No. 22A474

IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY; R.J. REYNOLDS VAPOR COMPANY; AMERICAN SNUFF COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; MODORAL BRANDS INC.; NEIGHBORHOOD MARKET ASSOCIATION, INC.; AND MORIJA, LLC, DBA VAPIN' THE 619

Applicants,

v.

ROBERT BONTA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF CALIFORNIA; AND SUMMER STEPHAN, IN HER OFFICIAL CAPACITY AS DISTRICT ATTORNEY FOR THE COUNTY OF SAN DIEGO,

Respondents.

To the Honorable Elena Kagan, Associate Justice of the Supreme Court of the United States and Circuit Justice for the Ninth Circuit

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Application from The United States Court of Appeals for the Ninth Circuit (No. 22-56052)

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF VAPOR TECHNOLOGY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF APPLICANTS WITHOUT 10 DAYS NOTICE AND IN PAPER FORMAT

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The Vapor Technology Association (VTA) respectfully moves for leave to file the enclosed brief as *Amicus Curiae* in support of Applicants' Emergency Application for Writ of Injunction (the "Application"). VTA is a national non-profit industry trade association whose members are sell electronic nicotine delivery systems (ENDS), also known vapor products, including flavored vapor products that are subject to the ban at issue in California state law being challenged by Applicants. 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 to and appeal of vapor products. Having constructively engaged with federal regulators, including the U.S. Food & Drug Administration (FDA), and state regulators over many years on myriad vaping issues, including on the issue of flavored ENDS regulation, VTA offers this Court its unique industry wide perspective.

Since 2018, VTA has commissioned an economic impact analysis of the new and growing independent nicotine vapor products industry to inform regulators on the true scope and size of the industry, and the impact of regulations, such as taxation and flavors ban, on both national and state economies. Economists at John Dunham & Associates have conducted such an analysis of the impact of the ban at issue in this proceeding. The findings presented in this proposed *amicus* brief are focused on the state law being challenged in the Application, and are directly relevant to Court's analysis of the irreparable harm and public interest prongs of the requested injunction.

In addition, the proposed *amicus* brief provides important scientific rationale for the Court to consider, specifically a seminal analytical essay published by leading tobacco-control scientists. The discussion is critically important for the Court's consideration of the public interest.

Finally, the proposed *amicus* brief offers the Court additional rationale for why the challenged law violates another important part of the Tobacco Control Act's preemption clause and explains why the question presented should be resolved in Applicants' favor.

Amicus Curiae also moves to file the brief without ten days' notice to the parties of their intent to file as ordinarily required by Sup. Ct. R. 37.2(a) and to file this brief in an unbound format on $8^1/_2$-by-11-inch paper rather than in booklet form. These requests are necessary due to the press of time related to the emergency nature of the Application.

Counsel for *Amicus Curaie* notified counsel for Applicants and Respondents to obtain consent for the proposed brief. All parties consented.

December 2, 2022

Respectfully submitted,

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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 flavored vaping products. Since its founding, VTA has 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 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

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[1] All parties have been notified and consented to the filing of this amicus 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).

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 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

[3] The Economic Impact of a Ban on Flavored Vapor Products, John Dunham & Associates, November 21, 2019, p. 6, available at https://bit.ly/3XVjMPh. (JDA 2019 Report).

[4] 21 & Done. A Comprehensive Plan to Address Underage Use of E-Cigarettes, Vapor Technology Association, October 21, 2019, available at http://bit.ly/3VG2HqA.

the subject Emergency Application for Writ of Injunction (the "Emergency Application").

