No. 22-1112

IN THE

Supreme Court of the United States

AVAIL VAPOR, LLC; BLACKSHIP TECHNOLOGIES DEVELOPMENT, LLC; BLACKBRIAR REGULATORY SERVICES, LLC,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

---

BRIEF OF THE VAPOR TECHNOLOGY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

ANTHONY L. ABBOUD
Counsel of Record
LAW OFFICES OF
TONY ABBOUD
950 Hawthorne Lane
Northbrook, IL 60062
(312) 498-6060
tony@abboudlegal.com

Counsel for Amicus Curiae

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

OTHER MATERIALS

TABLE OF AUTHORITIES
(continued)

Page(s)

INTEREST OF *AMICUS CURIAE*

The *Amicus Curiae*[1] Vapor Technology Association (VTA) is a national non-profit industry trade association whose members are dedicated to developing and selling high quality electronic nicotine delivery systems (ENDS), also known as e-cigarettes or vapor products[2], that provide adult consumers with an alternative to smoking combustible cigarettes. VTA's membership includes manufacturers of ENDS devices and nicotine-containing e-liquids, distributors, suppliers, and vape shop retailers that manufacture and/or sell a variety of vapor products, including open-system and closed-system vapor products and flavored vaping products. Since its founding, VTA has been engaged on critical regulatory issues confronting the vapor industry, advocating for science-based regulations to protect against youth access to and appeal of vapor products.

VTA has constructively engaged with Congress and federal regulators, including the U.S. Food &

---

[1] Notice was timely provided to counsel for Petitioner pursuant to Rule 37. Notice was provided to counsel for Respondent on June 9, 2023, inside the 10-day notice period. On June 12, 2023, counsel for all parties, including Respondent, provided consent for the filing of this brief. Respondent's response brief is due July 14, 2023. No counsel for any party authored this brief in whole or in part, and no person or entity other than amicus, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Petitioners are not and have not been members of VTA.

[2] Herein we refer to ENDS products as e-cigarettes and vapor products as those terms are used interchangeably. *See*, *Wages & White Lion Invs. LLC v. U.S. Food & Drug Administration*, 14 F.4th 1130, 1134 (5th Cir. 2021) (discussing the interchangeability of the terms).

Drug Administration (FDA), on myriad issues and specifically on the issue of flavored ENDS regulation. In 2018, when the FDA published its Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294 (Mar. 21, 2018) (hereafter, "Flavor ANPRM"), VTA submitted substantive comments to the FDA detailing all of the scientific studies examining the role that flavors play in both initiation and, as importantly, discontinuation of the use of tobacco products.

In 2019, when the Trump Administration announced its intention to temporarily ban all flavored vapor products through a modification of its deferred enforcement policy (which it later elected not to do), VTA shared information with the Administration on the role that flavored vaping plays in assisting adult smokers trying to quit, and presented an economic impact analysis, of economists at John Dunham & Associates (JDA), which demonstrated that the proposed national flavor ban would shut down the majority of the 13,000 small businesses whose adult customers relied on flavored vaping.[3]

The Administration ultimately elected not to ban open-system flavored vaping products (like the ones at issue in this petition) and, instead, modified is deferred enforcement policy to limit its flavor ban only to pod and cartridge closed system products that the FDA had tied directly to the problem of youth vaping. FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed

---

[3] *The Economic Impact of a Ban on Flavored Vapor Products*, John Dunham & Associates, November 21, 2019, p. 6, available at https://vaportechnology.org/wp-content/uploads/2022/11/Dunham-Economic-Impact-of-Flavor-Ban-11-21-19.pdf (the "JDA 2019 Report").

Products on the Market Without Premarket *Authorization*, January 2020. VTA also endorsed raising the age to purchase all tobacco products to 21 which the Administration endorsed and Congress passed in December 2019. *See* Further Consolidated Appropriations Act, 2020 Pub. L. No. 116-94, 133 Stat. 2534, 3123.

With this background on the issue of flavored vaping products, Amicus Curiae offer additional context that may assist the Court in assessing the importance of granting the subject Petition for a Writ of Certiorari (the "Petition").

