No. 23-207

IN THE

Supreme Court of the United States

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

Petitioners,

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.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* E-CIGARETTE BUSINESSES AND TRADE ASSOCIATIONS IN SUPPORT OF PETITIONERS

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INTERESTS OF THE *AMICI CURIAE*

Amici are businesses and trade associations consisting of diverse stakeholders in the electronic cigarette ("e-cigarette") industry.[1] They represent manufacturers, distributors, and retailers across the U.S. who offer non-tobacco flavored e-cigarette products (*i.e.*, e-cigarettes that have a characterizing flavor other than tobacco) that have been used by millions of adults to quit smoking more dangerous combustible cigarettes. *Amici*, therefore, have a substantial interest in the outcome of this litigation.

The ban on non-tobacco flavored products adopted by the State of California via Senate Bill 793[2], as well as similar prohibitions enforced by other state and local governments, prevent addicted adult smokers from acquiring e-cigarette products that may help them reduce the health risks associated with traditional cigarettes. Moreover, such restrictions upend the carefully designed federal regulatory scheme that assigns to the U.S. Food and Drug Administration ("FDA"), not state or local officials, the responsibility for evaluating the population-level health impacts of tobacco products and approving which ones may enter the marketplace, provided they are found to be "appropriate for the protection of the public health."

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[1] This brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for preparing or submitting this brief; and no one other than *amici* and its counsel have contributed money for preparing or submitting this brief. Notice was timely provided to counsel for all parties more than 10 days before the filing deadline for this brief pursuant to Rule 37.

[2] *See* S.B. 793, 2019–2020 Reg. Sess. (Cal. 2020) ("SB793") (approved by voters on November 8, 2022).

The individual business *amici* were all established with one goal in mind – to help adults finally break their smoking habits.[3] Indeed, these companies were started by individuals who themselves relied on e-cigarettes to successfully move away from more risky combustible cigarettes. These businesses currently have pending before FDA extensive pre-market applications (called Pre-Market Tobacco Product Applications or "PMTAs"), filed under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"),[4] covering thousands of non-tobacco flavored (e.g., menthol, fruit) e-cigarette products. Collectively, these companies have spent tens of millions of dollars and countless employee hours over many years assembling the technical and health data required for PMTAs.

The trade association *amici* advocate on behalf of their members for reasonable tobacco regulation and policies.[5] This includes promoting common sense PMTA reform so that e-cigarette manufacturers have a viable and cost-efficient regulatory pathway to commercialize non-tobacco flavored e-cigarette products, as well as helping their member companies navigate the complex and burdensome PMTA process. These trade associations represent hundreds of small busi

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[3] The individual business amici are: American Vapor Manufacturers (AZ); Bidi Vapor, LLC (FL); NicQuid, LLC (OH); SV3, LLC (NV); Wages and White Lions Investment d/b/a Triton Distribution (TX).

[4] Pub. L. No. 111-31, 123 Stat. 1776 (2009), *codified at* 21 U.S.C. §§387, *et seq.*

[5] The trade association *amici* are: American Vapor Manufacturers ("AVM") and the Ohio Vapor Trade Association ("OHVTA").

ness stakeholders who have dedicated themselves to reducing smoking-related disease and death in the U.S.

Amici are understandably concerned that keeping state and local flavor bans in place will not only jeopardize the best chance that adult smokers have at quitting combustible cigarettes, but also render moot in those jurisdictions *amici's* considerable efforts to secure market authorization for their non-tobacco flavored products under the Tobacco Control Act. Given their extensive experience with PMTAs and the scientific evidence substantiating the relative safety and cessation benefits of e-cigarettes, *amici* are well-positioned to discuss: (i) the unintended consequences of removing non-tobacco flavored e-cigarette products from the marketplace; and (ii) the legal and policy implications of allowing state and local officials to dictate, contrary to Congressional intent, which tobacco products are allowed to come to market.

SUMMARY OF ARGUMENT

E-cigarettes are now the most popular method of quitting combustible cigarettes in the U.S. Recent studies confirm that: (i) e-cigarettes present far fewer health risks than combustible cigarettes; (ii) adult smokers have a statistically better chance of quitting when using e-cigarettes as compared to other cessation methods; and (iii) addicted smokers are increasingly relying on non-tobacco flavored e-cigarettes to kick their cigarette habits. Indeed, many public health experts and researchers view e-cigarettes as now driving "harm reduction" in this country, in which adults who are addicted to nicotine, but are unable to immediately stop smoking, still have access to a relatively less risky nicotine product.

