No. 23-799

IN THE

Supreme Court of the United States

MAGELLAN TECHNOLOGY, INC.,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

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

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

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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 marketing denial order ("MDO") issued by the U.S. Food and Drug Administration ("FDA") under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") to Petitioner Magellan Technology, Inc. mimics MDOs issued across-the-board to hundreds of other e-cigarette manufacturers. Collectively, these MDOs denied marketing authorization for over one million such products and, in fact, effectively instituted a *de facto* ban on all non-tobacco flavored e-cigarettes. While FDA is tasked under the statute with evaluating *all* of the potential risks and benefits of each product before determining whether marketing the product would be "appropriate for the protection of the public health" ("APPH"), FDA in reality short-circuited the reviews by focusing largely on preventing underage use at the expense of addicted adult smokers.

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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. Timely notice was provided to counsel for all parties on February 14, 2024.

The individual business *amici* were all established with one goal in mind – to help adults finally break their smoking habits.[2] 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 Tobacco Control Act,[3] 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.[4]

The trade association *amici* advocate on behalf of their members for reasonable tobacco regulation and policies.[5] This includes promoting common sense

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[2] The individual business *amici* are: American Vapor Company d/b/a Red Star Vapor (AZ); Nicotine River (CA); SS Vape Brands (FL); Flavour Art North America (Canada); Vape Element d/b/a BLVK E-Liquid (CA); White Horse Vapor (RI); YLSN Distribution LLC d/b/a Happy Distro (AZ); SV3, LLC (CA); NicQuid, LLC (OH); Wages and White Lion Investments, LLC d/b/a Triton Distribution (TX).

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

[4] The Fifth Circuit recently described these efforts as industry having been forced by FDA to go on a "wild goose chase." *Wages and White Lion Invest. LLC v. FDA*, 90 F.4th 357, 362 (5th Cir. 2024).

[5] The trade association *amici* are: American Vapor Manufacturers (AZ); Breathe Easy Alliance of Alabama (AL); Florida Smoke Free Association, Inc. (FL); Georgia Smoke Free Association, Inc. (GA); Indiana Smoke Free Association, Inc. (IN); Kentucky Vaping Retailers Association, Inc. d/b/a Kentucky Smoke Free Association (KY); Michigan Vape Shop Owners, Inc. (MI); Montana Smoke Free Association, Inc. (MT); Ohio Vapor

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

Amici are understandably concerned as FDA has failed to authorize for marketing a single non-tobacco flavored e-cigarette. In doing so, FDA ignored one of the overarching goals of the Tobacco Control Act, in which Congress granted FDA authority to ensure addicted adult cigarette smokers in this country have access to lower risk tobacco products to help them move away from more dangerous, combustible cigarettes. 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 the unintended consequences of removing all non-tobacco flavored e-cigarettes from the marketplace.

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

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Trade Association (OH); South Carolina Vapor Association (SC); Tennessee Smoke Free Association, Inc. (TN); West Virginia Smoke Free Association, Inc. (WV).

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 FDA's approach to reviewing PMTAs for non-tobacco flavored e-cigarettes threatens to undo all of this. Congress gave FDA authority over granting or denying marketing authorization based on an e-cigarette product's potential health risks and benefits. This requires FDA to conduct a holistic, multi-disciplinary review of all information and data submitted by a manufacturer in a PMTA. But in its zeal to prevent underage use, FDA has mostly ignored the substantial health advantages of e-cigarettes to addicted adult smokers. That is directly contrary to the plain language of the statute and the federal regulatory scheme 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 2021 paper published in the *American Journal of Public Health* assessing the current state of e-cigarette regulation in

[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.").

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]

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).[8] 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."[9] This is because e-cigarettes do not burn tobacco leaf or even contain tobacco, and there is no combustion or 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

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[7] *Id.* at 1667.

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

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

less risk to an individual than combustible tobacco cigarettes."[10]

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."[11] Similarly, in 2019, Director Zeller stated in sworn testimony "it is likely that some [e-cigarette] products may reduce harm at the individual level."[12] 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.[13] Even going back 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

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[10] *Id.* at 11.

