

No. 23-1038

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**In the Supreme Court of the United States**

FOOD AND DRUG ADMINISTRATION,  
*Petitioner,*

*v.*

WAGES AND WHITE LION INVESTMENTS, LLC, DBA  
TRITON DISTRIBUTION, ET AL.,  
*Respondents.*

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ON WRIT OF CERTIORARI TO THE UNITED STATES  
COURT OF APPEALS FOR THE FIFTH CIRCUIT

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**BRIEF FOR MASSACHUSETTS, ARIZONA,  
CALIFORNIA, COLORADO, CONNECTICUT, THE  
DISTRICT OF COLUMBIA, HAWAII, ILLINOIS,  
MAINE, MARYLAND, MICHIGAN, MINNESOTA,  
NEW JERSEY, NEW YORK, NORTH CAROLINA,  
OREGON, PENNSYLVANIA, RHODE ISLAND,  
VERMONT, AND WASHINGTON AS *AMICI CURIAE*  
IN SUPPORT OF PETITIONER**

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## TABLE OF CONTENTS

|  | <u>Page</u> |
|--|-------------|
| INTERESTS OF <i>AMICI CURIAE</i> .....   | 1           |
| SUMMARY OF THE ARGUMENT .....  | 3           |
| ARGUMENT.....  | 5           |
| I. E-cigarettes pose serious health risks, especially to children.....   | 5           |
| II. Flavored e-cigarettes are largely responsible for high rates of youth tobacco use, even as use of other tobacco products continues to decline.....   | 10          |
| III. The FDA’s statutory authority over the introduction of new tobacco products into interstate commerce is a crucial complement to state and local regulation of flavored e-cigarettes. ....   | 15          |
| A. States have adopted a variety of measures to restrict sales of flavored e-cigarettes, but these products continue to flow through interstate commerce. ....   | 16          |
| B. Congress addressed the problem of tobacco use by young people when it enacted the Family Smoking Prevention and Tobacco Control Act and expressly granted FDA broad authority over new tobacco products entering interstate commerce..... | 21          |
| C. By working together, States and the federal government have made progress in stemming the increase of youth vaping.....   | 24          |
| CONCLUSION .....   | 25          |

## TABLE OF AUTHORITIES

| <b>Cases</b>  | <b><u>Page</u></b> |
|---|--------------------|
| <i>FDA v. Brown &amp; Williamson Tobacco Corp.</i> ,<br>529 U.S. 120 (2000).....              | 1-2, 21            |
| <i>Prince v. Massachusetts</i> , 321 U.S. 158 (1944) .....                                    | 1                  |
| <b>Statutes, Rules, and Legislative Materials</b>   |                    |
| 21 C.F.R. § 1100.....   | 22                 |
| 21 C.F.R. § 1140.....   | 22                 |
| 21 C.F.R. § 1114.5.....   | 23                 |
| 21 C.F.R. § 1114.7.....   | 23                 |
| 21 U.S.C. § 387a .....  | 22                 |
| 21 U.S.C. § 387j .....  | 2, 23              |
| 410 ILCS 86/25(d).....  | 16                 |
| Cal. Health & Safety Code, § 104559.5 .....   | 16                 |
| D.C. Code § 7–1721.08.....  | 16                 |
| Family Smoking Prevention and Tobacco Control<br>Act, Pub. L. No. 111-31, 123 Stat. 1776 .... | 3, 21-22           |
| Ky. 2024 HB 11 (eff. Jan. 1, 2025) .....  | 17                 |
| Mass. Gen. Laws ch. 270, § 28 .....   | 16                 |

|   |    |
|---|----|
| N.J. Stat. § 2A:170-51.12.....              | 16 |
| N.Y. Public Health Law §1399-MM-1.....      | 16 |
| R.I. Code R. § 216-RICR-50-15-6.10 (A)..... | 16 |
| Wis. Stat. § 995.15.....                    | 17 |

### **Miscellaneous**

|   |        |
|---|--------|
| <i>2024 Tobacco Facts</i> , AM. LUNG ASS'N,<br><a href="https://tinyurl.com/29pjkpup">https://tinyurl.com/29pjkpup</a> .....  | 5      |
| Ariz. Criminal Justice Comm'n, <i>2022 Arizona Youth Survey State Report</i> ,<br><a href="https://tinyurl.com/5n6pbktu">https://tinyurl.com/5n6pbktu</a> .....   | 19     |
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| Jennifer Byrne, <i>'We were shocked': Vaping considerably increases lung cancer risk among people who smoke</i> , HEALIO (May 20, 2024), <a href="https://tinyurl.com/24v5d9xh">https://tinyurl.com/24v5d9xh</a> .....  | 6      |

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- Colorado Department of Public Health & Environment, *Healthy Kids Colorado Survey Dashboard*, <https://tinyurl.com/4m53kc4r> ..... 21
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- E-cigarettes: Facts, stats and regulations*, TRUTH INITIATIVE (June 7, 2024), <https://tinyurl.com/5t3vw2w9>..... 12
- Economic Trends in Tobacco*, CENTERS FOR DISEASE CONTROL, <https://tinyurl.com/yc3mtw7p>..... 5
- Shivani M. Gaiha, et al., *Public Health Considerations for Adolescent Initiation of Electronic Cigarettes*, PEDIATRICS (May 1, 2020), <https://tinyurl.com/mwpwhr44> ..... 6-7

