

Scott Gottlieb, M.D., Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

*Re: Docket No. ID: FDA-2017-N-6565 Regulation of Flavors in Tobacco Products*

Dear Dr. Gottlieb:

The Competitive Enterprise Institute (CEI) welcomes the opportunity to offer comments regarding the regulation of flavors in tobacco products.

**Interest of the Commenters:** CEI is a non-partisan, non-profit public policy organization with a long history of research and advocacy with an emphasis on promoting rational risk regulation and consumer choice. Throughout our decades of research, we have frequently observed that attempts to limit exposure to certain risks—however well-intentioned—often unintentionally increase exposure to other, possibly more hazardous risks. In the case of tobacco harm reduction, anxieties about the unknown risks of non-combustible cigarette alternatives and their effect on adolescents have significantly undermined an objective analysis of the harms and benefits of regulating this market. We believe the overwhelming evidence indicates that a vibrant e-cigarette and e-cigarette flavor market is, not only beneficial for adult smokers, but also aids in reducing adolescent smoking. The proposed regulation of e-cigarette flavors is not only unwarranted, but would dire consequences for tobacco-harm reduction.

**Background:** Despite the efforts of public health campaigns, smoking continues to contribute to more than 7 million deaths worldwide each year.<sup>1</sup> In the U.S. alone, over 16 million Americans suffer from smoking-related diseases and half a million die each year as a result of health effects arising from their habit.<sup>2</sup> As with other public health crises, we ought to embrace *all* avenues of harm reduction rather than focus on an ineffective “abstinence only” approach. As the harmful nature of traditional cigarettes primarily stems from their use of combustion to burn tobacco, noncombustible nicotine delivery products, like e-cigarettes, are intrinsically less harmful than traditional cigarettes.<sup>3</sup>

Unfortunately, anxieties about the effect of e-cigarette availability on the non-smoking adolescent population have far outstripped a dispassionate analysis of the public health gains e-cigarette availability may achieve in both adult and adolescent smoking populations. Despite the inherently smaller risk of non-combustible tobacco, some individuals and groups continue to assert that the existence of e-cigarettes is a net negative for public health. In particular, their concerns center on the idea that the variety of e-flavors currently available attract non-smoking adolescents to vape, become addicted to nicotine, and progress onto smoking traditional cigarettes (the so-called “gateway” effect.)

Based on the government’s own evidence, such claims should be rejected. According to the Centers for Disease Control (CDC) annual Youth Tobacco Survey, the declining rate of tobacco use among high school and middle school students has only accelerated since the introduction of e-cigarettes on the U.S. market. Furthermore, since its peak in 2015, past month use of e-cigarettes among school-age children has also declined impressively:

- 2014 = 13.4%

- 2015 = 16.0%
- 2016 = 11.3%
- 2017 = 11.7%<sup>4567</sup>

**Are e-cigarettes a gateway to smoking:** Despite news headlines and lobbying by certain anti-tobacco groups about the supposed rise in popularity of e-cigarette usage among teens, between 2015 and 2016, high school use of e-cigarettes dropped an astonishing 30 percent and, based on the latest edition of that survey, that trend held steady in the following year.

The declines in teen vaping observed by the CDC contradict assertions that a wide variety of e-cigarette flavors increases teen use of e-cigarettes or traditional cigarettes since the availability of e-cigarettes and e-cigarette flavors has only increased since 2015.

One major criticism of the CDC's study is that it might not adequately capture teenage e-cigarette use because its survey asks teens about their previous use of 'electronic cigarettes' or 'e-cigarettes.' In a recent paper by the Truth Initiative, it was suggested that a certain portion of the adolescent population that uses the Juul, do not refer to it as an 'e-cigarette,' but simply as 'the Juul,' and do not refer to its use as 'vaping,' but rather 'Juuling.' Thus, the Truth Initiative paper's authors argue, any survey without these Juul-specific terms may end up underestimating the amount of teen e-cigarette use.<sup>8</sup>