SUMMARY OF ARGUMENT

The questions presented in the Petition merit consideration by this Court because they have major public health and economic impacts that will dramatically affect millions of Americans. When the world's leading tobacco and nicotine researchers undermine the scientific underpinnings of the FDA's decision making process, and call into question the public health objectives of removing flavored ENDS products from the market, further review by this Court is merited not to re-examine the science, but to evaluate the propriety of the highly questionable process used by the agency to implement the requirements of the Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776, 1777, *codified* at 21 U.S.C. §§ 387-387s ("TCA").

The need for review has been heightened since the issuance of the Fourth Circuit's decision because an independent panel of tobacco experts which conducted an external review of FDA's handling of pre-market tobacco applications, like those at issue in the Petition, revealed serious regulatory failings of

the agency, *including those specifically raised by Petitioners in the Petition*.

Finally, the questions presented are of exceptional importance since the FDA's conduct outside the bounds of the law will result in severe economic repercussions for the U.S. economy.

ARGUMENT

Granting the Petition is of exceptional importance for two principal reasons. First, the FDA's process for assessing what is "appropriate for the protection of public health" was heavily criticized as lacking clarity in terms of what applicants, like Petitioners, are required to submit and, as importantly, for the opacity of FDA's application of the applicable statutory test. The fact that the same concerns raised by Petitioners have now been validated by an independent panel of tobacco experts is crucial new information for this Court to consider. However, the Panel's findings are of even greater import since they emanated from a request of the FDA Commissioner for an external review of the FDA's Center for Tobacco Products which has been mired in controversy. The Panel's review revealed fundamental questions of fairness that underscore the violations asserted in the Petition.

Further, the scientific underpinnings relied on by the Fourth Circuit have been directly challenged by leading tobacco-control scientists who have contradicted the key objective of banning e-cigarette flavors and who have sounded the alarm that *decreasing* availability of *flavored* vaping products is harming the ability of adult smokers to quit smoking cigarettes. At the same time, these experts put in real perspective the unsound basis on which FDA's entire argument turns – that denial of Petitioners'

application is necessary, or appropriate, to protect youth.

Second, ENDS products, also known as e-cigarettes, were not regulated under the TCA when it was passed but were subsequently made subject to the TCA in 2016 upon the implementation of the Deeming Rule. FDA, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28973 (May 10, 2016, effective August 8, 2016) ("Deeming Rule"). Between the passage of the TCA in 2009 and the Deeming Rule in 2016, a new, independent distribution chain of vapor companies, including manufacturers, distributors, suppliers, and retailers, has steadily grown outside of the traditional tobacco products manufacturing and distribution chain, offering their customers non-combustible nicotine vapor products as alternatives to smoking cigarettes. *Wages & White Lion*, 14 F.4th at 1134 ("by the time the FDA got around to issuing the Deeming Rule, manufacturers were widely marketing e-cigarettes through the United States"). According to John Dunham & Associates in 2021, the independent vapor industry comprises more than 10,000 companies across the United States and is responsible for generating more than 130,000 jobs and more than $22 billion in economic output for the U.S. economy.[4]

---

[4] *The Vapor Industry Economic Impact Study*, prepared for the Vapor Technology Association, by John Dunham & Associates, September 20, 2021, at 2, accessible at https://vaportechnology.org/wp-content/uploads/2022/09/US-

A review and resolution of the questions presented is urgently needed to prevent the FDA from implementing its *de facto* ban on all flavored ENDS products under the guise of a supposed case-by-case review. Upholding the Fourth Circuit ruling will devastate the independent nicotine vapor products industry given its unique and substantial reliance on the sale of flavored vapor products to adult consumers.[5] Importantly, the potential shutdown of close to 10,000 businesses, loss of tens of thousands of jobs, billions of dollars of wages and benefits, and billions of dollars of economic output to the US also makes this issue exceptionally important for this Court's consideration.

I. THE QUESTIONS PRESENTED ARE EXCEPTIONALLY IMPORTANT FROM A PUBLIC HEALTH PERSPECTIVE.

Taking up the questions presented is exceptionally important because one week after the Fourth Circuit issued its decision in this case, an Independent Tobacco Expert Panel, convened by the FDA Commissioner himself to review his agency's handling of tobacco products, issued a critical report which condemned the very decision-making process which Petitioners challenge in the Petition. In addition, at the same time FDA was denying the

---

Vapor-Industry-Economic-Impact-Report-2021-Dunham-Associates-FINAL-COMBINED.pdf (the "JDA 2021 Study").