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| Andrea S. Gentzke, et al., <i>Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018</i> , CENTERS FOR DISEASE CONTROL (Feb. 15, 2019), <a href="https://tinyurl.com/p5xeuvs4">https://tinyurl.com/p5xeuvs4</a> .....                | 10  |
| <i>Health Effects of Cigarette Smoking</i> , CENTERS FOR DISEASE CONTROL, <a href="https://tinyurl.com/4np2vyrr">https://tinyurl.com/4np2vyrr</a> .....   | 5   |
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- Massachusetts Dep't. of Public Health, *Results of the Massachusetts Youth Health Survey 2021* (2022), <https://tinyurl.com/5cu2v2p3>..... 19
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- Jason J. Rose, et al., *Cardiopulmonary Impact of Electronic Cigarettes and Vaping Products: A Scientific Statement From the American Heart Association*, Vol. 148, No.8, AM. HEART ASS'N JOURNALS (July 17, 2023), <https://tinyurl.com/2wsn72d5> ..... 6-7
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|   |    |
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| Texas Department of State Health Services,<br><i>Youth Risk Behavior Survey Dashboard</i> ,<br><a href="https://tinyurl.com/3zdcbm2z">https://tinyurl.com/3zdcbm2z</a> .....  | 13 |
| <i>The Toll of Tobacco in Arizona</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/yeyrxcey">https://tinyurl.com/yeyrxcey</a> .....  | 20 |
| <i>The Toll of Tobacco in California</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/4brabrcb">https://tinyurl.com/4brabrcb</a> .....   | 20 |
| <i>The Toll of Tobacco in Iowa</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/36bpme47">https://tinyurl.com/36bpme47</a> .....   | 20 |
| <i>The Toll of Tobacco in Massachusetts</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/4x99cf5j">https://tinyurl.com/4x99cf5j</a> .....  | 20 |
| <i>The Toll of Tobacco in New York</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/2j8ps2e3">https://tinyurl.com/2j8ps2e3</a> .....   | 20 |
| <i>The Toll of Tobacco in Texas</i> , CAMPAIGN FOR TOBACCO-FREE KIDS,<br><a href="https://tinyurl.com/bdd983yc">https://tinyurl.com/bdd983yc</a> .....  | 20 |

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- Yong Yang, et al., *The Impact of a Comprehensive Tobacco Product Flavor Ban in San Francisco Among Young Adults*, 11 ADDICTIVE BEHAVIORS REPORTS 100273 (2020), <https://tinyurl.com/4mxatxw9>..... 19

**INTERESTS OF *AMICI CURIAE***

*Amici* States Massachusetts, Arizona, California, Colorado, Connecticut, the District of Columbia, Hawai'i, Illinois, Maine, Maryland, Michigan, Minnesota, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington share long-established interests in protecting the public health of our residents, especially children. *See, e.g., Prince v. Massachusetts*, 321 U.S. 158, 166, 168 (1944) (upholding state authority to “guard the general interest in youth’s wellbeing” and noting that “[t]he state’s authority over children’s activities is broader than over like actions of adults”). *Amici* States advance these interests by regulating drugs and addictive products in order to minimize harm, especially to our youth who are uniquely vulnerable to external influences during this formative period in their neurological development. But because drugs and other addictive products flow easily through interstate commerce, States also have a particular interest in the continued strength of the federal government’s nationwide system of oversight over such products. Regulation and control of these harmful products at the national level is critical to address the ease with which such products can be transported across state borders, whether purchased at brick-and-mortar stores or online.

The regulation of tobacco, especially as it pertains to minors, is of particular concern to *Amici* States. As this Court has recognized, “tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.” *FDA v. Brown & Williamson Tobacco*

*Corp.*, 529 U.S. 120, 161 (2000). Tobacco use, especially by minors, not only creates substantial public health challenges in the present, but also imperils future generations. *See id.* at 125 (noting “the thousands of premature deaths that occur each year because of tobacco use”).

The rise of e-cigarettes (also known as Electronic Nicotine Delivery Systems (ENDS) or vapes) in the past decade has exacerbated the ongoing public health crisis of underage tobacco use and nicotine addiction. It is well documented that flavored e-cigarettes (i.e., those that taste like candy, fruit, dessert, etc.) make these addictive products even more attractive to youth who might otherwise never have started using nicotine. In an effort to combat and mitigate the damaging effects of the youth vaping epidemic, States and local governments have implemented bans and other types of regulations prohibiting or limiting sales of flavored tobacco products.

The statutory authority of petitioner Food and Drug Administration (“FDA”) to approve or deny the entry of new flavored e-cigarettes into interstate commerce, *see generally* 21 U.S.C. § 387j, is a crucial complement to the efforts and progress States and local governments have made in protecting our youth from harmful tobacco products and in mitigating the damage that has already occurred due to the youth vaping epidemic. The FDA’s exercise of its authority in this case is illustrative. The FDA denied respondents’ applications to market new flavored e-cigarettes because they “lack[ed] sufficient evidence demonstrating that [respondents’] flavored ENDS will provide a benefit to adult users that would be

adequate to outweigh the risks to youth.” Pet. App. 279a. *Amici* States have a strong interest in vindicating the authority of the FDA to deny applications on such grounds. The FDA’s conclusions are consistent with *Amici* States’ experience and are supported by scientific evidence demonstrating that flavored e-cigarettes are exceedingly harmful to youth. Because current rates of underage vaping remain high and the harms associated with underage vaping require the expenditure of significant state resources, the interest of *Amici* States in preventing a new wave of youth tobacco addiction is fully aligned with Congress’s intent in enacting the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776. The FDA’s denial of respondents’ applications was well within the authority conferred upon it by that Act, and *Amici* States join the FDA in urging this Court to reverse the judgment below.