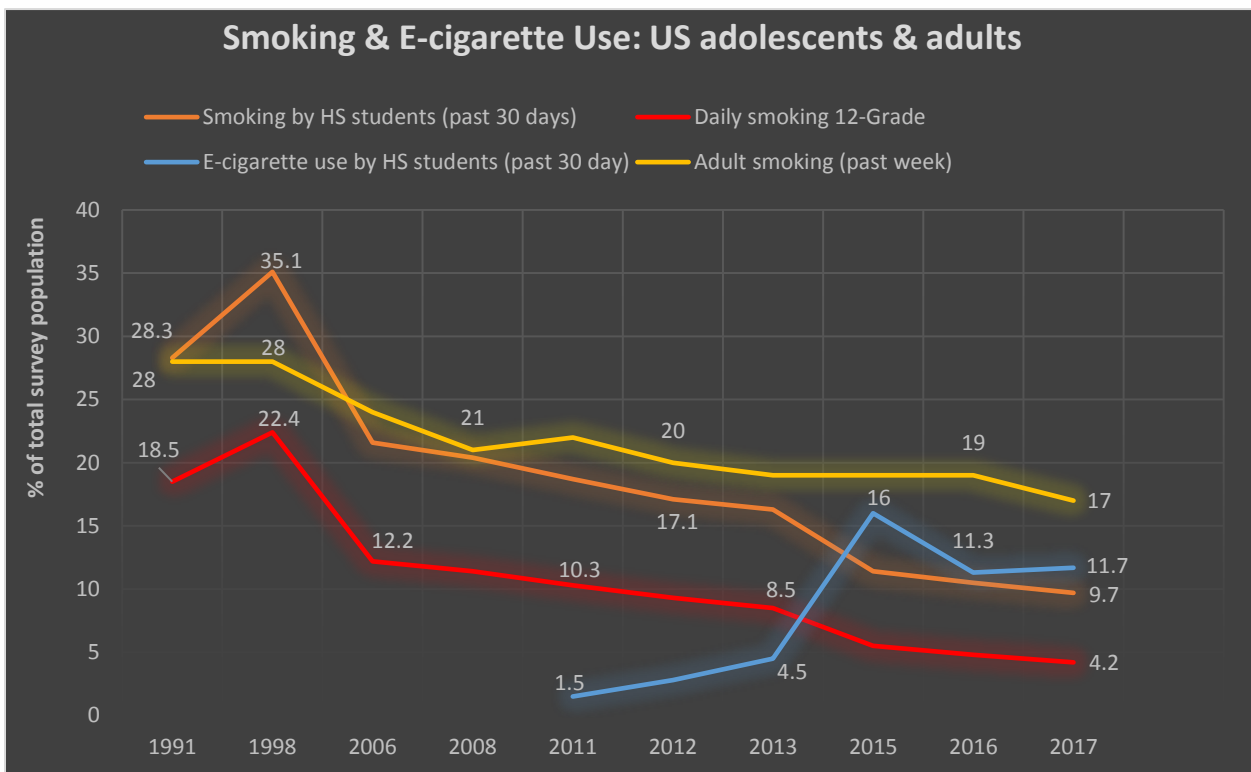
As the Campaign for Tobacco-Free Kids put it, the study "found that a quarter of youth and young adult JUUL users don't refer to JUUL use as "e-cigarette use" or "vaping," but rather as "JUULing."<sup>9</sup> But, this is not what the survey found. When the 253 adolescents (ages 15 through 24) that recognized the Juul were asked "what do people your age call these products," just 86 individuals responded that they called the device 'the Juul.' 159 individuals responded that they refer to it as an 'e-cigarette.' While the study highlights that 25 percent of respondents (63 people) said they called using the Juul 'Juuling,' more than half (129 people) said they called it 'vaping.'