SUMMARY OF ARGUMENT

The Emergency Application should be granted and the question presented – whether the Tobacco Control Act expressly preempts state and local laws that prohibit the sale of flavored tobacco products – taken up by this Court not only for the reasons set forth therein, but because the enforcement of Senate Bill 793, which indiscriminately bans the sale of flavored vapor products, SB793, §104559.5(b)(1), will cause irreparable harm to hundreds of businesses in California's independent nicotine vapor products industry, businesses 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 sells less harmful vapor 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 draconian flavor bans, enforcement of SB793 will throw more than 6,600 Californians out of work, eliminate more than $425 million in wages, carve a $1.45 billion hole in California's economy.[5]

[5] Economic Impact of a Sales Ban on Flavored Vapor Products on the Economies of the United States and California, prepared for the Vapor Technology Association, John Dunham & Associates, November 30, 2022, available at https://bit.ly/JDA-SB793-Report (JDA SB793 Report).

In addition, the public interest militates in favor of issuing the injunction. Since the passage of SB793, leading tobacco-control scientists have raised the alarm that flavored vapor product bans, driven by what they call policymakers' "singular focus" on youth, are not in the public interest since they also reduce the ability of adults to use vapor products to quit smoking cigarettes. Moreover, these staunchly anti-tobacco scientists explain the immediate proven threat to adults – 480,000 of whom die from smoking every year – and the hypothetical threat that vaping may pose to youth in calling for balancing policy considerations on e-cigarettes. Further, the economy of California will suffer by the loss of nearly $1.5 billion in economic output and the loss of $147 million in state tax revenue. At the same time, the federal government will suffer the loss of another $100.2 million in tax revenue.

The injunction requested is necessary given that, in addition to SB793 being preempted as tobacco product standard preemption, it is also barred by the TCA which expressly preempts requirements that conflict with the TCA's premarket review process. Pursuant to the TCA, science is the determiner of whether a tobacco product may or may not be sold. The FDA is currently and actively exercising its statutory and regulatory authority to conduct a scientific assessment – through both its exclusive tobacco product standard and premarket review authorities – to determine which flavored vapor products should be sold. However, state and local flavor bans, like SB793, which indiscriminately ban all such products frustrate the fundamental purpose of the TCA in that they prevent companies from selling including flavored e-cigarettes even when they have met the arduous regulatory

requirements for doing so and even when those products have been authorized for sale by the FDA after determining that they are "appropriate for the protection of public health" – a determination within the FDA's exclusive and statutorily prescribed authority. For these additional reasons, enforcement of SB793 must be enjoined and the question presented taken up for full consideration by this Court.

ARGUMENT

Granting the Emergency Application is of exceptional importance for three 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.[6]

A more recent analysis by JDA on SB793's economic impact on the independent nicotine vapor products industry in California concludes that small businesses would be irreparably harmed given the industry's unique and substantial dependence on the sale of flavored vapor products to adult consumers.[7] As set forth in the JDA SB793 Report, the irreparable harm attested to by Applicant Morija, LLC., could likely be suffered by up to 600 other small businesses which could similarly be forced to close after losing 75% of their revenue. *Id.* ("No business can continue to exist were it to lose nearly three-quarters of its revenue"). Because California SB793, if enforced, will likely cause an "overnight shutdown" of hundreds of small California businesses, and throw more than 6,000 Californians out of work, the issuance of an

[6] The Vapor Industry Economic Impact Study, prepared for the Vapor Technology Association, by John Dunham & Associates, September 20, 2021, at 2, accessible at https://bit.ly/JDA-2021-Study (JDA 2021 Study).

[7] JDA SB793 Report at 14a.

injunction while the Court reviews and resolves the question presented is urgently necessary. *Id.* at 3a.

Second, since the original passage of the SB793 in 2020 – which makes it illegal to sell flavored tobacco products, including all flavored e-cigarettes or vapor products – leading tobacco-control scientists have warned that *decreasing* availability of *flavored* vapor products is against the public interest because it limits the ability of adults to quit smoking cigarettes.[8] These anti-tobacco scientists further articulated that the public interest in reducing cigarette smoking is not advanced by what they refer to as policies with an "singular focus" on youth and they go further to demonstrate that the public health is better served by implementing balanced policies that include access to flavored vaping products. *Id.* To that end, instead of flavored e-cigarette bans, these tobacco-control scientists endorse alternative time, place and manner restrictions for the sale of flavored vaping products. This combined with the additional direct fiscal impact on the State of California necessitates an injunction and review by this Court.