[5] *The Economic Impact of a Sales Ban on Flavored Vapor Products on the Economies of the United States and the States Comprising the Ninth Circuit*, prepared for the Vapor Technology Association, John Dunham & Associates, November 9, 2022, available at https://vaportechnology.org/wp-content/uploads/2022/11/Dunham-Supreme-Court-Report-11-14-22-Web.pdf (the "JDA 2022 Report").

applications at issue, the world's leading tobacco-control scientists publicly called into question the core scientific underpinnings of FDA's actions in this matter. With this backdrop, the public health implications of the propriety of FDA's actions could not be more important for this Court to review, particularly since FDA has used its heavily criticized process to reject PMTAs covering millions of products. Moreover, while FDA has seen fit to authorize the marketing of a scant six vaping devices (one of which is a disposable product) as "appropriate for the protection of public health," FDA has at the same time authorized the marketing of more than 1,200 combustible tobacco products, including almost 900 new cigarettes for the U.S. market.[6]

Amicus curiae recognize that evaluating policy considerations are generally outside the province of the Court, but in this case the FDA has improperly used a now highly criticized process, that an independent panel of tobacco experts says is in need of urgent reform, to effectuate a major policy initiative – the removal of all flavored ENDS products from the market – outside of the required notice and comment rulemaking process.

---

[6] *Report: FDA Approves More Than 1200 Combustibles and 900 New Cigarettes,* Vapor Technology Association, March 2023, available at https://vaportechnology.org/wp-content/uploads/2023/04/VTA-Report-%E2%80%93-FDA-Approves-Combustibles.pdf.

A. The FDA process for reviewing PMTAs was heavily criticized by an independent tobacco expert panel which called out the FDA's failure to consistently apply the APPH test.

The concerns raised by the Petitioners have been verified by an independent tobacco expert panel. The centerpiece of the TCA is the pre-market tobacco application (PMTA) requirement through which FDA must review applications for a specific product and determine whether *that product* is "appropriate for the protection of public health." *See* 21 U.S.C. §§387j. The Fifth Circuit explained the three prongs of the APPH test. "In determining whether a product is appropriate for the protection of the public health (referred to as the "APPH" standard), FDA must consider [1] 'the risks and benefits to the population as a whole.'" *Id.* § 387j(c)(4)." *Wages & White Lion,* 41 F.4th at 432. "This includes, [2] 'the increased or decreased likelihood that existing users of tobacco products will stop using such products,' *id.* § 387j(c)(4)(A), as well as [3] "the increased or decreased likelihood that those who do not use tobacco products will start using such products," *id.* § 387j(c)(4)(B)." *Id.*

On December 19, 2022, just one week after the Fourth Circuit issued its order, an Independent Tobacco Expert Panel – convened at the request of FDA Commissioner Robert Califf under the auspices of the Congressionally-created Reagan-Udall Foundation to review the FDA's Center for Tobacco Products – released its report which indicted the

FDA's handling of, among other things, PMTAs.[7] Not only do the Independent Tobacco Expert Panel's findings buttress Petitioners' claim that FDA's requirements for establishing what products are "appropriate for the protection of public health" are unclear, the Panel also concurred that FDA was not transparent in explaining how it was evaluating what products are appropriate for the protection of public health and that FDA didn't even have a clearly articulated basis for making its determinations.

The Independent Tobacco Expert Panel called out the FDA for its lack of clarity in what Petitioners, and every other applicant, should submit to FDA to satisfy an APPH determination:

> "**Applicants, however, will struggle to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations**. A lack of clarity results in extraneous work on both sides--for applicants and for the Agency. **CTP has a responsibility to clearly identify application requirements,** if for no other reason than to reduce the burden on the Agency itself and improve efficiency."