The assertion that this study demonstrates some inadequacy of the CDC study is wholly unsupported by its results. In addition to a sample size so small the results cannot be generalized to the wider U.S. adolescent population, the study does not provide information about the portion of adolescents that might not recognize the Juul as an electronic cigarette in other surveys. The key failing of the Truth Initiative study is that it did not allow participants to choose multiple answers. As a result it's impossible to know if the adolescents that reported calling the device 'the Juul' and its use 'Juuling' are or are not aware that it might *also* be referred to as 'an e-cigarette' and 'vaping.' Thus, it's impossible to conclude, from this study, that any adolescents would fail to respond accurately to a CDC or any other survey that didn't contain Juul-specific question about e-cigarette use.

It is actually more likely that the CDC survey *overestimates* adolescent use of e-cigarettes because it asks about "any use" in the previous 30 days. Research into adolescent vaping patterns indicates that most who experiment with e-cigarettes do not go on to become habitual users. For example, a study of high school teenagers published in the Journal of Pediatrics in 2015 found that of the nearly 2,000 students who reported ever using e-cigarettes, just two percent reported using them on a daily basis and only eight percent reported using e-cigarettes three or more times in the previous month.<sup>10</sup> Furthermore, the national data does not ask about these teen vapers' nicotine consumption, which is the primary public health concern when investigating youth use

of e-cigarettes. A 2017 study of students in grades 12, 10, and 8 that did ask adolescent e-cigarette users about nicotine consumption found that less than 22 percent reported using e-cigarettes with nicotine with around 65 percent vaping only flavoring.<sup>11</sup>

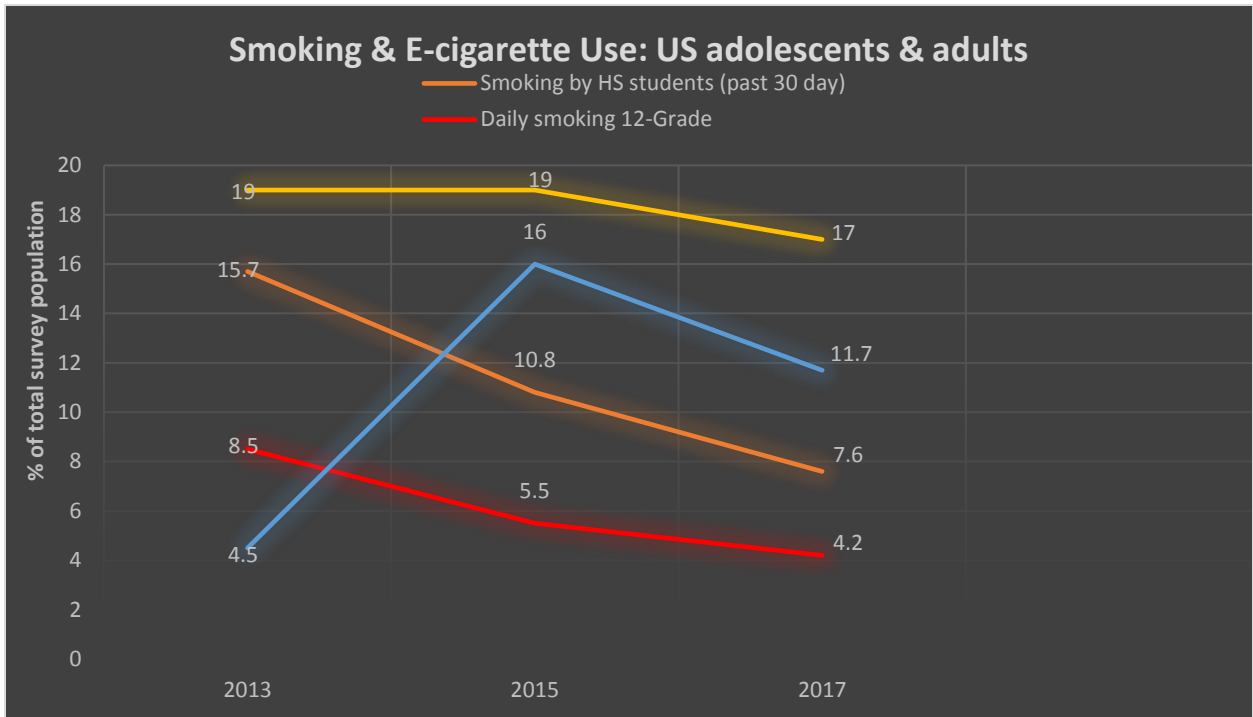
In reality, the claim that e-cigarettes are a “gateway” to smoking has no basis in research: none of the empirical studies purporting to have found such a relationship has actually demonstrated that it exists.<sup>12</sup> Furthermore, the idea that e-cigarette use in adolescence eventually leads to a habit of smoking traditional combustible cigarettes in adulthood is contradicted by the fact that adolescent smoking rates have continued to decline since the introduction of e-cigarettes onto the market. In fact, they have declined plummeted to their lowest levels ever recorded, falling by half between 2011 and 2016 (along with teen cigar use, pipe smoking, and smokeless tobacco use which also declined by a third, two-thirds, and a quarter, respectively).<sup>13</sup> Smoking has also decreased among U.S. adults. The decades’ long drop in adult smoking experienced a plateau