Yet the State of California's ban on non-tobacco flavored e-cigarettes threatens to undo all of this. Congress gave the U.S. Food and Drug Administration ("FDA") sole authority over granting or denying marketing authorization based on an e-cigarette product's potential health risks and benefits. Yet if bans like the State of California's are upheld, state and local officials will be able to ban e-cigarette sales even where those products provide an overall health benefit to the consuming public. That is directly contrary to the federal regulatory scheme established by Congress governing the marketing of tobacco products in this country. Accordingly, *amici* request that this Court grant the Petition.

ARGUMENT

"Fourteen percent of U.S. adults smoke; smoking annually causes nearly half a million deaths. Anything that can reduce that toll deserves serious attention."[6] This according to 15 former presidents of the Society for Research on Nicotine and Tobacco ("SRNT"), a professional and scientific society focused on tobacco and nicotine research, in a recent paper published in the *American Journal of Public Health* assessing the current state of e-cigarette regulation in this country. They specifically pointed to e-cigarettes as offering a compelling opportunity to reduce smoking-related harms by helping addicted consumers move away from traditional cigarettes and ultimately quit smoking.[7]

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[6] David J. K. Balfour, et al., *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, AM. J. PUB. HEALTH 2021; 111(9):1661, at 1665-66 ("Balfour, et al.").

[7] *Id.* at 1667.

These experts warned, however, that many governmental entities, in focusing almost solely on e-cigarette use by underage individuals, have lost their way. In their zeal to guard against youth vaping, state and local governments have swung the pendulum to one extreme and put at risk the substantial interests of current and former adult smokers.[8] Indeed, recent scientific research demonstrates that e-cigarette bans, such as the non-tobacco flavor ban adopted by the State of California, may be counterproductive and that a more balanced approach is needed to effectively address tobacco use and promote cessation in the U.S.

I. E-Cigarettes Pose Substantially Less Health Risk Than Combustible Cigarettes And Can Promote Harm Reduction

In 2018, the National Academies of Sciences ("NAS") completed a comprehensive review of thousands of research and scientific papers examining e-cigarettes, including their role in "harm reduction" – a public health approach that prioritizes diminishing, but not necessarily eliminating, the damaging impacts of a particular behavior (in this case, using nicotine-containing tobacco products).[9] In doing so, NAS found "**substantial evidence** that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes."[10] This is because e-cigarettes do not burn tobacco leaf or even contain tobacco, and there is no combustion or

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[8] *Id.*

[9] National Academies of Sciences, *Public Health Consequences of E-Cigarettes*, NAT'L ACADEMIES PRESS, at 589 (2018).

[10] *Id.* at 18 (emphasis in original).

smoke. Rather, the aerosol produced by an e-cigarette is created by heating and vaporizing an e-liquid solution. Not surprisingly, NAS concluded that the "evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."[11]

FDA agrees. In 2017, then-FDA Commissioner Scott Gottlieb and then-Director of FDA's Center for Tobacco Products ("CTP") Mitchell Zeller, published an article in *The New England Journal of Medicine* outlining FDA's tobacco and nicotine strategy, and stating that e-cigarettes, when combined with measures to reduce nicotine levels in cigarettes, "represent[] a promising foundation for a comprehensive approach to tobacco harm reduction."[12] Similarly, in 2019, Director Zeller stated in sworn testimony "it is likely that some [e-cigarette] products may reduce harm at the individual level."[13] In 2020, FDA sought to balance various interests in written guidance setting forth its e-cigarette enforcement priorities, including maintaining the "availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from" cigarettes.[14] Even going back

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[11] *Id.* at 11.

[12] Scott Gottlieb, M.D. and Mitchell Zeller, J.D., *A Nicotine-Focused Framework for Public Health*, NEW ENG. J. MED. 377:12, at 1113 (2017).

[13] Mitchell Zeller Decl., *Am. Academy of Pediatrics v. FDA*, Case No. 8:18-cv-883-PWG, ECF 120-1, at 12 (June 12, 2019) ("Zeller Decl.").

