No. 22-338

IN THE

Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY;
AMERICAN SNUFF COMPANY; AND
SANTA FE NATURAL TOBACCO COMPANY,

Petitioners,

v.

COUNTY OF LOS ANGELES; COUNTY OF LOS ANGELES BOARD OF SUPERVISORS; AND HILDA L. SOLIS, HOLLY MITCHELL, SHEILA KUEHL, JANICE HAHN, AND KATHRYN BARGER, each in her official capacity as a member of the Board of Supervisors,

Respondents.

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

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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

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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 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 and strict enforcement to protect against youth access and appeal to vapor products.

VTA has constructively engaged with federal regulators, including the U.S. Food & Drug Administration (FDA) and U.S. Congress, 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

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[1] All parties have been notified and consented to the filing of this brief as required by Rule 37. 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.

[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).

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 ban all flavored vapor products (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] As a more sensible option, VTA endorsed raising the age to purchase all tobacco products to 21 which the Administration endorsed and Congress passed in December 2019. Further Consolidated Appropriations Act, 2020 Pub. L. No. 116-94, 133 Stat. 2534, 3123. VTA simultaneously advocated for implementing various other time, place and manner restrictions[4] on flavored vapor products at the federal and state level to protect youth. VTA also has participated in FDA's other rulemaking

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[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.

[4] *21 & Done. A Comprehensive Plan to Address Underage Use of E-Cigarettes*, Vapor Technology Association, October 21, 2019, available at https://vaportechnology.org/wp-content/uploads/2019/10/21-and-done-final-combined.pdf.

processes regarding tobacco product standards, including its ongoing tobacco product standard process which purports to ban menthol in cigarettes.

With this background on the issue of flavors, 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 question presented in the Petition merits consideration by this Court not only for the reasons set forth therein, but because determination of the proper preemptive scope of the Tobacco Control Act in this specific context – a blanket flavor ban – will have a dramatic impact on an entire network of companies in the independent nicotine vapor products industry that did not exist when the Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776, 1777, *codified* at 21 U.S.C. §§ 387-387s ("Tobacco Control Act" or "TCA") was passed. This new network of companies sell less harmful ENDS products, which do not contain tobacco but, because they contain nicotine were deemed by FDA regulation to be tobacco products and are thus defined as "tobacco products" under the Food Drug & Cosmetic Act (FDCA). FDCA, 21 U.S.C. §321rr. While Congress and the FDA have refused to implement blanket flavor bans, the growing patchwork of local and state flavor bans portends a proverbial death by a thousand cuts, that will be no less painful to the thousands of small business owners (and their tens of thousands of employees) who will be forced to close unless authority over tobacco product standards and premarket review is properly reserved to the federal government.

The question presented is of even greater import when one considers that FDA is currently and actively exercising its statutory and regulatory authority to conduct a scientific assessment – through its exclusive tobacco product standard and premarket review authorities – of how flavored tobacco products should be regulated. Science must be the driving force behind any tobacco product standard and that is particularly true here, where renowned tobacco-control experts have directly challenged US policies seeking to ban flavored vaping products. Moreover, local and state flavor bans frustrate the fundamental purpose of the TCA in that they prevent companies from selling tobacco products, including flavored e-cigarettes, even when authorized for sale by the FDA as "appropriate for the protection of public health" pursuant to the FDA's exclusive and statutorily prescribed authority. For these additional reasons, the Ninth Circuit's reading of the TCA's preemption and savings clauses would neuter if not undermine the TCA.

ARGUMENT

Granting the Petition is of exceptional importance for two reasons. First, today the "substantial effect on the Nation's economy" created by the sale of tobacco products is of even greater significance than when it was originally recognized by Congress in the Tobacco Control Act. FDCA, 21 U.S.C. § 387, note 10. Vapor 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. To avoid an overnight shutdown of the entire e-cigarette industry, the FDA delayed enforcement of the Deeming Rule"). According to an economic impact study prepared by economists at 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.[5]

While the Ninth Circuit ruling may not cause an "overnight shutdown" of the entire industry, a review and resolution of the question presented by this Court is urgently necessary to prevent the same outcome over time. Apart from the adverse impact that the unchecked proliferation of local and state flavor bans

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[5] *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-Vapor-Industry-Economic-Impact-Report-2021-Dunham-Associates-FINAL-COMBINED.pdf (JDA 2021 Study).

would have on the traditional combustible tobacco products industry, a report on the economic impact of the Ninth Circuit ruling concludes that the independent nicotine vapor products industry would be devastated by unrestricted flavor bans given their unique and substantial reliance on the sale of flavored vapor products to adult consumers.[6] 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 and state economies makes this issue exceptionally important for this Court's consideration.