### SUMMARY OF THE ARGUMENT

Over the last decade, the proliferation of new flavored e-cigarettes has created a youth vaping epidemic that has resulted in a whole new generation of tobacco users. These e-cigarettes are addictive, poisonous, and lead to long-term negative health consequences. Survey research indicates that children as young as those in the sixth grade use e-cigarettes on a continuous basis, and that e-cigarettes are more attractive to youth than traditional combustible cigarettes. Research also demonstrates that young tobacco users have consistently preferred flavored e-cigarettes over tobacco-flavored or unflavored e-cigarettes. While focused actions on both the state and federal levels have helped mitigate the scope of this

public health crisis, e-cigarette use rates among children remain troublingly high, underscoring the need for continued state and federal work in combatting this youth vaping epidemic.

Many states and local jurisdictions have passed laws and enacted regulations to restrict the sale and distribution of flavored tobacco products. Despite these efforts, flavored e-cigarettes continue to flow through interstate commerce, and young users are often able to obtain these harmful products through sources beyond their own States' borders, including from online retailers. Addressing the harms resulting from these youth-oriented and highly addictive products is resource-intensive for state and local governments and is less effective than prevention.

Federal actions can supplement the States' efforts. In passing the Family Smoking Prevention and Tobacco Control Act, Congress empowered the FDA to prevent new tobacco and nicotine products from entering the marketplace unless the FDA approves the products after a showing that they are appropriate for the protection of public health. The FDA has exercised its regulatory authority to endeavor to limit harmful e-cigarettes from infiltrating the national market, but significant hurdles still remain with the continuous introduction of new e-cigarettes. The FDA's authority to prevent harmful new flavored e-cigarettes from entering interstate commerce, based on an assessment of whether the known significant risks of these products to young people outweigh any public health benefit, is a crucial complement to *Amici* States' own efforts to advance our interest in the public health of our citizens, especially our youth.

## ARGUMENT

### I. E-cigarettes pose serious health risks, especially to children.

Tobacco use, and smoking in particular, has posed one of the most serious public health crises in this nation’s history.<sup>1</sup> Nearly half a million Americans die prematurely every year because of tobacco use, making cigarette smoking “the leading cause of preventable death in the United States.”<sup>2</sup> And in addition to the human toll, addressing harms from smoking costs this nation staggering sums of money each year; the Centers for Disease Control estimate an impact of over half a *trillion* dollars in 2018 alone.<sup>3</sup>

As the harms associated with smoking combustible cigarettes became widely understood and cigarette sales in the United States declined,<sup>4</sup> companies began promoting e-cigarettes as “better” alternatives to traditional combustible cigarettes, and as tools to help

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<sup>1</sup> See *2024 Tobacco Facts*, AM. LUNG ASS’N, <https://tinyurl.com/29pjkpup>. (“Smoking is the number one preventable cause of death in the U.S., killing over 480,000 people per year”).

<sup>2</sup> *Health Effects of Cigarette Smoking*, CENTERS FOR DISEASE CONTROL, <https://tinyurl.com/4np2vyrr>.

<sup>3</sup> *Economic Trends in Tobacco*, CENTERS FOR DISEASE CONTROL, <https://tinyurl.com/yc3mtw7p>.

<sup>4</sup> See, e.g., Lungile Nkosi et al., *20-Year Trends in Tobacco Sales and Self-Reported Tobacco Use in the United States, 2000–2020*, 19 *PREV. CHRON. DIS.* 210435, 1 (July 2022), <https://tinyurl.com/3zeds82s> (reporting steady decline in cigarette sales from 2000 to 2020, from a per capita average of 101.01 packs to 42.29 packs per year).

smokers quit smoking.<sup>5</sup> But studies now demonstrate that e-cigarettes, like combustible cigarettes, pose serious health risks to users. In fact, some studies have demonstrated that certain negative health outcomes are more likely to occur from e-cigarette use than from combustible cigarette smoking.

For example, e-cigarette use has been linked to an elevated risk of lung cancer: one study revealed “a fourfold higher risk for lung cancer among those who vaped and smoked cigarettes . . . compared with those who only smoked cigarettes.”<sup>6</sup> E-cigarette use has also been demonstrated to result in higher levels of particle inhalation than combustible cigarette smoking.<sup>7</sup> This inhalation of harmful particles, such as the formaldehyde contained in e-cigarette aerosols, can

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<sup>5</sup> See Jason J. Rose, et al., *Cardiopulmonary Impact of Electronic Cigarettes and Vaping Products: A Scientific Statement From the American Heart Association*, Vol. 148, No.8, AM. HEART ASS’N JOURNALS (July 17, 2023), <https://tinyurl.com/2wsn72d5> (hereinafter “AHA Statement”) (“[E]-cigarettes and vaping products are often touted as safer alternative and tobacco-cessation products”); Shivani M. Gaiha, et al., *Public Health Considerations for Adolescent Initiation of Electronic Cigarettes*, PEDIATRICS (May 1, 2020), <https://tinyurl.com/mwpwhr44> (“Electronic cigarettes . . . are presented as a potential solution for adult smoking cessation, an argument made by e-cigarette manufacturers, some physicians, and adult smokers who are in favor of e-cigarettes.”)

<sup>6</sup> Jennifer Byrne, ‘We were shocked’: Vaping considerably increases lung cancer risk among people who smoke, HEALIO (May 20, 2024), <https://tinyurl.com/24v5d9xh>.