[14] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market*

to 2016, when FDA deemed e-cigarettes under the Tobacco Control Act, it recognized that "completely switching from combusted cigarettes to [e-cigarettes] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products."[15]

In fact, in the Tobacco Control Act itself, Congress authorized FDA to explicitly account for harm reduction. A stated purpose underlying the statute is to "provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products."[16] FDA is also directed to "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers."[17] And FDA is to "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases."[18] Although only having been recently introduced to the market when the Tobacco Control Act was adopted in 2009, e-cigarettes

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Without Premarket Authorization (Revised): Guidance for Industry, at 20 (April 2020) ("Enforcement Priorities Guidance").

[15] 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. 28974, 29030 (May 10, 2016) (final rule "deeming" e-cigarettes to be regulated under the Tobacco Control Act pursuant to 21 U.S.C. §387a).

[16] 21 U.S.C. §387 note (4).

[17] 21 U.S.C. §387 note (7).

[18] 21 U.S.C. §387 note (9).

now fall comfortably within this reduced harm approach.

II. A Growing Body Of Evidence Demonstrates E-Cigarettes Help Adult Smokers Quit Combustible Cigarettes

Most adult e-cigarette users in this country are either current or former smokers, with many of these individuals turning to e-cigarettes to reduce or completely quit their smoking habits.[19] Recent studies validate these efforts.

In its 2018 report, NAS found "**moderate evidence** from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation."[20] NAS also concluded that "[w]hile overall evidence from observational trials is mixed, there is **moderate evidence** from observational studies that more frequent use of e-cigarettes is associated with increased likelihood of cessation."[21] *See also* Zeller Decl. (CTP Director Zeller

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[19] Ping Du, MD, Ph.D, et al., *Changes in E-Cigarette Use Behaviors and Dependance in Long-term E-Cigarette Users*, AM. J. PREV. MED. 2019:57(3):374-383, at 375 (2019) ("Du, et al."); Yoonseo Mok, MPH, et al., *Associations between e-cigarette use and e-cigarette flavors with cigarette smoking quit attempts and quit success: Evidence from a US large, nationally representative 2018-2019 survey*, NICOTINE AND TOBACCO RESEARCH, at 5 (2022) ("Mok, et al.").

[20] NAS, *supra* note 9, at 19 (emphasis added). Randomized controlled trials (or "RCTs"), which reduce bias and provide a rigorous tool to examine cause-effect relationships, are considered to be the "gold standard" of public health research. *See* Eduardo Hariton, MD, et al.*, Randomized controlled trials – the gold standard for effectiveness research*, BJOG 125(13):1716 (Dec. 2018).

[21] NAS, *supra* note 9, at 19 (emphasis in original).

testifying that "[d]ramtically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use [e-cigarettes] and are addicted to nicotine would migrate to combustible tobacco products.")[22]; 81 Fed. Reg. at 29,039 (FDA conceding in final deeming rule that e-cigarettes "may potentially provide cessation benefits").

Since then, research demonstrating that e-cigarettes are a significant harm reduction tool has only grown. A recent Cochrane Systematic Review is particularly instructive.[23] A group of university researchers from the U.S. and around the world reviewed 78 completed studies, including randomized controlled trials and cross-over trials, that investigated whether e-cigarettes help adults stop smoking.[24] They concluded that "people are more likely to stop smoking for at least six months using nicotine e-cigarettes than using… e-cigarettes without nicotine."[25] In terms of the number of individuals, "this might translate to an additional four quitters per 100."[26] As such, based on these studies, there is "high-certainty evidence that [e-cigarettes] with nicotine increase quit rates compared to…[e-cigarettes] without nicotine."[27]

Multiple studies also show that smokers are better able to move away from cigarettes with regular or

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[22] Zeller Decl., *supra* note 13, at 12.

[23] J. Hartmann-Boyce, et al., *Electronic cigarettes for smoking cessation (Review)*, Cochrane Database of Systematic Reviews (2022), *available at* www.cochraneliabrary.com.

[24] *Id.* at 1-2.

[25] *Id.* at 3.

[26] *Id*. at 2.