Id. at 20. (emphasis supplied). The Independent Tobacco Expert Panel also concurred with Petitioners' argument regarding the lack of clear rules, finding that, "While CTP has issued some foundational regulations and guidances, many gaps remain." *Id.* As a result, the Independent Tobacco Expert Panel

---

[7] Operational Evaluation of Certain Components of FDA's Tobacco Program: A Report of the Tobacco Independent Expert Panel, Silvis, et. al; 2022 available at https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf

expressed the urgent need for FDA to create a strategic plan "now" and demanded that "the plan must … explain how FDA is interpreting the APPH standard." *Id.* at 15.

Petitioners rightly raise the concern that FDA implemented a policy of banning all flavored vaping products under the guise of its scientific review of Petitioners' application. This concern was also supported by the Independent Tobacco Expert Panel which cited FDA's inability to separate policy decisions, at the core of Petitioners' MDOs, and scientific decisions:

> "One such question that scientific analysis alone will not resolve is how to weigh the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible tobacco products against the potential public health harms that youth who use ENDS will acquire a lifelong addiction to nicotine or proceed to use combustible tobacco products. At times, a lack of clarity about the distinction between, and the intersection between, policy and science has created controversy within CTP and may lead to a perception that the Center's scientific integrity is being challenged when, in fact, policy decisions that transcended the science are being made."

Id.

Finally, the Independent Tobacco Expert Panel also offered its support for Petitioners' complaint that FDA inappropriately failed to consider all aspects of its application (i.e., its plan to restrict youth access and appeal) in making its APPH determination:

> "To the extent that CTP intends to review certain critical sections of an application first, and if

> deficient, not proceed to other sections, such a policy should be reflected in a public guidance that explains to applicants how CTP will triage its substantive reviews."

Id. at 20.

While these are just some of the Independent Tobacco Expert Panel's concerns, the report wholly serves as an indictment of the broken process through which FDA has opaquely implemented major public health responsibilities unvetted by any rulemaking process. This is particularly true with respect to FDA's heightened standard for flavored ENDS. To be clear, the FDA did initiate a policy making process to evaluate "flavors in tobacco products" when it published its advance notice of proposed rulemaking – the Flavor ANPRM – in which it explained, "The [Food Drug & Cosmetic] statute also authorizes the Agency to issue additional product standards, including to address flavors in tobacco products (*See* section 907(a)(3)) and preserves FDA's authority to act with respect to menthol (section 907(e)(3))." Flavor ANPRM, 83 Fed. Reg. at 12295.

In the Flavor ANPRM, the FDA made clear its authority and intentions related to regulating flavors in "noncombusted" products (i.e., ENDS and other non-combustible nicotine products):

> "FDA explained that it did intend to consider the issues surrounding the role of flavors in tobacco products, including the role flavors play in youth and young adult use, as well as the existence of preliminary data that some adults may use flavored noncombusted tobacco products to transition away from combusted tobacco use. *See* 81 FR 28973 at 29014 and 29055."

Id. Importantly, the FDA wanted to examine the scientific data that examined adults' use of flavored non-combustible products to "transition away from" smoking. *Id.* FDA received thousands of comments in response to the Flavor ANPRM, including VTA's comment supported by a complete set of all the published research pertaining to flavors and ENDS products.[8]

Since then, FDA has moved forward with two tobacco product standards related to flavors. On May 4, 2022, FDA published its Proposed Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (May 4, 2022), seeking to limit menthol in cigarettes. FDA also published its Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396 (May 4, 2022), seeking to limit characterizing flavors in cigar products.

However, FDA never issued any proposed rule on flavored ENDS, choosing instead to misuse the PMTA review process as described in the Petition. Only this Court can now consider and correct the impact that the numerous failings called out by the FDA Commissioner's Independent Tobacco Expert Panel. While the Fourth Circuit did not have the benefit of considering this independent indictment of the review process at issue in the Petition, this Court does and should grant the petition for certiorari to examine Petitioners' claims.

---

[8] *See*, VTA Comments in Response to FDA's ANPRM: Regulation of Flavors in Tobacco Products, July 19, 2018, available at: https://www.regulations.gov/comment/FDA-2017-N-6565-22935.

B. Leading tobacco control scientists undercut FDA's concerns about youth vaping, as overblown, and warn against flavored vaping bans.