<sup>7</sup> See Divay Chandra, et al., *Electronic cigarette menthol flavoring is associated with increased inhaled micro and sub-micron particles and worse lung function in combustion cigarette smokers*, RESPIRATORY RESEARCH (Apr. 11, 2023), <https://tinyurl.com/mw58kann>.

cause various health problems, including lung inflammation, impaired lung function, and DNA damage.<sup>8</sup> E-cigarette products have also been shown to result in cardiopulmonary toxicity that leads to cardiovascular disease.<sup>9</sup>

Children and adolescents are particularly vulnerable to the harms associated with e-cigarettes. Studies have found that children are more likely to become addicted to nicotine through e-cigarettes, because they begin smoking at younger ages with e-cigarettes than with combustible cigarettes.<sup>10</sup> And minors who initiate a nicotine addiction with e-cigarettes are more likely to use combustible cigarettes later in life.<sup>11</sup> Studies have also demonstrated that young people are more likely to become nicotine dependent and addicted through e-cigarette use than through cigarette smoking because e-cigarettes contain higher concentrations of nicotine than combustible cigarettes.<sup>12</sup> Over time, adolescents who begin using e-cigarettes often “progress to increased frequency and intensity of nicotine use over time.”<sup>13</sup> Further contributing to this cycle of addiction is the fact that e-cigarette producers have dramatically increased the nicotine strength and volume of e-liquid in e-cigarettes over the past

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<sup>8</sup> *Id.*

<sup>9</sup> See AHA Statement, *supra*, note 5.

<sup>10</sup> See Gaiha, *supra*, note 5.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Jonathan P. Winickoff, et al., *Vaping in Youth*, JAMA NETWORK (Aug. 7, 2024), <https://tinyurl.com/5cv6akna>.

decade.<sup>14</sup> In particular, between January 2017 and September 2022, the average nicotine strength of e-cigarettes increased by an astonishing 294%, and the average e-liquid capacity increased by 518%.<sup>15</sup>

Other studies have shown additional health harms that specifically affect young users, such as nicotine poisoning and inhalation of poisonous substances other than nicotine contained in e-cigarettes.<sup>16</sup> Of particular concern is the presence of heavy metals in e-cigarettes. Data drawn from a sample in a Population Assessment of Tobacco and Health (“PATH”) Study<sup>17</sup> panel of adolescents between thirteen and seventeen years old revealed that an increase in intensity and frequency of e-cigarette use is linked to higher urine lead and uranium levels.<sup>18</sup>

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<sup>14</sup> See Megan C. Diaz, et al., *Bigger, stronger and cheaper: growth in e-cigarette market driven by disposable devices with more e-liquid, higher nicotine concentration and declining prices*, BMJ JOURNALS — TOBACCO CONTROL (Aug. 3, 2023), <https://tinyurl.com/2hynaebc>.

<sup>15</sup> See *id.*

<sup>16</sup> See Nicole A. Tashakkori, et al., *Notes from the Field: E-Cigarette-Associated Cases Reported to Poison Centers — United States, April 1, 2022–March 31, 2023*, MORBIDITY AND MORTALITY WEEKLY REPORT 2023, <https://tinyurl.com/5xdcxxw3>.

<sup>17</sup> See *Study Overview*, NAT’L INSTITUTES OF HEALTH, <https://tinyurl.com/yr79evje> (last visited Aug. 26, 2024) (PATH Study is “collaboration between the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), the study was launched in 2011 and started the first wave of data collection in 2013...and looks at tobacco use and how it affects the health of people in the U.S.”)

<sup>18</sup> Andrew Kovchar, et al., *Biomarkers of metal exposure in adolescent e-cigarette users: correlations with vaping frequency and flavouring*, BMJ JOURNALS - TOBACCO CONTROL, (Apr. 29, 2024), <https://tinyurl.com/2vxbekd2>.

Exposure to such heavy metals in early life through e-cigarette use could harm brain and organ development.<sup>19</sup> The trace metals found in e-cigarettes have also been shown to affect the central and peripheral nervous systems which play an important role in mood regulation.<sup>20</sup>

Studies have also found a strong association between e-cigarette use and depression.<sup>21</sup> Prolonged nicotine exposure has been shown to amplify stress signals and disrupt depression coping mechanisms.<sup>22</sup> Adolescent nicotine use has also been shown to result in “long-term increases in impulsivity and impaired attention.”<sup>23</sup>

In short, the use of e-cigarettes, especially by children, is associated with a variety of significant and well-documented risks of harm. *Amici* States therefore have a strong interest in leveraging all the tools available to us to control this burgeoning public health crisis that poses particular risks to children.

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<sup>19</sup> *Id.*

<sup>20</sup> See Olufunmilayo H. Obisesan, et al., *Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System, 2016-2017*, JAMA NETWORK (Dec. 4, 2019), <https://tinyurl.com/ms4by46d>.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> Winickoff, *Vaping in Youth*, *supra*, note 13, at “Other Cognitive and Mental Health Effects.”

**II. Flavored e-cigarettes are largely responsible for high rates of youth tobacco use, even as use of other tobacco products continues to decline.**

The past decade has seen a dramatic increase in youth tobacco use driven by rapidly growing consumption of e-cigarettes by minors, even as consumption of combustible cigarettes has declined.<sup>24</sup> National surveys of youth demonstrate that young tobacco users have a strong preference for e-cigarettes over other tobacco products. And, significantly for purposes of this case, young users report a specific preference for flavored e-cigarettes over non-flavored products.<sup>25</sup>

An analysis of data from the National Youth Tobacco Surveys (“NYTS”) between 2011 and 2015 showed a significant increase in e-cigarette use coupled with a decrease in conventional, combustible tobacco (cigarettes and cigars) use.<sup>26</sup> The survey found that the use of e-cigarettes during this time period shot up from 1.5% to 16% among all high school students and from 0.6% to 5.3% among all middle school students—surpassing use rates of other tobacco

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<sup>24</sup> See Andrea S. Gentzke, et al., *Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018*, CENTERS FOR DISEASE CONTROL (Feb. 15, 2019), <https://tinyurl.com/p5xeuvs4> (“JUUL entered the U.S. market in 2015 and subsequently became a commonly used tobacco product among U.S. youths”).

<sup>25</sup> Like petitioner, we use the term “flavored” to refer to products with flavors other than tobacco. See Pet’r Br. at 6 n.1.