[27] *Id.*

daily (as opposed to occasional) use and increased nicotine levels that mimic the nicotine delivery of cigarettes. For instance, U.S. and Canadian researchers examined data from the 2018-19 Tobacco Use Supplement-Current Population Survey ("TUS-CPS") to determine the "role of e-cigarettes in smoking quit attempts and quit success (remaining quit from smoking for at least 3 months)."[28] The TUS-CPS is a nationally representative survey carried out as part of the U.S. Census Bureau's Current Population Survey.[29] The results were encouraging. The study concluded that the data "clearly indicate that those who use e-cigarettes more intensely (at least 20 of the past 30-days)…have…a higher odds of making a quit attempt and of succeeding in quitting cigarette smoking."[30] As the authors noted, this was consistent with results of other randomized control trials and observational studies demonstrating that "e-cigarettes can help people who smoke quit."[31]

Additional research shows similar results even for smokers who did not initially plan to completely quit. *See*, *e.g.*, Foulds, et al. (randomized controlled trial demonstrating that "if smokers continue to use an [e-cigarette] with cigarette-like nicotine delivery, a greater proportion completely switch to e-cigarettes, as compared with a placebo or a cigarette substitute. [E-cigarettes] with nicotine delivery approaching that of a cigarette are more effective in enabling

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[28] Mok, et al., *supra* note 19, at 6.

[29] *Id.*

[30] *Id.* at 14.

[31] *Id.*

ambivalent cigarette smokers to quit smoking.")[32]; Kasza, et al. (survey data from the U.S. and three other countries showing "a strong positive association between vaping uptake and cigarette smoking cessation among smokers with no initial plans to quit smoking. Specifically, those not planning to quit in the next 6 months who started vaping daily experienced a 32% cigarette quit rate compared with a 7% cigarette quit rate among their counterparts who did not take up vaping.")[33]; Du, et al. (survey data collected from hundreds of former smokers in 2012-14, and in a 2017-2018 follow-up, demonstrating that "e-cigarette-use behaviors remain stable in long-term e-cigarette users and that the risk of relapse to cigarette smoking is low.").[34]

Not surprisingly, FDA recently determined that, as of 2018, approximately 9 million adults in the U.S. currently use e-cigarettes.[35]

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[32] Jonathan Foulds, Ph.D, et al., *Effect of Electronic Nicotine Delivery Systems on Cigarette Abstinence in Smokers With No Plans to Quit: Exploratory Analysis of a Randomized Placebo-Controlled Trial*, NICOTINE AND TOBACCO RESEARCH 2022:955-961, at 959-60 (2021) ("Foulds, et al.").

[33] Karin A. Kasza, *Associations between nicotine vaping uptake and cigarette smoking cessation vary by smokers' plans to quit: longitudinal findings from the International Tobacco Control Four Country Smoking and Vaping Surveys*, ADDICTION 2022:1-13, at 1-2, 7 ("Kasza, et al.").

[34] Du, et al., *supra* note 19, at 374, 378-81.

[35] FDA, Enforcement Priorities Guidance, *supra* note 14, at 24.

III. Scientific Research Shows That E-Cigarettes Are A More Effective Quit Aid Than Nicotine Replacement Therapies

Emerging scientific evidence also suggests that nicotine containing e-cigarettes are more effective than existing conventional cessation treatments, like nicotine replacement therapy ("NRT") (e.g., nicotine gums and patches), in helping smokers quit combustible cigarettes.

A one-year clinical trial published in *The New England Journal of Medicine* found vaping is nearly twice as effective as NRTs when both are combined with behavioral support.[36] U.K. researchers looked at the 1-year abstinence rate between an e-cigarette group and an NRT group.[37] The e-cigarette group quit smoking at an 18% rate, with the NRT group only achieving cessation at a 9.9% rate.[38] This study, which used refillable e-cigarette devices that are more efficient at delivering nicotine than earlier generations of e-cigarettes, concluded that such devices "had greater efficacy than [NRTs], even though [NRTs were] provided in combinations and under expert guidance."[39]

Similarly, the Cochrane Systematic Review discussed above also compared the cessation benefits of e-cigarettes to NRTs. Again, based on a comprehensive public literature review, there is "high-certainty

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[36] Peter Hajek, Ph.D., et al., *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, NEW ENG. J. MED. 380:7, at 629 (2019).

[37] *Id.*

[38] *Id.*

[39] *Id.* at 637.

evidence that [e-cigarettes] with nicotine increase quit rates compared to NRT…In absolute terms, this might translate to an additional four quitters per 100."[40]

IV. Non-Tobacco Flavored E-Cigarettes Are Particularly Important For Adult Smokers Attempting to Quit Combustible Cigarettes

As to the non-tobacco flavor ban adopted by the State of California, as well as similar state and local measures implemented across the U.S., recent studies place into serious question the wisdom of preventing adult access to menthol and sweet flavored e-cigarettes which are increasingly recognized as a key factor in enhancing adult smokers' ability to quit combustible cigarettes for good.