Second, since the passage of the L.A. County Ordinance – which makes it illegal to "sell or offer for sale,…any flavored tobacco product," L.A. Cnty. Code § 11.35.070(E) (2019) ("L.A. County Ordinance")– leading tobacco-control scientists have squarely challenged the notion of banning e-cigarette flavors and have sounded the alarm that *decreasing* availability of *flavored* vaping products is harming the ability of adult smokers to quit smoking cigarettes. Instead of blanket bans, these tobacco-control scientists endorse alternative time, place and manner restrictions for the sale of flavored vaping products.

As importantly, for years the FDA has been (and is currently) implementing its ongoing, science-based

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[6] *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 (JDA Ninth Circuit Report).

regulatory scheme pertaining to flavored tobacco products, including the implementation of tobacco product standards regarding flavors and the onerous premarket review process for e-cigarettes established under the TCA. *Wages & White Lion*, 14 F.4th at 1134 ("the FDA required e-cigarette manufacturers to submit premarket tobacco applications ("PMTAs"). The PMTA process is "onerous," to put it mildly") (citation omitted). As set forth herein, a fundamental purpose of the TCA is the premarket review process through which FDA must make a determination of which tobacco products may or may not be sold. FDCA, 21 U.S.C. §387 (note 36) ("It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole").

Not only is the premarket review process the centerpiece of the TCA's requirements for protecting the public health, Congress expressly found that the FDA, not the states, had the "relevant scientific expertise" to conduct the premarket review and, thus, the responsibility to make the decision of which specific products would or would not be sold. Congress gave FDA "broad authority" to make these decisions, *Wages & White Lion*, 41 F.4th at 431, so it is not surprising that, along with establishing tobacco product standards, Congress included premarket review in the TCA's preemption clause. FDCA, 21 U.S.C. §387p(a)(2)A. Thus, permitting local and state governments to implement non-science-based blanket sales bans which directly interfere with the fundamental purpose of the TCA and which would overrule FDA's decision that a specific product is appropriate for the protection of public health, is not

only unlawful, but is dangerous from a public health perspective.

I. THE QUESTION PRESENTED IS 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 independent vapor products industry in the JDA 2021 Study.[7] In addition, JDA has examined the economic impact of flavor bans since 2019.[8]

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.

However, 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.

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[7] *See*, JDA 2021 Study at 2.

[8] *See*, JDA Ninth Circuit Report.

The small business component of the vapor product industry is also very significant and is often overlooked as regulators and lawmakers focus their attention on the largest tobacco companies in the industry. 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.

Further, 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 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 (*See* Table 2 of JDA 2021 Study for a breakdown of all the taxes generated by industry both at the federal and state/local levels).

Given the enormous growth and presence of the e-cigarette or vapor products industry today, determining the proper test for TCA preemption is of even greater importance than it was when Congress passed the TCA with its preemption language.

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

If local and state laws banning flavored tobacco product sales are not checked, as Petitioners are requesting, their impact on the e-cigarette industry will severely hurt the U.S. economy. This Court recognized in *Engine Manufacturers* that, "if one State or political subdivision may enact such rules, then so may any other; and the end result would undo Congress's carefully calibrated regulatory scheme." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.,* 541 U.S. 246, 255 (2004). Here, not only will the "end result" undo Congress's tobacco product regulatory scheme, but it 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.

This danger is neither hypothetical nor academic. The court below already has recognized that hundreds of local jurisdictions have imposed restrictions on flavored tobacco products. Pet.App.14a. Moreso, this Court's need to address this issue has been accelerated due to the passing of the California state-wide flavor ban pursuant to a referendum on November 8, 2022.[9]

To understand what is at stake, VTA asked JDA to apply its prior modelling to assess the impact of the

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[9] Wiley, Hannah, *California voters approve ban on sale of flavored tobacco products,* Los Angeles Times, November 8, 2022, https://www.latimes.com/california/story/2022-11-08/2022-california-election-prop-31-ban-flavored-tobacco-results.

