenditures . . . 15.2% of Medicaid expenditures . . . and 32.8% of expenditures from other federal government-sponsored insurance programs").

[113] Sue Landry, *He Wanted You To Know*, Tampa Bay Times (June 15, 1999), https://tinyurl.com/2nwz44ca.

[114] *Id*.

[115] Sami Emory, *Bryan's Daughter Calls [B.S.] on Your Conspiracy Theories*, Vice (Feb. 16, 2017), https://tinyurl.com/5x8pp9xk.

[116] Landry, *supra* note 113.

government, "searching for the most gruesome, affecting anti-smoking images they could find,"[117] opted to use it as a warning label on cigarettes, placed in contrast to a photo of him taken only ten weeks earlier, apparently healthy.[118]

Bryan's death, like every single other death caused by tobacco, was preventable. But as soon as he *started* smoking at 13, it became significantly less preventable, and continued to become less preventable each time he smoked another cigarette. Indeed, Bryan's addiction to nicotine was so powerful that he continued smoking as he was dying until "it became impossible."[119] He "knew how hard it is to quit. But when he learned he would die because of his habit, he thought maybe he could persuade at least a few kids not to pick up that first cigarette."[120]

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Bryan understood a simple truth: far and away the most effective way to prevent tobacco-related illnesses and death is to prevent kids from taking up tobacco use in the first place. Congress recognized the same in designing and passing the Act, and FDA's work to date has been guided by that truth as well. Adopting any part of the Fifth Circuit's opinion would inexorably lead to more youth beginning to use tobacco products—contravening Congressional intent in the

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[117] Emory, *supra* note 115.

[118] Rachel Wells, *Dead man Bryan tells his life's tale to all smokers*, Sydney Morning Herald (Dec. 18, 2012), https://tinyurl.com/3nhk4xn4.

[119] Landry, *supra*, note 113.

[120] *Id*.

passage of the Act and subjecting countless individuals to the misery and death that accompany tobacco use.

CONCLUSION

The judgment of the Fifth Circuit should be reversed.

Respectfully submitted,

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SEPTEMBER 2024