In September 2021, only a few weeks after FDA issued its Market Denial Orders (MDOs) to Petitioners, and issued identical MDOs to hundreds of other manufacturers covering nearly a million substantially similar open system flavored bottled e-liquids, fifteen of the past presidents of the staunchly *anti-tobacco* Society for Research on Nicotine and Tobacco (SRNT) – the world's most esteemed scientific society on tobacco and nicotine – published a seminal analytical essay in which they directly challenge US policies regarding vaping generally and flavored vaping products specifically.[9] The significance of this essay is its clarion call for a balanced discussion on e-cigarettes, and flavors, and its summation of the current science demonstrating the importance of embracing the harm reduction potential of vaping products.

First, the 15 past presidents of SRNT frame their concerns about the imbalanced U.S. policy in striking terms: "We agree with former Surgeon General C. Everett Koop who, in 1998, urged that '[A]s we take every action to save our children from the ravages of tobacco, we should demonstrate that our commitment to those who are already addicted . . . will never

---

[9] Balfour, David J. K., Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow, Caryn Lerman, Robin J. Mermelstein, Raymond Niaura, Kenneth A. Perkins, Ovide F. Pomerleau, Nancy A. Rigotti, Gary E. Swan, Kenneth E. Warner, and Robert West: *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, American Journal of Public Health 2021; 111(9):1661-1672, https://doi.org/10.2105/AJPH.2021.306416.

expire.' *The latter appears at risk today*." *Balfour, et al.* at 1662 (emphasis supplied). Moreover, these scientists starkly explain how smoking disproportionately affects vulnerable smoking populations:

> "The need to pay attention to adult smokers is particularly important from a social justice perspective. African Americans suffer disproportionately from smoking-related deaths, a disparity that, a new clinical trial shows, vaping could reduce. Today's smokers come disproportionately from lower education and income groups, the LGBTQ…community, and populations suffering from mental health conditions and from other drug addictions. […] Smoking accounts for a significant proportion of the large life expectancy difference between affluent and poorer Americans. For smokers with serious psychological distress, two thirds of their 15-year loss of life expectancy compared with nonsmokers without serious psychological distress may be attributable to their smoking. Vaping might assist more of these smokers to quit."

Id. at 1667. The 15 past presidents of SRNT explain why these and other adult smokers have been forgotten:

> "To the more privileged members of society, today's smokers may be nearly invisible. Indeed, many affluent, educated U.S. persons may believe the problem of smoking has been largely 'solved.' They do not smoke. Their friends and colleagues do not smoke…Yet 1 of every 7 U.S. adults remains a smoker today. Smoking will claim the lives of 480,000 of our fellow citizens this year alone."

Id.

Second, the 15 past presidents of SRNT declare, "Many, including this article's authors, believe that vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking's toll." *Id.* at 1662. Even more directly they warn:

> "While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind. *That is not happening*."

Id. (emphasis supplied).

Third, and perhaps most importantly, the 15 past presidents of SRNT directly warn that U.S. regulators' myopic focus on youth vaping and flavors has hindered U.S. smoking cessation efforts:

> "To date, the singular focus of US policies on decreasing youth vaping may well have reduced vaping's potential contribution to reducing adult smoking. **Those policies include … decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation** and convincing the public—including smokers—that vaping is as dangerous as smoking."

Id. at 1666 (emphasis supplied).

*Fourth***,** the world's leading tobacco-control scientists explain away each of the supposed scientific conclusions cited by the FDA on which the Fourth Circuit based its decision. *Avail Vapor LLC v. US*

Food & Drug Administration, 55 F4th 409, 420-421 (4th Cir. 2022). Specifically, they detail why the "singular focus" on youth is both hyperbolic and unjustified based on a *balanced* review of the science.

Initially, the experts call into question "whether, for youth as a whole, vaping creates dangerous levels of nicotine exposure that would not have occurred in the absence of vaping." *Balfour, et al.* at 1665. The explain, "The large majority of nontobacco product–using young people do not vape and, thus, have no nicotine exposure. Among those who vape, most do so infrequently; many are short-term experimenters." *Id.*

Next, the 15 past presidents unequivocally dismantle the supposed "massive risk of addicting a new generation to nicotine" posed by flavored vaping products," *Avail Vapor,* 55 F4th at 421, being greatly overstated:

> "Vaping likely addicts some young people to nicotine. However, the evidence does not suggest it is addicting very large numbers. Jarvis et al. concluded that 'Data ... do not provide support for claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes.' Jackson et al. recently reported that the e-cigarette–driven increase in nicotine product use among high-school students is not associated with an increase in population-level dependence."