Numerous studies highlight the fact that adult vapers prefer non-tobacco flavored e-cigarettes over tobacco-flavored versions. For instance, an online survey of more than 69,000 adult vapers found that just 16% identified tobacco, menthol, or mint as flavors they used most often; the vast majority preferred fruit and dessert flavors.[41] Another large online survey found that among adults 18 and over, non-tobacco flavors were preferred by most current e-cigarette users and that flavors were a common reason for adult e-cigarette initiation.[42]

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[40] Hartmann-Boyce, et al., *supra* note 23, at 2.

[41] Konstantinos Farsalinos, et al., *Patterns of flavored e-cigarette use among adult vapers in the United States: an internet survey*, *available at* https://tinyurl.com/yc7wnczy.

[42] Robin L. Landry, et al., *The role of flavors in vaping initiation and satisfaction among U.S. adults*, ADDICT. BEHAV. Dec99:106077, *available at* https://tinyurl.com/24j47x8c.

Moreover, evidence shows that non-tobacco flavors are more effective in aiding cessation efforts than tobacco-flavored products. For example, returning to the study examining census data from the TUS-CPS survey, U.S. and Canadian experts considered the role that non-tobacco flavors play in cessation.[43] The TUS-CPS data included "specific information on quit attempts in the last year for people who smoke[d] at the time of the survey, and the time since quitting for people who previously smoked."[44] The authors found that "e-cigarette non-tobacco flavors can be helpful for smoking cessation."[45] Specifically, they concluded that "those who use flavored e-cigarettes," including mint/menthol, "have…higher odds of making a quit attempt and of succeeding in quitting cigarette smoking."[46] Accordingly, the authors reasoned that, at a minimum, it may benefit smokers to have access to mint/menthol flavored e-cigarettes,[47] and that a lack of access to other sweetened flavors might also adversely impact smoking cessation efforts.[48]

Similarly, a 2023 published study reported the results of a cross-sectional survey of almost 70,000 U.S. adult vapers (aged 18 years and over) that looked at smoking status and patterns of flavor use at the time they initiated e-cigarette use, at the time of the survey, and at the time of smoking cessation.[49] The study authors

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[43] Mok, et al., *supra* note 19, at 6.

[44] *Id.*

[45] *Id.* at 15.

[46] *Id.* at 14.

[47] *Id.* at 3.

[48] *Id.* at 15.

[49] Konstantinos Farsalinos, et al., *Patterns of flavored e-cigarette use among adult vapers in the USA: an online cross-*

concluded that the participants overwhelmingly used non-tobacco flavors (with fruit flavor being the most popular choice) when they quit smoking and that adult use of tobacco-flavored e-cigarettes declined over time.[50] The authors warned against outright flavor bans, stating that "regulators should be careful in striking the right balance in order to avoid unintended adverse public health effects."[51]

An earlier study produced a similar outcome. Li, et al. investigated ITC 4CV longitudinal survey data collected in 2016 and 2018 from 886 concurrent (or dual) users of cigarettes and e-cigarettes in the U.S., Australia, Canada, and England.[52] The researchers examined the extent to which sweet flavors are associated with smoking cessation.[53] Specifically, by 2018, 11.1% of these dual users had quit smoking combustible cigarettes, but the greatest success in quitting occurred among adult smokers using flavored e-cigarettes (13.8%) relative to tobacco flavored e-cigarettes (9.6%).[54] The results also showed that "[o]verall, there was a net shift away from tobacco flavor among those who continued to vape at follow-up," thus substantiating adult consumer preferences

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sectional survey of 69,233 participants, HARM REDUCTION JOURNAL, (2023) 20:147, *available at* https://tinyurl.com/5x8cvbpf.

[50] *Id.* at 1.

[51] *Id.* at 12-13.

[52] Lin Li, Ph.D., et al., *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys*, NICOTINE AND TOBACCO RESEARCH 2021:1490-1497, at 1490-91 ("Li, et al.").