Ninth Circuit's ruling by examining what would happen if local and state flavor bans, like the ordinance at issue, were permitted to proliferate throughout the country or just in the states comprising the Ninth Circuit.[10] JDA's assessment is deeply concerning.

JDA concludes that while the nicotine vapor products industry currently generates more than $22 billion in economic output, "were all states and localities allowed to ban the sale of flavored vapor products, the impact on the economy would be $16,449,776,269." JDA Ninth Circuit 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 in 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.

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. Fixed costs, such as rent, insurance, electricity and interest still must be paid, and represent at least 23.0 percent of a retail store's operating budget."

Id. at 11a-12a.

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[10] *See* JDA Ninth Circuit Report at 1a.

Similarly, JDA explains that its report focuses only on the vapor products industry and, therefore, *understates* the economic repercussions for the US economy since, "the full impact of any blanket ban on all flavored tobacco products would be larger when losses of traditional combustible tobacco products are calculated." *Id.* at 9a-10a.

Such adverse economic impacts make the question presented of exceptional importance and underscore the need for product standards and premarket decisions on which products may be sold (as opposed to when, where and how they may be sold) to be set at a national level as intended by Congress in the TCA.

C. Even if sales bans were limited to the Ninth Circuit, the impact on the affected states' economies, and particularly California, will be severe.

The economies within the states covered by the Ninth Circuit's ruling would be severely impacted as more and more sales bans proliferate throughout the Ninth Circuit. "Looking at the nine states in a vacuum, the total loss in jobs would be over 14,030 [full time equivalent] positions, paying $801.0 million in wages and benefits." *Id.* at 13a. Thus, "collectively" the economies of Alaska, Arizona, California, Hawaii, Idaho, Montana, Nevada, Oregon, and Washington "would be over $2.5 billion smaller than they would be if flavored vapor products continue to be sold."[11] *Id.* at 3a;13a.

[11] Interestingly, because of cross-border trade, the overall US economy would not be as severely impacted as the states within the Ninth Circuit, but we would still see the loss of "10,925 FTE

Further, JDA examined the economic impact on the economies of each state comprising the Ninth Circuit and found that lost economic output ranged from $22.1 million (Alaska) to $1.457 billion (California). *Id.* at 13a-20a (*See* Tables 7a-7i). Moreover, in addition to lost jobs and economic output, there would be "reductions in taxes paid by businesses and workers" such as income taxes, profits taxes, social security payments, and even property taxes." *Id.* at 21a. The loss for each state is dependent on the size its industry and the lost taxes to the federal treasury and each state's treasury are laid out at Table 8 of JDA's Ninth Circuit Report. *Id.* at 21a.

In light of California's recent passage of the ballot referendum to ban most flavored tobacco products, and the impending enforcement of that new law, this Court has even more reason to grant the Petition. California has a substantial number of companies in the nicotine vapor products industry and by far represents the largest segment of the industry of all the states within the Ninth Circuit. According to JDA's Ninth Circuit Report, "In the state of California, where the majority of e-liquid manufacturers of the independent vapor products industry are based, total job loss would be approximately 6,925 FTE positions, paying $445,565,776 in wages and benefits, and the economic output of the California economy would be diminished by $1,497,332,882 if flavored vapor products could not be sold." *Id.* at 15a.

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jobs across the entire US economy and the overall loss to the US economy would be $2.1 billion." *Id. at* 12a.

Given this is the now-certain future of California, now is the time for this Court to take up and resolve this important issue.

II. THE QUESTION PRESENTED IS EXCEPTIONALLY IMPORTANT FROM A SCIENTIFIC AND PUBLIC HEALTH PERSPECTIVE.

Taking up the question presented is also exceptionally important because leading tobacco-control scientists, based on a growing body of research, have warned against flavored e-cigarette bans. There can be little question that local and state legislative bodies are not ideally situated to assess rigorous scientific questions associated with whether flavored vapor products should be sold. To be sure, Congress not only reserved that responsibility to the FDA but also found that FDA is the entity suited to make the requisite scientific determinations of which products should be sold. Such decisions need to be based on science and not upon the whims or vagaries of the political process.