<sup>26</sup> Tushar Singh, et al., *Tobacco Use Among Middle and High School Students — United States, 2011–2015*, CENTERS FOR DISEASE CONTROL (Apr. 15, 2016), <https://tinyurl.com/ms34xpj3>.

products.<sup>27</sup> By 2015, an estimated 4.7 million middle and high school students were current users<sup>28</sup> of tobacco, including 3 million e-cigarette users.<sup>29</sup>

These concerning levels of youth tobacco use continued year after year. By 2019, a total of 6.2 million middle and high schoolers self-reported as current users of tobacco products.<sup>30</sup> E-cigarettes were again the most popular product, with 27.5% of high schoolers and 10.5% of middle schoolers reporting being current e-cigarette users.<sup>31</sup> In all, 5.4 million students reported being current e-cigarette users.<sup>32</sup>

As the strategies implemented by national, state, and local actors to curb youth e-cigarette use were rolled out beginning in around 2016, *see infra* Part III, rates of use among youth began to fall from their peak in 2019, but even years later, overall use by young people remains stubbornly high.<sup>33</sup> In the most recent

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<sup>27</sup> *Id.*

<sup>28</sup> “Current use” is defined as use in the past 30 days. *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> In fact, a total of 10.9 million middle and high schoolers reported having ever tried a tobacco product (53.3% of high schoolers at 8 million and 24.3% of middle schoolers at 2.9 million). Teresa W. Wang, et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019*, CENTERS FOR DISEASE CONTROL (Dec. 6, 2019), <https://tinyurl.com/yc3kz9xe>.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *See, e.g., U.S. E-cigarette Sales Climbed during 2020-2022*, CENTERS FOR DISEASE CONTROL (June 22, 2023), <https://tinyurl.com/2phd4pfp> (decrease of e-cigarette sales from May 2022 through December 2022 reflects multiple factors, including local and state restrictions on flavored tobacco product

survey, results of which were released at the end of 2023,<sup>34</sup> a total of 2.13 million students reported being current users of e-cigarettes, representing 10% of all high schoolers and 4.6% of all middle schoolers in the country.<sup>35</sup> Of these young e-cigarette users, 25.2% reported using these products daily, and a staggering 89.4% reported using flavored e-cigarettes.<sup>36</sup>

Individual state-level youth health surveys over the past decade followed similar trends to those identified in the NYTS, illustrating that e-cigarette use has consistently been higher than use of traditional tobacco products. These surveys illustrate the prevalence of e-cigarette use at an even more granular level. For example, a 2019 Massachusetts survey included a breakdown of results by grade, revealing that 65.6% of 12th graders reported ever using e-cigarettes, while 46.3% reported using e-cigarettes in the past 30 days, as compared to 29.5% who ever smoked combustible cigarettes and only 9.7% who smoked combustible cigarettes in the past

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sales and FDA regulatory actions). *See also E-cigarettes: Facts, stats and regulations*, TRUTH INITIATIVE (June 7, 2024), <https://tinyurl.com/5t3vw2w9> (“While e-cigarette use among young people has declined in recent years, it remains a serious public health threat: 10% of high school students used e-cigarettes in 2023, many of whom were not smokers in the first place.”)

<sup>34</sup> The results of the 2024 NYTS have not yet been published.

<sup>35</sup> Jan Birdsey, et al., *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, Nov. 3, 2023*, Centers for Disease Control and Prevention, 72 MORBIDITY & MORTALITY WKLY. REP. 1173, 1175 (2023), <https://tinyurl.com/3k57tj3t>.

<sup>36</sup>*Id.*

30 days.<sup>37</sup> A Texas study from 2021 found that 45% of 12th graders surveyed had ever used e-cigarettes and 25.9% reported being current e-cigarette users, as compared to 8.7% being current cigarette or cigar smokers.<sup>38</sup> A 2023 Minnesota survey showed the same trends, with 27.7% of high school students reporting ever using e-cigarettes and 13.9% being current e-cigarette users, as compared to 4.5% reporting being current combustible cigarette smokers.<sup>39</sup> The 2023 Minnesota survey included rates of “signs of dependence,” where 87.7% of middle school and 78.7% of high school current e-cigarette users reported signs of e-cigarette dependence.<sup>40</sup>

The results of these state surveys are consistent with extensive academic research demonstrating children’s preference for e-cigarettes over combustible cigarettes and the particular attractiveness of flavored e-cigarettes to minors. For example, the PATH Study gathered evidence “indicating youth who first tried a flavored tobacco product have a higher likelihood of current tobacco use compared to those who first tried an unflavored product.”<sup>41</sup> Another study found that “adolescents who vaped e-cigarettes in nontraditional

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<sup>37</sup> Massachusetts Department of Elementary and Secondary Education and Department of Public Health, *Spring 2019 Student Survey Result Highlights* (2019), at 28-29, <https://tinyurl.com/3s2p5t5f>.

<sup>38</sup> Texas Department of State Health Services, *Youth Risk Behavior Survey Dashboard*, <https://tinyurl.com/3zdcbm2z> (last accessed Aug. 26, 2024).

<sup>39</sup> Minnesota Department of Health, *Data Highlights from the 2023 Minnesota Youth Tobacco Survey* (2024), at 1-2, <https://tinyurl.com/45s5jyc8>.

<sup>40</sup> *Id.* at 2.