[53] *Id.*

[54] *Id.* at 1490, 1494.

for non-tobacco flavors.[55] Although stating that clinical trials will be needed to definitively confirm the observed association between sweet flavors and cessation, the researchers nevertheless concluded "it [is] possible that limiting smokers' access to fruit and other sweet vaping flavors may have an overall negative impact on quitting…"[56] According to the authors, these impacts should be considered by policy-makers when considering the regulation of e-cigarette flavors.[57]

In another recent study, the greater efficacy of non-tobacco flavored e-cigarettes in supporting adult smokers quitting use of combustible cigarettes was explored in depth by Gades, et al. Researchers at the University of Minnesota conducted an extensive literature review of survey, animal, human laboratory, and clinical studies from 2007 to 2020.[58] Results from 104 of those studies suggested that access to a variety of non-tobacco flavors is likely to be associated with higher use levels and appeal for cigarette smokers, and that flavor variety "might facilitate complete substitution for cigarettes."[59] As such, the researchers warned "[r]egulation of…flavors aimed at decreasing naïve uptake may inadvertently decrease uptake and complete switching among smokers, reducing the

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[55] *Id.* at 1494.

[56] *Id.* at 1495.

[57] *Id.* at 1491.

[58] Mari S. Gades BA, *The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review*, NICOTINE AND TOBACCO RESEARCH 2022:1332-1343, at 1332 ("Gades, et al.").

[59] *Id.* at 1332, 1339.

harm reduction potential of e-cigarettes. Evidence-based effects of regulating…flavors must be considered for the population as a whole, including smokers.[60] *See also id*. ("This study's findings may provide guidance on the prospective effectiveness of regulations such as…flavor bans on overall public health").[61]

In fact, a potential unintended consequence of e-cigarette flavor bans is the possibility that adult smokers who no longer have access to their preferred e-cigarette flavors will relapse back to combustible cigarettes. A group of U.S. academics recently conducted a survey of 247 18-34 year-olds following San Francisco's ban on non-tobacco flavored e-cigarettes.[62] For the 18-24 age group, the data showed a "significant increase in cigarette smoking overall," leading the authors to conclude that flavor bans "can also increase, or not reduce, cigarette smoking as some former users of the banned flavored tobacco products switch to smoking."[63]

Indeed, the 15 former SRNT presidents, in critiquing current tobacco regulatory strategies, wrote that bans "may well have reduced vaping's potential

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[60] *Id.* at 1332.

[61] *Id.* at 1339.

[62] Yong Yang, et al., *The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults*, ADDICT. BEHAV. REPORTS 2020:100273, at 1-2 ("Yang, et al."). *See also* Abigail S. Friedman, PhD, et al., *E-Cigarette Flavor Restrictions' Effects on Tobacco Product Sales*, SSRN (Sept. 26, 2023), *available at* https://tinyurl.com/79dey8jv (economic analysis of hundreds of state and local e-cigarette, non-tobacco flavor restrictions and bans showing an increase of 15 additional cigarettes purchased for every 1 less 0.7 mL pod-style e-cigarette sold).

[63] *Id.* at 3, 5.

contribution to reducing adult smoking…[by] decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation."[64]

V. Underage Use Of E-Cigarettes Is Declining

Amici are vehemently against underage e-cigarette use and recognize that the benefits of flavored products to adult smokers and harm reduction must be balanced against the health risks to teenage users. Fortunately, recent data show significant declines in youth uptake of e-cigarettes, a trend that should be fully considered by policymakers when deciding whether to limit adult access to e-cigarettes.[65]

The National Youth Tobacco Survey ("NYTS"), administered by the FDA and Centers for Disease Control and Prevention ("CDC"), monitors annual trends in youth tobacco use over time.[66] The recent NYTS data from 2022 make clear that underage e-cigarette use has substantially fallen and is now below peak 2019 levels. Specifically, the survey indicated that 1.02 million fewer U.S. youth are currently using e-cigarettes compared to 2020 and 2.75 million fewer compared to 2019.[67] In 2022, more

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[64] Balfour, et al., *supra* note 6, at 1666.

[65] The federal minimum age requirement for purchasing e-cigarette products was recently raised from 18 to 21 years. 21 U.S.C. §387f(d)(5).