A. Leading tobacco control scientists warn against flavored e-cigarette bans and recommend time, place and manner restrictions.

In September 2021, fifteen of the past presidents (including the immediate past president) of the staunchly anti-tobacco Society for Research on Nicotine and Tobacco (SRNT) published a seminal analytical essay in the American Journal of Public Health, in which they directly challenge US policies regarding vaping and popularized misconceptions regarding harm to youth and adults.[12] The

[12] Balfour, David J. K., Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow,

significance of this essay is its clarion call for a balancing of e-cigarette policy, particularly on flavors, and its summation of the current science demonstrating the importance of recognizing and embracing the harm reduction potential of vaping products.

First, the 15 past presidents of SRNT state, "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 state:

> "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.

Second, these highly respected tobacco-control scientists raise the striking concern that efforts to restrict adult access to flavored vaping products is hampering public health objectives of reducing adult smoking:

> "To date, the singular focus of US policies on decreasing youth vaping may well have reduced

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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.

> 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.

Third, instead of flavor bans, these scientists explain the need for balanced policies: "Policies regarding flavors reflect the more general issue considered in this article: the need to create a balance between the sometimes-conflicting goals of preventing youth vaping and supporting adults' smoking cessation attempts, particularly for smokers unable or unwilling to quit otherwise." *Id.* at 1664. So, to right the imbalance and correct the wrongfooted priorities on the issue of flavored vapor products, these tobacco-control leaders endorse limiting the "retail sale of flavored e-cigarettes to adult-only outlets such as vape shops." *Id.* at 1666. Such restrictions they say would protect both youth and adults. *Id.*

Given that the Ordinance indiscriminately bans less harmful flavored vaping products along with all other flavored tobacco products, this Court may wish to consider both the concerns raised these staunchly anti-tobacco experts and the alternative time, place and manner restrictions they have endorsed. As Petitioners' thoughtful explication of the TCA's preemption, savings and preservation clauses makes clear, localities and states can implement numerous regulatory options, other than blanket bans, without running run afoul of the TCA or public health concerns. Pet.30.

B. The question of whether adult smokers will have continued access to less harmful flavored vapor products can only be decided by the FDA, as Congress intended and prescribed in the TCA.

Given the myriad concerns raised by the fifteen past presidents of SRNT about the importance of flavored vapor products to national public health concerns, whether American smokers will be able to choose a less harmful flavored vaping alternative to smoking cigarettes is a question that, as Congress dictated, must only be decided by the FDA on a scientific basis. Unless this Court grants the Petition, and reverses the Ninth Circuit ruling, the FDA's on-going tobacco product standard process for flavored tobacco products and the outcomes of its Congressionally mandated premarket review process will be completely usurped by a patchwork of state and local flavor bans.

1. In 2016, the FDA published the "Deeming Rule"[13] which first deemed electronic nicotine delivery systems (ENDS) as "tobacco products" subjecting them to the comprehensive requirements of the TCA. FDCA, 21 U.S.C. §§387a-387s. A central question which has occupied considerable attention by the FDA and federal regulators is how flavored ENDS and other tobacco products should be regulated. In the Deeming Rule, FDA explained that it was not banning flavored ENDS products and that it would evaluate flavors pursuant to its premarket review process. 81 Fed. Reg at 29055.; *see*, *Wages & White Lion Inv. LLC v. U.S. Food & Drug Administration*, 41 F.4th 427, 432 (5th Cir. 2022) ("the Deeming Rule subjected e-cigarette manufacturers to

[13] 81 Fed. Reg. 28973.

the TCA's prior authorization requirement—manufacturers of "new tobacco product[s]" must submit premarket tobacco product applications ("PMTAs"). *See* 21 U.S.C. § 387j(a)(2)").

Premarket review is one of the specific areas for which local and state action is expressly preempted under the TCA. FDCA, 21 U.S.C. §387p(a)(2)A (preempting "any requirement…relating to tobacco product standards, premarket review…"). As Petitioners' correctly point out, the Ninth Circuit's interpretation of the TCA's preemption and savings clauses would make the Congressionally mandated premarket review process a nullity as the L.A. County Ordinance would ban products which the FDA fully authorized as "appropriate for the protection of public health." Pet.14. This would be an absurd result.