[11] 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).

[12] 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.").

[13] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry*, at 20 (April 2020) ("Enforcement Priorities Guidance").

individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products."[14]

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."[15] 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."[16] And FDA is to "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases."[17] Although only having been recently introduced to the market when the Tobacco Control Act was adopted in 2009, e-cigarettes now fall comfortably within this reduced harm approach.

Indeed, in 2021 and 2022, studies predicted that converting smokers to e-cigarettes would avoid 1.8 million

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[14] 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).

[15] 21 U.S.C. § 387 note (4).

[16] 21 U.S.C. § 387 note (7).

[17] 21 U.S.C. § 387 note (9).

U.S. deaths and save 38.9 million life years by 2060,[18] and substantially reverse mortality risks.[19] A January 2024 presentation shows that e-cigarettes are well on their way to achieving this prediction, having already saved 1.66 million life years between 2007 and 2019.[20] These conclusions dovetail with those found in an October 2023 study that between 2010 and 2022 the lower smoking rates linked to ENDS products saved 113,000 lives, preserved $137 billion in gross domestic product and saved $39 billion in healthcare costs.[21]

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.[22] Recent studies validate these efforts.

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[18] David T. Levy, et al., *Public Health Implications of Vaping in the USA: the Smoking and Vaping Simulation Model*, POPUL. HEALTH METRICS (Apr. 17, 2021).

[19] Blake Thomson, et al., *Association Between Smoking, Smoking Cessation, and Mortality by Race, Ethnicity, and Sex Among US Adults*, JAMA NETWORK OPEN, 2022;5(10) (Oct. 24, 2022).

[20] Michael Pesko, et al., *Pharmaceutical Drug Regulation and Mortality: The Peculiar Case of E-cigarettes*, Tobacco Online Policy Seminar (Jan. 5, 2024).

[21] Robert J. Shapiro, et al., *The Major Benefits and Modest Risks of Nicotine Vaping Products*, Center for Black Equity 5 (Oct. 2023).

[22] 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*

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."[23] 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."[24] *See also* Zeller Decl. (CTP Director Zeller 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.")[25]; 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.[26] A group of university researchers from

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2018-2019 survey, NICOTINE AND TOBACCO RESEARCH, at 5 (2022) ("Mok, et al.").

[23] NAS, *supra* note 8, 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).

[24] NAS, *supra* note 8, at 19 (emphasis in original).

[25] Zeller Decl., *supra* note 12, at 12.

[26] Nicola Lindson, et al., *Electronic cigarettes for smoking cessation (Review), Cochrane Database of Systemic Reviews* (2024), *available at* https://www.cochranelibrary.com.

the U.S. and around the world reviewed 88 completed studies, including randomized controlled trials and cross-over trials, that investigated whether e-cigarettes help adults stop smoking.[27] They concluded that "people are more likely to stop smoking for at least six months using nicotine e-cigarettes than using nicotine replacement therapy…or e-cigarettes without nicotine."[28] More specifically, "[f]or every 100 people using nicotine e-cigarettes to stop smoking, 8 to 10 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy, 7 of 100 using e-cigarettes without nicotine, or 4 of 100 people having no support or behavioural support only."[29] As such, based on these studies, there is "high certainty that nicotine [e-cigarettes] increase quit rates compared to nicotine replacement therapy (NRT)."[30]

Multiple studies also show that smokers are better able to move away from cigarettes with regular or 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)."[31] The TUS-CPS is a nationally representative survey carried out as part of the U.S. Census Bureau's Current Population

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

[28] *Id.* at 3.

[29] *Id*.

[30] *Id.*

[31] Mok, et al., *supra* note 22, at 6.

Survey.[32] 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."[33] 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."[34]

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 ambivalent cigarette smokers to quit smoking.")[35]; 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

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[32] *Id.*

[33] *Id.* at 14.

[34] *Id.*

[35] 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.").

up vaping.")[36]; 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.").[37]

Not surprisingly, FDA recently determined that, as of 2018, approximately 9 million adults in the U.S. currently use e-cigarettes.[38]

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.[39] U.K. researchers looked at the 1-year abstinence rate between an e-cigarette

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[36] 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.").