<sup>41</sup> Diaz, *supra* note 14.

flavors” were both more likely to keep vaping and “more likely to take more puffs per vaping occasion 6 months later.”<sup>42</sup> When asked about their motivation for using e-cigarettes, “[y]ouths report that flavors are a primary reason they use e-cigarettes, and most youth e-cigarette users first initiate use with flavored products.”<sup>43</sup>

Notably, the preferences of young e-cigarette users stand in contrast to the preferences of adult users. One report studying this issue found that adult e-cigarette users preferred “non-sweet” flavors, whereas adolescent e-cigarette users preferred sweet flavors (for example, respondents’ flavors like “Pink Lemonade” or “Suicide Bunny Mother’s Milk and Cookies,” JA 546-49, 606-08).<sup>44</sup> Crucially, the study found that among adults, the presence of flavors in e-cigarettes did not correlate with the frequency of use, whereas youth preference for flavors was associated with more days of e-cigarette use.<sup>45</sup> In other words, while “specific flavor preferences and the use of multiple flavors is associated with more frequent e-cigarette use among youth,” this correlation was not observed among adults.<sup>46</sup> Research has further shown

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<sup>42</sup> Adam M. Leventhal, et al., *Flavored E-cigarette Use and Progression of Vaping in Adolescents*, 144 PEDIATRICS (2019), <https://tinyurl.com/yrau3kbn>.

<sup>43</sup> Brian A. King, *Flavors Are a Major Driver of the Youth E-cigarette Epidemic*, 110 AM. J. PUBLIC HEALTH 773 (2020), <https://tinyurl.com/48xu4prd>.

<sup>44</sup> Meghan E. Morean, et al., *Preferring More E-cigarette Flavors Is Associated with Increased E-cigarette Use Frequency Among Adolescents but Not Among Adults*, 13 PLOS ONE (2018), <https://tinyurl.com/4tddjnev>.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

that a majority of young e-cigarette users express the intent to discontinue vaping if tobacco-flavored e-cigarettes were the only option available.<sup>47</sup>

The unambiguous conclusion of these surveys and studies is that minors are particularly drawn to flavored e-cigarettes, which are directly linked both to minors' initiation into tobacco use, and to their continued or more frequent use of such products. Given the data showing millions of children currently using tobacco products, and flavored e-cigarettes being their preferred type of product, existing research strongly supports *Amici* States' and the FDA's focus on regulating flavored e-cigarettes to protect children.

**III. The FDA's statutory authority over the introduction of new tobacco products into interstate commerce is a crucial complement to state and local regulation of flavored e-cigarettes.**

As the rise in e-cigarette use among young people has reached epidemic levels, States have taken a variety of actions to curb the availability and prevalence of flavored e-cigarettes. As discussed below, although these efforts are important, federal authority to regulate e-cigarettes remains crucial because e-cigarettes move readily through interstate commerce. Congress, recognizing this problem, conferred express authority on the FDA to control the introduction of new tobacco products, including e-

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<sup>47</sup> See Natasha K. Sidhu, et al., *Adolescent and Young Adult Response to Hypothetical E-liquid Flavor Restrictions*, 84 JOURNAL OF STUDIES ON ALCOHOL AND DRUGS 303 (2023), <https://tinyurl.com/mr4aa58w>.

cigarettes, into interstate commerce, and the FDA's exercise of that authority is critical to *Amici* States' efforts to protect our young people from the harms of vaping, and specifically from exposure to the flavored e-cigarettes that are at the heart of the youth vaping epidemic.

**A. States have adopted a variety of measures to restrict sales of flavored e-cigarettes, but these products continue to flow through interstate commerce.**

In order to protect young people from the harms associated with tobacco use, several states and localities have taken decisive action to limit the availability and distribution of flavored e-cigarettes. Massachusetts, California, and the District of Columbia ban the retail sale of flavored tobacco products, including e-cigarettes.<sup>48</sup> New Jersey, New York, and Rhode Island specifically prohibit the sale of flavored e-cigarettes.<sup>49</sup> Other states have taken action to stem the tide of youth e-cigarette use short of an outright sales ban. Illinois prohibits e-cigarette advertisements that are meant to be attractive to persons under 21.<sup>50</sup> Wisconsin, beginning in the second half of 2025, will require manufacturers selling e-cigarettes to certify their approval status under the FDA's certification process in order to be legally sold

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<sup>48</sup> Mass. Gen. Laws ch. 270, § 28; Cal. Health & Safety Code, § 104559.5 *et seq.*; D.C. Code § 7-1721.08.

<sup>49</sup> N.J. Stat. § 2A:170-51.12; N.Y. Public Health Law §1399-MM-1 (prohibiting sale of flavored e-cigarettes not preapproved by the FDA pursuant to 21 U.S.C. § 387j); R.I. Code R. § 216-RICR-50-15-6.10 (A).

<sup>50</sup> 410 ILCS 86/25(d).

in the state.<sup>51</sup> Kentucky’s similar law goes into effect January 1, 2025.<sup>52</sup> And numerous other states—including Hawai’i, Indiana, Maryland, New Mexico, Oregon, and Vermont—recently introduced legislation seeking to limit or prohibit the sale of flavored tobacco products.<sup>53</sup>

On the enforcement side, state and local agencies conduct inspections at retail stores to assess compliance with these various regulations and impose penalties on retailers that sell e-cigarettes in violation of state law.<sup>54</sup> States have also brought litigation against sellers of e-cigarettes who have targeted young users with advertising that appeals to children.<sup>55</sup>

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<sup>51</sup> Wis. Stat. § 995.15.

<sup>52</sup> Ky. 2024 HB 11 (eff. Jan. 1, 2025).

<sup>53</sup> Parker Beene, *Recent Federal and State Actions to Limit Flavored Tobacco Products*, ASS’N OF STATE AND TERRITORIAL HEALTH OFFICIALS, Mar. 2, 2023, <https://tinyurl.com/8fb72rea>.