In *Wages & White Lion,* a case specifically examining the FDA's decision on a company's flavored ENDS PMTA, the Fifth Circuit explained, "In determining whether a product is appropriate for the protection of the public health (referred to as the 'APPH' standard), FDA must consider 'the risks and benefits to the population as a whole.'" *Id.* § 387j(c)(4)." *Wages & White Lion,* 41 F.4th at 432. The court went on to explain that the public health evaluation is a fundamental purpose of the TCA. *Id.* at 431 (explaining "the TCA's purpose sounds in … protecting public health"). Most importantly for this analysis, Congress found that only the FDA, not local or state legislative bodies, has the relevant scientific experience to evaluate the numerous premarket review requirements set forth in the TCA:

> "Congress also found that FDA had the relevant 'scientific expertise to . . . evaluate scientific studies supporting claims about the safety of products[] and to evaluate the impact of labels,

> labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health.' TCA § 2(44), 123 Stat. at 1780." *Id. To that end, Congress gave FDA broad authority* to regulate tobacco products, requiring that most 'new tobacco products' receive authorization from the FDA prior to marketing. 21 U.S.C. § 387j(a)(2)(A)."

Id. (emphasis supplied).

For the foregoing reasons, little credence can be given to the Ninth Circuit's dismissive downplaying of the FDA's exclusive premarket review authority as a "limited exception", particularly when the "appropriateness for the protection of public health" standard of the premarket review process is, in fact, a fundamental purpose of the TCA. Pet.App.19a. And, for this reason alone, no sound reading of the preemption and savings clauses could allow a local or state authority to reject or supplant entirely a scientific decision that a flavored e-cigarette is appropriate for the protection of public health, particularly when Congress placed that decision making authority, which is the prerequisite to selling the product, solely within the province of the FDA.

2. This is especially true for the flavored e-cigarette category of tobacco products which the FDA has made clear it is reviewing because of these products' potential for advancing public health (as the 15 past presidents of SRNT have argued they do). In 2018, long before the passage of the L.A. County Ordinance, the FDA initiated its "flavors in tobacco products" regulatory process by publishing 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.

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.*

VTA, and many other stakeholders, participated extensively in the Flavor ANPRM regulatory process. For its part, VTA provided a comprehensive response to each of the questions sought to be addressed by the FDA, supported by a complete set of all the published research that examined the relevant questions pertaining to flavors and ENDS products.[14] VTA's response also underscored the unique role that flavored vapor products can play in helping adult smokers transition away from cigarettes and why

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[14] *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.

noncombusted flavored vapor products should be treated differently than combustible tobacco products. *Id.*

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. That same day, FDA 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. Importantly, the FDA noted that these two new proposed tobacco product standards involving flavors arose out of the Flavor ANPRM which the agency initiated in 2018. *See, e.g.*, 87 Fed. Reg. at 26455 (FDA "issued two advance notices of proposed rulemaking (ANPRMs) to solicit data and information about menthol cigarettes").

There is no question that FDA has been evaluating the science related to the core question of whether flavored tobacco products meet the standard set forth in the Tobacco Control Act (e.g., "appropriate for the protection of public health") through a comprehensive regulatory process. While FDA has not yet issued a tobacco product standard relating to flavored ENDS products, it has been evaluating the central question of whether flavored vapor products meet the same standard as part of FDA's exclusive authority over the pre-market review process.

Thus, the question of whether some or all flavored tobacco products should be available to adult consumers must continue to be evaluated pursuant to the FDA's ongoing federal scientific review process, and state and local efforts to impose parochial or prohibitionist policies should be curbed. Ultimately,

in evaluating the complex interaction between the TCA's preemption, preservation and savings clauses, the following question must be reconciled: if the FDA, pursuant to the exclusive authority granted it by Congress, determines that *any* flavored tobacco product meets the TCA's standard for market authorization, what reading of the statute could countenance an outcome in which every town, village, city, county or state could simply replace that judgment and ban outright the sale of a product that is "appropriate for the protection of public health"?

CONCLUSION

The Court should grant certiorari and reverse the decision below.

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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 Curaie