[37] Du, et al., *supra* note 22, at 374, 378-81.

[38] FDA, Enforcement Priorities Guidance, *supra* note 13, at 24.

[39] 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).

group and an NRT group.[40] The e-cigarette group quit smoking at an 18% rate, with the NRT group only achieving cessation at a 9.9% rate.[41] 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."[42]

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 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."[43]

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

As to FDA's *de facto* ban of non-tobacco flavored e-cigarettes, achieved through the mass denial of PMTAs and marketing authorization for such products, recent studies place into serious question the wisdom of preventing adult access to non-tobacco flavored e-cigarette products 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

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[40] *Id.*

[41] *Id.*

[42] *Id.* at 637.

[43] Lindson, et al., *supra* note 26, at 2.

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.[44] 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.[45]

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.[46] 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."[47] The authors found that "e-cigarette non-tobacco flavors can be helpful for smoking cessation."[48] 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

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[44] 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 (last visited Feb. 20, 2024).

[45] 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.

[46] Mok, et al., *supra* note 22, at 6.

[47] *Id.*

[48] *Id.* at 15.

smoking."[49] Accordingly, the authors reasoned that, at a minimum, it may benefit smokers to have access to mint/menthol flavored e-cigarettes,[50] and that a lack of access to other sweetened flavors might also adversely impact smoking cessation efforts.[51]

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.[52] The study authors 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.[53] 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."[54]

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.,

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[49] *Id.* at 14.

[50] *Id.* at 3.

[51] *Id.* at 15.

[52] Konstantinos Farsalinos, et al., *Patterns of flavored e-cigarette use among adult vapers in the USA: an online cross-sectional survey of 69,233 participants,* HARM REDUCTION JOURNAL, (2023) 20:147, *available at* https://tinyurl.com/5x8cvbpf.

[53] *Id.* at 1.

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

Australia, Canada, and England.[55] The researchers examined the extent to which sweet flavors are associated with smoking cessation.[56] 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%).[57] 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 for non-tobacco flavors.[58] 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…"[59] According to the authors, these impacts should be considered by policy-makers when considering the regulation of e-cigarette flavors.[60]

A randomized controlled clinical trial funded by the Swiss National Science Foundation and recently published in the *New England Journal of Medicine*

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[55] 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.").

[56] *Id.*

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

[58] *Id.* at 1494.

[59] *Id.* at 1495.

[60] *Id.* at 1491.

demonstrates the effectiveness of e-cigarettes as a smoking cessation tool. In the study, significantly more participants in the intervention group, who were given the option to choose from a variety of flavored e-cigarettes, quit smoking cigarettes completely compared to the control group (28.9% vs. 16.3%); at the 6-month follow-up, 59.6% of the participants in the intervention group had maintained abstinence from smoking compared to 38.5% in the control group.[61]

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.[62] 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."[63] 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 harm reduction potential of e-cigarettes. Evidence-based effects of regulating…flavors must be con-

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[61] Reto Auer, M.D., et al., *Electronic Nicotine-Delivery Systems for Smoking Cessation,* NEW ENG. J. MED., *390*(7), 601–610 (2024) ('Auer, et al.").

[62] 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.").

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

sidered for the population as a whole, including smokers.[64] *See also id*. ("This study's findings may provide guidance on the prospective effectiveness of regulations such as…flavor bans on overall public health").[65]

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.[66] 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."[67]

Indeed, the 15 former SRNT presidents, in critiquing current tobacco regulatory strategies, wrote that bans "may well have reduced vaping's potential contribution to reducing adult smoking…[by] decreas-

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[64] *Id.* at 1332.

[65] *Id.* at 1339.

[66] 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).

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

ing adult access to flavored e-cigarettes that may facilitate smoking cessation."[68]

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.[69]

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.[70] The recent NYTS data from 2023 make clear that underage e-cigarette use has substantially fallen and is now below peak 2019 levels and at its lowest levels since 2014. Specifically, the survey indicated that over 3 million fewer U.S. youth are currently using e-cigarettes compared to 2019. In 2023, more than 90% of high school and middle school students combined reported no e-cigarette use in the past 30 days, with overall past

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

[69] 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).