Third, the injunction should be granted because Applicants' likelihood of success on the merits is augmented by the fact that the TCA also preempts SB793 because it violates TCA's preemption of laws that impinge upon the FDA's premarket review process, in addition to FDA's tobacco product standards. The characterization

[8] 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.

that SB793 is merely a sales ban ignores the fact that the TCA's fundamental purpose is to require the FDA to decide which tobacco products may or may not be sold through an onerous, sophisticated and complex scientific decisions making process. For years the FDA has been (and is currently) implementing its ongoing, science-based 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, like California, to implement non-science-based blanket sales bans which directly interfere with the fundamental purpose of the TCA and which overrule FDA decisions that products are appropriate for the protection of public health, is not only unlawful, but is dangerous from a public health perspective.

Finally, should the Court decline to issue the injunction requested in the Emergency Application, it is imperative that the Court take up the question presented as a Writ of Certiorari since, if SB793 is not reversed, the proliferation of such bills throughout the country will devastate an entire national industry. As explained in the JDA SB793 Report, at risk is the likely closure of the "vast majority of the 9,847 independent vapor shops," and the certain loss of nearly 100,000 jobs, the elimination of more than $5 billion of wages and benefits, and a massive economic loss to the U.S. economy of more than $16 billion. JDA SB793 Report at 11a-12a.

I. GRANTING THE EMERGENCY APPLICATION WILL PREVENT IRREPARABLE HARM TO HUNDREDS OF SMALL BUSINESSES IN CALIFORNIA.

A. The Independent Nicotine Vapor Products Industry is a Significant Part of the California 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 analysis of the independent nicotine vapor products industry, which it recently updated in 2021 to assess the industry's size and impact on the U.S.

economy.[9] In addition, JDA has examined the economic impact of national and state flavor bans since 2019.[10]

The State of California is "home to the majority of e-liquid manufacturers and the second largest number of the independent vapor retailers" in the U.S. JDA SB793 Report at 12a. JDA found that California vapor companies *directly* employ 6,015 people to whom they pay $349.3 million in wages. *Id.* at 13a, Table 6. Further, JDA found that the *direct* economic output of the industry in California is $1.11 billion. *Id.* However, when direct, indirect and induced job creation is taken into consideration, JDA's model concluded that the nicotine vapor industry accounts for $2.93 billion in economic output and employs 13,559 Californians, paying them wages and benefits totaling $939.2 million. *Id.*

B. Refusal to Grant the Emergency Application Will Result in Irreparable Harm To Hundreds of California Small Businesses and their Employees.

Unless the injunction requested is granted, and the lower courts' orders reversed, California businesses, workers and the overall economy will be severely impacted. As set forth in the Emergency Application, Applicant Morija, LLC., will be forced to close its businesses unless an injunction issues. *See,* App.42a (Sylvester Decl. ¶¶ 7-8). JDA's analysis explains why so many more independent vape retailers, like Applicant Morija, will face closure.

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

[10] *See*, *e.g.,* JDA 2019 Report .

In its last survey of the market in 2021, JDA found that there were "609 adult-only specialty vapor shops" in California. *Id.* at 14a. The overwhelming majority (93.6%) of products sold by the independent vapor product industry are menthol and other flavored vapor products. *Id.* at 11a, Table 4. JDA found that, if all sales of flavored vaping products were banned – after accounting for those consumers who switch to vaping only tobacco-flavored vapor products (which would not be banned) – the "legal sales of vapor products would fall to roughly $2,057,967,509, resulting in a net sales loss of $6,029,469,895" or about a 75% decrease. *Id.*

These lost sales would not only irreparably harm Applicant Morija, but they would irreparably harm vape shops all across the state which are similarly situated: "Due to the fact that a large portion of their inventory (about 93.6 percent) comprises menthol and other flavored vaping products, it is likely that all of these small businesses would have to close following the California flavor ban." *Id.* at 14a. After all, as JDA explained, "No business can continue to exist were it to lose nearly three-quarters of its revenue," particularly when "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.*

More broadly, JDA's SB793 Report reveals dramatic losses. All told, when the total economic impact of the California flavor ban is taken into account, including job losses in all related industries served by the vapor industry, JDA reported that "applying our model to the State of California alone, we found that a California-only flavor ban would result in a total job loss of 6,687 FTE positions and $426,647,783 in

wages and benefits, diminishing the economic output of the California economy by $1,445,940,303 if flavored and menthol vapor products could not be sold." *Id.* at 12a.