Balfour et al., at 1664. These leading scientists starkly conclude that, "Vaping may addict some youths to nicotine, but many fewer than popularly believed." *Id.*

Next, the experts categorically reject the myth about youth vaping and harm to the developing brain

cited by the Fourth Circuit, *Avail Vapor,* 55 F.4th at 414-415, as "speculative" at best:

> "[S]tudies lead some researchers to suspect that adolescent nicotine use in any form may lead to long-term structural and functional brain changes with associated negative implications for cognition or impulse control. However, given species differences and questions about the relevance of experimental animal nicotine dosing paradigms to human use patterns, the validity of extrapolation to humans is speculative."

Balfour et al., at 1665. Most importantly, these experts explain that no research has been done which longitudinally examines the impact on the brain of adolescent nicotine use. *Id.* ("Research has yet to isolate nicotine use in the adolescent years and then examine later sequelae.")

Next, the 15 past presidents dispel the myth cited by the Fourth Circuit that there is a "growing body of evidence showing a link between ENDS use and subsequent smoking among youth," *Avail Vapor,* 55 F.4th at 421, *explaining* that that in the studies used to assert a gateway, the "numbers of cigarettes smoked at follow-up are frequently very low, only one or two in the past 12 months in one study." *Balfour, et al.,* at 1665. They go on to note that, "*Shahab et al.* reported that less than 1% of U.S. students who initiated nicotine or tobacco use with e-cigarettes were established cigarette smokers." *Id.* After reviewing the various studies on both sides, they conclude that the actual risk to youth is remarkably small:

> "If vaping causes some young people to try cigarettes, the aggregate impact must be small. A recent study estimated that if vaping increases

> non-smoking youths' odds of trying cigarettes by 3.5 (as reported by *Soneji et al.*), smoking initiation among young adults would increase less than 1 percentage point. Furthermore, U.S. survey data demonstrate that smoking among young people has declined at its fastest rate ever during vaping's ascendancy. If vaping increases smoking initiation, other unknown factors more than compensate."

Id. The scientists also explain that any correlation between youth vaping and eventual smoking must be driven by other factors such as "youths' use of other psychoactive substances, including marijuana and alcohol." *Id.*

Given the FDA's rejection of Petitioners' flavored vaping products based on its generalized framing of "risk" to youth, along with FDA's identical denials of virtually every other similarly situated PMTAs for a flavored ENDS product, this Court should take heed of these staunchly anti-tobacco scientists' warnings, take up the Petition, and assess the propriety of FDA's conduct.

C. The Fourth Circuit wrongly excused the FDA's failure to balance the three prongs of the "appropriate for the protection of public health" test required by the TCA.

FDA would likely argue that these leading tobacco-control scientists' evaluation of the risks of flavored vaping to youth are not relevant because they are not specific to Petitioners' products at issue. But, such an argument would be disingenuous since FDA is guilty of using the same approach. To wit, none of the "youth" science cited by FDA in the Technical Project Lead (TPL), and relied on by the

Fourth Circuit, was specific to Petitioners' products, revealing the fundamental failing of FDA to properly apply the statutorily required "appropriate for the protection of public health" (APPH) balancing test.

FDA has repeatedly asserted that each application is "evaluated on a case-by-case basis." *Wages & White Lion,* 14 F.4th at 1140. Even the Fourth Circuit acknowledges FDA's "case-by-case" approach but unwittingly limits it to only one prong of the APPH balancing test. *Avail Vapor,* 55 F.4th at 412. Yet, nothing in the TPL cites any connection between Petitioners' *specific* products and actual youth usage. For example, FDA did not cite any evidence that Petitioners' products were identified on the CDC's National Youth Tobacco Survey which collects data on the specific brands popular with youth, or that Petitioners' products were involved in any of FDA's enforcement actions for illegal sales to youth, or, for that matter, that *any* open-system flavored ENDS products had any material youth use.