[70] *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; Cornelius Birdsey, et al., *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey*, 2023, MMWR Morb Mortal Wkly Rep 2023;72:1173–1182, *available at* https://www.cdc.gov/mmwr/ volumes/72/wr/mm7244a1.htm.

30-day vaping prevalence declining by nearly 42% between 2020 and 2023 (13.2% to 7.7%), and a 61.5% decline from the 2019 rate of 20%.[71]

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.[72] 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.[73]

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.[74]

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[71] *Id.*

[72] *Id.*

[73] *Id.*

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

VI. FDA Violated The Plain Language Of The Tobacco Control Act When It Did Not Conduct A Full Scientific Review And Instead Issued MDOs For All Non-Tobacco Flavored E-Cigarettes Based On The Absence Of Merely One Type Of Study

By its plain language, the Tobacco Control Act requires FDA to conduct a complex, science-based evaluation of each PMTA based on *all* contents in the application to determine whether a product satisfies the APPH standard. Once FDA receives a complete PMTA, it must do more than a cursory evaluation; it must review and assess the application's contents in its entirety.

The Tobacco Control Act explicitly provides that a PMTA shall only be denied if "*upon the basis of the information submitted* to [FDA]…and any other information before [FDA]" the product is not APPH.[75] The statute defines APPH in broad terms with respect to "the risks and benefits to the population *as a whole*," including "users and nonusers of the tobacco product."[76] In this context, the statute enumerates numerous forms of evidence that must be in any PMTA, including data on health risks, ingredient and additive information, product design, manufacturing practices, product samples, labeling specimens, and any other information required by FDA.[77] The Tobacco Control Act also obligates FDA to evaluate, among other things, whether an e-cigarette product will help people

[75] 21 U.S.C. § 387j(c)(2) (emphasis added).

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

[77] 21 U.S.C. § 387j(b)(1).

quit other tobacco products (*i.e.*, cessation) or compel them to start (*i.e.*, initiation).[78]

More specifically, when the Tobacco Control Act says FDA must consider the *whole* population, this includes not only underage non-smokers, but also any other demographics that might be impacted by a particular e-cigarette product, including adult smokers. FDA must also consider all other *risks and benefits* of a given product, including health factors, such as the extent to which a product results in relatively less or more exposure to hazardous constituents.[79] The statute also explicitly envisions that FDA consider the impact that restrictions on the sale or distribution of a product could have on the APPH determination.[80] These include constraints on access to a given product, as well as advertising and marketing limitations, aimed at reducing underage use (*e.g.*, only allowing face-to-face transactions in adult-only facilities).[81]

Unfortunately, FDA did not adhere to the Tobacco Control Act. Despite the statute's clear language, FDA interpreted the statute as permitting it to issue cookie-cutter MDOs for over one million non-tobacco flavored e-cigarette products without conducting a full scientific review of each PMTA. As detailed in Magellan Technology's Petition, FDA denied marketing authorization for every non-tobacco flavored e-cigarette product for the same reason – because the PMTAs did

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[78] 21 U.S.C. § 387j(c)(4).

[79] *See*, *e.g.*, 21 U.S.C. § 387g(a)(4) (defining APPH in context of tobacco control standards as including *reduction* or elimination of harmful constituents).

[80] 21 U.S.C. § 387j(c)(1)(B).

[81] *Id.* (referencing examples of restrictions identified in 21 U.S.C. § 387f(d)).

not contain a single, highly-specific study designed to elicit a discrete datapoint in which the cessation benefits of the applicant's non-tobacco flavored e-cigarettes were compared to the applicant's tobacco-flavored products. It also refused to review extensive youth marketing and access restrictions implemented by each applicant. FDA therefore unlawfully applied a one-size-fits-all approach which also, as a practical matter, swung the pendulum far to one side, unduly emphasizing underage use to the substantial detriment of addicted adult smokers.

CONCLUSION

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

Respectfully submitted,

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