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

II. GRANTING THE EMERGENCY APPLICATION IS IN THE PUBLIC INTEREST.

A. Leading Tobacco-Control Scientists Warn That Flavored E-Cigarette Bans Are Not In The Public Interest.

Granting the Emergency Application is essential in part because leading tobacco-control scientists, based on an extensive body of research, have warned that such flavored e-cigarette bans are not in the public interest. 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) – the world's most esteemed scientific group on tobacco and nicotine – published a seminal analytical essay in which they directly challenge US policies regarding vaping and popularized misconceptions regarding harm to youth and adults. *Balfour, et al.* at 1661. The 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 embracing the harm reduction potential of vaping products.

First, the 15 past presidents of SRNT frame their concerns: "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 expire.' *The latter appears at risk today*." *Id.* at 1662 (emphasis supplied).

Second, the 15 past presidents 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. More importantly they warn, "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, these tobacco-control scientists are bluntly critical of flavored vaping bans, like SB793: "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…*" *Id.* at 1666 (emphasis supplied). Instead of flavor bans, the 15 past presidents recommend 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.*

Fourth, the 15 past presidents challenge the appropriateness of the heretofore "singular focus" on youth vaping:

> "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. Frequent vaping is most common among current or former smokers, individuals already exposed to nicotine. The most dangerous form of youth exposure to nicotine, cigarette smoking, has declined at an unprecedented rate during the era of youth vaping."

Id. at 1665 (also noting, "Vaping may addict some youths to nicotine, but many fewer than popularly believed").

Finally, the 15 past presidents of SRNT put the attenuated risk to youth in stark relief to the acute and real harms being suffered by the more than 30 million addicted adult smokers, most of whom are in vulnerable populations,[11] who have essentially 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.' … 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. at 1667. In contrast, these leading tobacco-control scientists explain that, "Young people will not experience smoking-related (and conceivably vaping-related) chronic diseases for three decades, and likely not at all if they quit within a decade or two. Social pressures to quit smoking will probably remain strong, and quitting aids may improve. Furthermore, as noted previously, the rate of smoking among young people has declined while vaping has increased." Id.

[11] "African Americans suffer disproportionately from smoking-related deaths, a disparity that, a new clinical trial shows, vaping could reduce," and that smokers today come "disproportionately from lower education and income groups, the LGBTQ….community, and populations suffering from mental health conditions and from other drug addictions." *Id.*

Given the foregoing, and that SB793 indiscriminately bans less harmful flavored vaping products, it is clear that the public's interest in reducing cigarette smoking through continued availability such products militates strongly in favor of granting the Emergency Application.

B. The Fiscal Impacts on the State of California Will Be Significant.

Applicants are correct in warning that "the broader economic costs…to state and federal tax revenues" militate in favor of a stay. Emer.App.40. According to the JDA SB793 Report, in addition to state and local sales tax losses noted above, the State will suffer significant losses in the related business taxes collected from operating businesses:

> "If the ban were to be implemented in California alone, the impact on the state's finances and those of its localities would be significant. California would see a reduction of $53.0 million in taxes on the sale of vapor products as well as an additional $94.0 million in lost state and local taxes from businesses and employees who would lose their jobs or their firms as a result of the ban. This totals $147.0 million in lost revenues."