Instead, relying only on generalized data FDA made sweeping declarations that *all* flavored ENDS products (not Petitioners' specific products) are attractive to youth to satisfy its review of one prong of the APPH test (i.e., use initiation) and then used that generalized conclusion as the agency's justification to impose never-before announced requirements of a heightened standard of *product-specific* evidence on another prong of the APPH balancing test (i.e., use discontinuation). Because FDA did not and cannot cite any connection between Petitioners' open-system flavored e-liquids and risk to youth, and because the FDA applied the same generalized rationale to millions of flavored ENDS product PMTAs which the agency summarily denied on the same grounds, it appears clear that FDA implemented a substantive

rule against flavored ENDS under the guise of its supposed "case-by-case" analysis.

The Fourth Circuit swallowed hook, line and sinker the FDA's bald assertion that youth would be equally attracted to Petitioners' and all open-system products as they are to the closed-system products for which FDA previously banned flavors. *Avail Vapor*, 55 F.4th at 420, 427 (finding "FDA determined that the scientific evidence shows that 'the role of flavor is consistent' between open and closed systems"). The Fourth Circuit unwittingly accepted FDA's claim of "substantial migration of youth towards single-use ENDS, which remained on the market as a flavored option after the 2020 Enforcement Guidance cracked down on other flavored products popular with youth". *Id*.

What the Fourth Circuit calls FDA's "scientific evidence" was nothing more than a migration fiction created to capture all flavored ENDS products into its scientific net. FDA's says that when it banned flavors in one form of closed-system product (i.e., pods and cartridges) in 2020, youth migrated to another form of *closed*-system product (i.e., "single use") that shared the same design features that were "of particular concern" when FDA issued its closed-system flavor ban the January 2020 Enforcement Guidance:

> "[W]e have found that these products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. … Of particular concern are the design features that appear to make the cartridge-based products so popular with young people….a relatively small size that allows for easy scalability, and intuitive and convenient features that facilitate ease of use, including draw

> activation, prefilled cartridges or pods, and USB rechargeability."[10]

Extrapolating migration from one type of closed-system product to another closed-system product, which shares the same design features is logical (and perhaps "scientific"), but claiming that as evidence of a migration to an open-system product with completely different design features is rank speculation.

For this reason, VTA immediately challenged this FDA's migration argument in September 2021:

> "Open-system devices share none of the design features that FDA relied upon in removing closed-system device flavors from the market. So, if FDA is in possession of new data which proves that America's youth are using large, complex, cumbersome, inconvenient, impossible to conceal, hard to use discreetly, [and] difficult to access open-systems at any material rate, we would greatly appreciate that data being disclosed publicly…Without data, FDA's generalized statement that all flavored ENDS are attractive to youth is simply untethered from fact.
>
> Moreover, any suggestion that FDA is concerned that youth might simply switch to open-system flavored ENDS, as they did to disposables after the pod/cartridge ban, is speculative and unscientific…FDA's experience with disposables offers no justification, much less empirical data,

---

[10] See, FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, January 2020, pp. 15-16, available at https://www.fda.gov/media/133880/download.

for any concern that youth would take up open-systems."[11]

Very simply, FDA cannot use generalized, non-product specific data on one prong of what is a product-specific balancing test, to create a presumption against that product which can only be overcome by the highest level of product-specific evidence on another prong of the balancing test. At the end of the day, for FDA to balance the prongs of the APPH *balancing* test on a case-by-case basis, it must determine whether there is any product-specific evidence of youth initiation and weigh that against product-specific evidence of adult smoking reduction. FDA has no justification for imposing its convenient "all flavored" products are attractive to youth presumption to ensure that no open-system flavored product (or any other flavored product for that matter) would be authorized.