<sup>54</sup> See, e.g., Press Release, N.J. DIV. OF CONSUMER AFFAIRS, <https://tinyurl.com/22hajymt> (“AG Platkin: Division of Consumer Affairs Issues 19 Notices of Violation to Stores After Investigation into Illegal Sales of Flavored Vapor Products Banned in New Jersey”); Cigarette and Tobacco Products Inspection Program, CAL. DEP’T OF TAX AND FEE ADMIN., <https://tinyurl.com/2sbunxbd> (inspections include ensuring retailers do not include flavored cigarettes in inventory); Local, State and Federal Laws Related to Tobacco, MASS. DEP’T OF PUBLIC HEALTH, <https://tinyurl.com/3wrr6pb9> (local boards of health conduct retailer inspections and levy penalties such as warnings, fines, or license suspensions to those who sell to minors).

<sup>55</sup> Among other states, California, Colorado, Illinois, Massachusetts, New Mexico, New York, North Carolina, and

However, although the enforcement efforts of state and local governments are vital to protect young people from obtaining dangerous flavored e-cigarettes, *Amici* States know from experience that state action alone is insufficient to combat an epidemic that transcends state borders. *Amici* States cannot fully prevent flavored e-cigarettes from crossing state lines, especially because, while several states have enacted restrictions on flavored e-cigarettes, many others have not. The wide variety of restrictions and laws from one state to the next renders enforcement efforts difficult where such products flow easily through interstate commerce. And enforcement is further complicated by the ready availability of flavored e-cigarettes online. Studies have revealed that where young users cannot easily or legally obtain e-cigarettes from nearby

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Washington, D.C., sued and secured settlements from JUUL, a manufacturer of e-cigarettes, for its marketing that targeted youth. See Karen Matthews, *Juul Labs agrees to pay \$462 million settlement to 6 states*, ASSOCIATED PRESS (Apr. 12, 2023), <https://tinyurl.com/33nr82>; N.C. Dept. of Justice, *Attorney General Stein Reaches Agreement with JUUL for \$40 Million and Drastic Business Changes* (June 28, 2021), <https://tinyurl.com/43yccf4z>.

sellers, online retailers present a convenient and popular alternative to evade sales bans.<sup>56, 57</sup>

The continued availability of flavored e-cigarettes in the marketplace also forces states to contend with the significant and long-term harmful health ramifications that befall minors who become addicted to nicotine. The overall costs borne by states for smoking-related health care and losses in productivity are exceedingly high. In 2023, smoking-caused health care costs in Texas were estimated at \$10.29 billion per year, and smoking-caused losses in productivity

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<sup>56</sup> See, e.g., Ariz. Criminal Justice Comm'n, *2022 Arizona Youth Survey State Report*, at 55, <https://tinyurl.com/5n6pbktu> (16.4% of 8th graders who used e-cigarettes in the past 30 days obtained the device over the internet); Yong Yang, et al., *The Impact of a Comprehensive Tobacco Product Flavor Ban in San Francisco Among Young Adults*, 11 ADDICTIVE BEHAVIORS REPORTS 100273 (2020), <https://tinyurl.com/4mxatxw9> (study done on young adults after implementation of San Francisco's flavored tobacco ban showed that, of those participants who "evad[ed] the ban in various ways," the most popular option was "purchasing online" (15%, followed by "purchasing from outside the city (12%)").

<sup>57</sup> To further complicate enforcement efforts, even in those states where flavored tobacco products are banned, children are still able to obtain such products from sources elsewhere. For instance, the Massachusetts Youth Health Surveys for 2021 and 2023 indicate, respectively, that 75.8% and 81.2% of high schoolers who used tobacco products in the past 30 days bought them from another state, gave someone else money to buy them, got them from friends or family members (who may themselves have gotten the products from out of state), or got them online. Massachusetts Dep't. of Public Health, *Results of the Massachusetts Youth Health Survey 2021* (2022), at 16, <https://tinyurl.com/5cu2v2p3>; Massachusetts Dep't. of Public Health, *Results of the Massachusetts Youth Health Survey 2023* (2024), at 19, <https://tinyurl.com/3cufyxf6>.

were an estimated \$24.4 billion per year;<sup>58</sup> in Wisconsin, \$3.09 billion and \$5.6 billion, respectively;<sup>59</sup> in Massachusetts, \$4.74 billion and \$7 billion, respectively;<sup>60</sup> in Iowa, \$1.49 billion and \$3.1 billion, respectively;<sup>61</sup> in California, \$15.44 billion and \$28.1 billion, respectively;<sup>62</sup> in Arizona, \$2.76 billion and \$5.2 billion, respectively;<sup>63</sup> and in New York, \$12.07 billion and \$18.2 billion, respectively.<sup>64</sup> Another prominent resource drain is the urgent need for schools to implement tobacco prevention and treatment plans.<sup>65</sup> Students can experience peer pressure in schools because they widely believe that a

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<sup>58</sup> *The Toll of Tobacco in Texas*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/bdd983yc>.

<sup>59</sup> *The Toll of Tobacco in Wisconsin*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/y5rv89>.

<sup>60</sup> *The Toll of Tobacco in Massachusetts*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/4x99cf5j>.

<sup>61</sup> *The Toll of Tobacco in Iowa*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/36bpme47>.

<sup>62</sup> *The Toll of Tobacco in California*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/4brabrbc>.

<sup>63</sup> *The Toll of Tobacco in Arizona*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/yeyrxcey>.

<sup>64</sup> *The Toll of Tobacco in New York*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://tinyurl.com/2j8ps2e3>.