Id. at 15a. Further, the shutdown of the sale of flavored vaping products in California will cost the U.S. treasury another $100 million in lost business taxes that otherwise would have been paid by vapor product companies. *Id.*

III. SB793 VIOLATES THE PREEMPTION CLAUSE IN WAYS OTHER THAN WITH RESPECT TO TOBACCO PRODUCT STANDARDS.

Granting the Emergency Application is necessary because SB793 violates the TCA's preemption clause in more ways than with respect to tobacco product standards. Specifically, the lower courts misapprehend the importance of the TCA's

express preemption of state and local requirements related to the "premarket review" process which is precisely the statutorily mandated and heavily regulated process by which Congress requires determinations of which products can and cannot be sold are made. In so doing, SB793 brazenly disregards the scientific process mandated by Congress for determining which products can be sold. As a result, 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 enforcement of SB793 – an outcome that cannot be countenanced through a plain reading of the TCA's preemption and savings clauses.

1. In 2016, the FDA published the "Deeming Rule"[12] 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 the TCA's prior authorization requirement—manufacturers of "new

[12] 81 Fed. Reg. 28973.

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 Applicants' 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 SB793 would ban products which the FDA fully authorized as "appropriate for the protection of public health." Emer.App.7. 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. *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 should be given to the Ninth Circuit's dismissive downplaying of the FDA's exclusive premarket review authority as a "limited exception." *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F4th 542, 550 (9th Cir. 2022). This is particularly true when the "appropriateness for the protection of public health" standard of the premarket review process is, in fact, a fundamental purpose of the TCA. 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 concern is heightened 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 SB793, 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.[13] VTA's response also underscored the unique role that flavored vapor products can play in helping adult smokers transition away from

[13] *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.

cigarettes and why 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 is using it comprehensive statutory and regulatory authority to ascertain which flavored tobacco products meet the "appropriate for the protection of public health" standard of the Tobacco Control Act. There is also no question that decisions of whether some or all flavored tobacco products should be available to adult consumers must continue to be determine by the FDA's federal scientific review process, and not by state and local efforts to impose parochial or prohibitionist policies that have been challenged by leading tobacco-control scientists. Ultimately, this leaves only one essential question for this Court to resovle: if the FDA, pursuant to the exclusive authority granted it by Congress, determines that *any* flavored tobacco product meets the TCA's standard for

premarket 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"?

IV. IT IS EXCEPTIONALLY IMPORTANT FOR THIS COURT TO RESOLVE THE PROPER SCOPE OF THE TCA'S PREEMPTION CLAUSE NOW.

A. The Independent Nicotine Vapor Products Industry is a Significant Part of the U.S. Economy.

The question presented in the Emergency Application is of national importance. 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, when the indirect and induced impacts of the industry are taken into consideration, JDA found 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 small business component of the vapor product industry is also very significant and is often overlooked by regulators and lawmakers who prefer to focus their attention on the largest tobacco companies. 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, the fiscal impact of the vapor products industry is significant. In addition to sales and consumption taxes, vapor businesses generate billions of dollars in revenue for federal and state/local governments through myriad taxes paid by firms and their employees totaling, "$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).

B. Failure to Grant Certiorari and Reverse the Lower Courts' Rulings Would Result in Severe Economic Repercussions for the U.S. Economy, Small Businesses and Workers.

If SB793 and similar local and state laws banning flavored tobacco product sales are not checked, as Applicants are requesting, their impact on the vapor product 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/benefits earned.

This danger is neither hypothetical nor academic. The court in *L.A. County* already recognized that hundreds of local jurisdictions have imposed bans on flavored tobacco products. *L.A. County*, 29 F4th at 551. And, the passage of SB793 has brought the question into stark relief. To understand what is at stake, VTA asked JDA to apply its modelling to assess the impact of a ban on menthol and flavored vaping products by examining what would happen if similar flavored vaping bans, like SB793, were permitted to proliferate throughout the country.[14] 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 SB793 Report at 9a-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 throughout the U.S., 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

[14] *See* JDA SB793 Report at 1a.

> 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.

Importantly, because JDA's analyses focus exclusively on vapor products, "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 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.

CONCLUSION

The Court should grant the Emergency Application, issue an injunction, take up the question presented and reverse the decision below.

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Respectfully submitted,

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