II. THE QUESTIONS PRESENTED ARE EXCEPTIONALLY IMPORTANT FROM AN ECONOMIC PERSPECTIVE.

A. The independent nicotine vapor products industry is a significant part of the U.S. economy.

Economists at John Dunham & Associates (JDA) have been studying the economics of the independent vapor products industry for years. In 2018, JDA conducted its first economic impact assessment of the independent nicotine vapor products industry, which it then updated to assess the size and impact of the

---

[11] VTA Letter to FDA Center for Tobacco Products Director Mitchell Zeller, September 14, 2021, p. 2, available at https://vaportechnology.org/wp-content/uploads/2023/06/Letter-to-Director-Zeller-Changing-PMTA-Standards-9-14-21.pdf.

independent vapor products industry in the JDA 2021 Study.[12] In addition, JDA has examined the economic impact of flavor bans since 2019.[13]

In the JDA 2021 Study, JDA found that "the vapor industry reaches into all corners of the United States, employing 66,364 and generating $2.74 billion in wages" and also that its "businesses directly generate $8.09 billion in economic activity nationally." JDA 2021 Study at 3.

Applying its model for examining the full economic impact of such industries when direct, indirect and induced job creation is taken into consideration, JDA concluded that "the nicotine vapor industry is a dynamic part of the U.S. economy, accounting for about $22.09 billion in output or about 0.10 percent of GDP" and "employs approximately 133,573 Americans who earned wages and benefits of about $7.00 billion." *Id.* at 2.

The majority of companies in the industry are small businesses. Of the 10,527 vapor industry firms JDA identified, 9,847 of them are small retail vape shops and small vape shop manufacturers. *Id.* at 6, Table 3. JDA also found that small shops generate a significant number of the overall industry's 133,000 jobs, as they explained, "about 53,212 jobs are held by people working for the 9,847 independent retail and blending vape shops located across the country." *Id.* at 7, Table 4.

JDA assessed the fiscal impact of the vapor products industry and found that, in addition to sales and consumption taxes, vapor businesses generate billions of dollars in revenue for federal and

---

[12] *See*, JDA 2021 Study at 2, *supra* at 6.

[13] *See*, JDA 2022 Report, *supra* at 7.

state/local governments. Of the myriad business taxes paid by firms and their employees, the vapor industry provides, "$1.48 billion to the federal government and $3.23 billion to state and local governments including income taxes, property taxes, profits taxes, etc." *Id.* at 4.

B. Failing to grant certiorari and reverse the Fourth Circuit ruling could result in severe economic repercussions for the U.S. economy, small businesses and workers.

A refusal to review the Fourth Circuit's ruling will literally upend an entire industry built on thousands of small businesses and tens of thousands of American workers, scuttle hundreds of millions of dollars in wages and benefits earned, and billions of dollars in economic output.

JDA evaluated the impact on the U.S. economy of the removal of all flavored vaping products from the market.[14] As part of its report on the impact of a flavored ENDS ban in California, JDA examined the national implications of a ban on flavored ENDS and concluded that while the nicotine vapor products industry currently generates more than $22 billion in economic output, if we "ban the sale of flavored vapor products, the impact on the economy would be $16,449,776,269." JDA 2022 Report at 10a. This $16.5 billion loss in economic output would follow the "loss of nearly 99,160 jobs, [and] $5,258,906,715 in wages and benefits," which otherwise would have been paid to those workers employed in the vapor industry and the industries supported and induced by the vapor industry. *Id.* at 11a.

---

[14] *See* JDA 2022 Report at 1a.

For perspective, JDA also notes that the impact on small vape businesses, which rely heavily on the sale of flavored vapor products, would be disproportionate:

> "Importantly, the independent vapor segment of the market would cease to exist in any meaningful way and the impact might even be larger since the vast majority of the 9,847 independent vapor shops in the country (which currently generate 53,212 full-time equivalent jobs) would likely have to close. No business can continue to exist were it to lose nearly three-quarters of its revenue."

Id. at 11a-12a.

Such adverse economic impacts make the questions presented of exceptional importance and underscore the need to ensure that a highly suspect and criticized process is not used to undermine the entire independent vaping business sector that has grown to compete with cigarette companies.

CONCLUSION

The Court should grant certiorari and reverse the decision below.

June 14, 2023

Respectfully submitted,

ANTHONY L. ABBOUD
Counsel of Record
LAW OFFICES OF
TONY ABBOUD
950 Hawthorne Ln
Northbrook, IL 60062
(312) 498-6060
tony@abboudlegal.com
Counsel for Amicus Curiae