[66] *NYTS 2011-2021 and earlier data*, *National Youth Tobacco Survey*, CDC (Mar. 14, 2022), https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm - nyts-historical; Maria Cooper, et al., *Notes from the Field: E-cigarette Use Among Middle and High School Students — United States*, MMWR Morb. Mortal Wkly. Rep. 2022;71:1283–1285, *available at* http://dx.doi.org/10.15585/mmwr.mm7140a3.

[67] *Id.*

than 90% of high school and middle school students combined reported no e-cigarette use in the past 30 days, with overall past 30-day vaping prevalence declining by 28% between 2020 and 2022 (13.2% to 9.6%), and a 53% decline from the 2019 prevalence rate of 20%.[68]

Moreover, between 2019 and 2022, use of an e-cigarette on 20 or more days in the past 30 days decreased by 33% among all students.[69] Importantly, the data show that daily use of e-cigarettes remains rare among youth. Significantly, only 2.6% of students reported using e-cigarettes daily in 2022.[70]

After citing similar data from the 2020 NYTS, the former SRNT presidents advised in their policy paper:

> [A]s public health groups, the media, policymakers, and the general public focus on youth vaping, vaping's potential to help adults quit smoking too often gets lost. That may come at a significant public health cost…We believe the potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks of youth.[71]

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[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] Balfour, et al., *supra* note 6, at 1665-66.

VI. FDA, Not State Or Local Governments, Has Sole Authority Under The Tobacco Control Act To Evaluate E-Cigarette Products And Either Grant Or Deny Marketing Authorization

In the Tobacco Control Act, Congress gave FDA exclusive authority to evaluate each PMTA and decide whether that product may be marketed because it satisfies the statute's "appropriate for the protection of the public health" ("APPH") standard.[72] Indeed, the Tobacco Control Act's preemption clause explicitly prohibits states and political subdivisions from establishing or continuing in effect any requirements that are different from, or in addition to, a federal requirement relating to "premarket review."[73] It therefore strains all credulity to conclude that Congress intended for state and local governments, without going through anything remotely resembling the PMTA process, to simply override FDA's marketing authorization decisions and ban sales of flavored tobacco products, especially harm reduction products like flavored e-cigarettes.

PMTAs are the most time-consuming, costly, and complex pathway to commercialization for products under the Tobacco Control Act. In 2019, FDA finalized a guidance document running over 50 pages that outlines the extensive types of information and data that manufacturers must submit in support of an APPH finding. These include, *inter alia*, health risk studies, toxicological and pharmacological testing, public literature reviews, pharmacokinetic evalua-

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[72] 21 U.S.C. §387j (Section 910 establishing PMTA requirements).

[73] 21 U.S.C. §387p(a)(2)(A).

tions, consumer perception and intention studies, clinical and observational studies, and underage marketing and sales restrictions.[74] In 2021, FDA issued a final rule setting forth similarly comprehensive PMTA requirements.[75]

Once submitted, PMTAs must undergo a complex, science-based evaluation of the PMTA to determine whether the particular product is APPH. Section 910 of the Tobacco Control Act directs FDA to make that determination "with respect to the risks and benefits to the population *as a whole*," including a product's tendency to increase or decrease the use of combustible cigarettes.[76] As such, FDA cannot limit its consideration to just one demographic, such as underage users. Moreover, as FDA noted in the final PMTA rule, an APPH determination is made on an "individualized" basis, considering the "risks and benefits of a specific tobacco product," and "based on *all* of the contents of the [PMTA]."[77] This would include, among other factors, any harm reduction benefits of the product.

However, neither the State of California, nor any other state or local entity adopting flavor bans, adhered to this process. *Amici* relied on Congress's delegation of exclusive pre-market authority to FDA when committing millions of dollars over the span

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[74] FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* (June 2019).

[75] FDA, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 86 Fed. Reg. 55300 (Oct. 5, 2021) (codifying 21 C.F.R. §1114.7, listing extensive information and data required for PMTAs).

[76] 21 U.S.C. §387j(c)(4) (emphasis added).

[77] 86 Fed. Reg. at 55320, 55390.

of years to prepare and submit their PMTAs. Those applications are pending before FDA, but apparently they may be all for naught. If the statute in this case stands, we will continue to see sales bans spread across the country that are based on something other than a full scientific review envisioned under the Tobacco Control Act. Congress could not have intended such an anomalous result.

CONCLUSION

Based on the foregoing, this Court should grant the Petition.

Respectfully submitted,

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