<sup>65</sup> See Jessica Liu, *et al.*, *Barriers and facilitators to address vaping in Massachusetts schools: a mixed-methods study of school-based stakeholders*, *TRANSL. BEHAV. MED.* (Aug. 2023), <https://tinyurl.com/4h22ff4y> (Massachusetts school administrators who took part in study “unanimously reported the need for more access to at least one of the resources listed, such as screening services, Alternative-to-Suspension programs, and mental health support” to prevent and treat adolescent vaping).

large number of their peers use flavored e-cigarettes.<sup>66</sup> *Amici* States recognize that their limited State resources are negatively impacted not only by individual tobacco users within each state, but also by persons who first become addicted in other states, where flavored e-cigarettes may be more easily obtainable.

**B. Congress addressed the problem of tobacco use by young people when it enacted the Family Smoking Prevention and Tobacco Control Act and expressly granted FDA broad authority over new tobacco products entering interstate commerce.**

Congress has recognized that youth tobacco use is a national crisis requiring national regulatory efforts. After this Court held in *FDA v. Brown & Williamson Tobacco*, 529 U.S. 120, 161 (2000), that the FDA lacked the authority to regulate tobacco products under its then-existing statutory authority, Congress in 2009 passed the Family Smoking Prevention and Tobacco Control Act, which empowered the FDA to enact regulations to curb tobacco use, including the

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<sup>66</sup> See, e.g., Massachusetts Department of Public Health, *Results of the Massachusetts Youth Health Survey 2023*(2024), at 18, 20, <https://tinyurl.com/45h8s2ed> (81.9% of 12th graders believe most peers their age use e-cigarettes; 64.5% of 8<sup>th</sup> graders believe most peers their age use e-cigarettes); Colorado Department of Public Health & Environment, *Healthy Kids Colorado Survey Dashboard*, <https://tinyurl.com/4m53kc4r> (last accessed Aug. 26, 2024) (2023 survey showed 55.3% of 12th graders who used e-cigarettes did so because a friend or family member used them).

use of non-traditional tobacco and nicotine products such as e-cigarettes. *See generally* Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781-82. In passing the Act, Congress recognized the use of tobacco products by children to be “a pediatric disease of considerable proportions,” and observed that the federal government (like the States) has a “substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use.” Pub. L. No. 111-31, § 2, 123 Stat. at 1777, 1779. Congress further recognized that “past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents,” which necessitated “comprehensive restrictions on the sale, promotion, and distribution of such products” in the flow of interstate commerce. *Id.* §§ 2(6), 2(10), 123 Stat. at 1777.

Critically, Congress expressly authorized the FDA to “deem” non-traditional tobacco and nicotine products, like e-cigarettes, to be subject to regulation. *See* 21 U.S.C. § 387a(b). Accordingly, in the wake of an increasing crisis of youth tobacco use, the FDA in 2016 promulgated the “Deeming Rule,” which formally extended the FDA’s authority to regulate almost all tobacco and nicotine products—including e-cigarettes—and prohibited the sale of all such products to individuals under 18 years old. *See* 21 C.F.R. §§ 1100, 1140.<sup>67</sup>

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<sup>67</sup> Respondents do not challenge the Deeming Rule.

Equally critically, Congress *required* that the FDA deny approval for a new tobacco product (i.e., one not on the market as of February 15, 2007, *see* 21 U.S.C. § 387j(a)(1)(A)) if “the Secretary [of Health and Human Services] finds that there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.” 21 U.S.C. § 387j(c)(2)(A). The FDA makes this assessment through a Pre-Market Tobacco Application (“PMTA”). *See* 21 C.F.R. § 1114.5; *see also* 21 C.F.R. § 1114.7(k) (requiring PMTAs to contain all available information regarding the potential health risks of the product subject to the application, including “[t]he likelihood that consumers who have never used tobacco products, particularly youth, young adults, and other relevant vulnerable populations, will initiate use of the tobacco product”). And, as the FDA has explained in its brief, *see, e.g.*, Pet’r Br. at 3-4, 6-7, 18–20, the PMTA process is designed to provide the FDA with enough information to answer the essential question that Congress posed, namely, will the introduction of a particular new product into interstate commerce be “appropriate for the protection of the public health”? Given the overwhelming evidence linking flavored e-cigarettes to vaping by children, it is unsurprising that applicants have had a difficult time establishing that a new flavored e-cigarette could meet that standard.

**C. By working together, States and the federal government have made progress in stemming the increase of youth vaping.**

In recent years, the concerted efforts of state and federal government actors have been essential in reversing the dramatic upward trend in youth e-cigarette use. Since 2016, the FDA has approved the marketing of only about three dozen new e-cigarette products, “most of them tobacco flavored,” while “den[ying] applications for authorization to market more than a million e-cigarette products with non-tobacco flavors, including candy, fruit, various desserts, and menthol.” Pet’r Br. at 5-6. These FDA actions, together with the state and local actions described above, have directly contributed to a decline in youth e-cigarette use. As one study explains, “[t]he decline since 2022 in high school student e-cigarette use is likely attributable to multiple factors, such as ongoing efforts at the national, state, and local levels to implement tobacco control strategies, including Food and Drug Administration (FDA) regulatory actions.” Birdsey, *supra* n.35, at 1178.

Despite this laudable progress, significant hurdles remain. While the total percentage of middle- and high-school users of e-cigarettes has declined since 2020, *see* Part II, *supra*, at 10-12, those numbers remain stubbornly high—well into the millions—and significantly higher than reported in 2011.

In sum, the goals of *Amici* States in preventing youth vaping, and in curtailing the harms that have already befallen this new generation of smokers,

cannot be fully realized without the FDA's critical regulatory and enforcement role. Only the FDA can prevent flavored e-cigarettes from entering interstate commerce; once these products have done so, *Amici* States know that widespread distribution to minors becomes inevitable. Careful exercise of the PMTA authority that Congress expressly conferred on the FDA—such as the FDA's determination to deny approval in this case—is essential to ensuring that such products never reach children in the first place.

### CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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