between 2006 and 2008, with the prevalence of adult smokers remaining stubbornly at 21 percent. It wasn't until 2009 that the decline began again and by 2015 the adult smoking rate dropped to just 15 percent—the lowest adult smoking rate ever.<sup>14</sup>

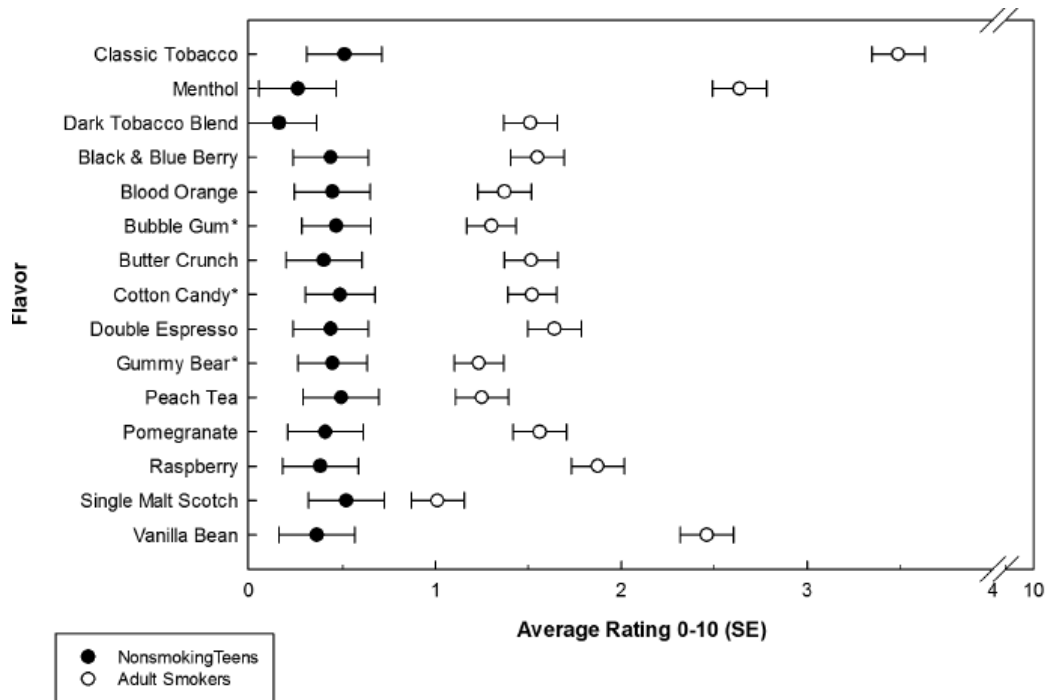
Not only has the presence of e-cigarettes on the U.S. market not stopped the decline in smoking, but there is compounding evidence that e-cigarettes might be a cause of reduced smoking.<sup>15</sup> As such, **government officials should be very cautious about implementing restrictions or communicating messages that make e-cigarettes less attractive to smokers looking to quit**, regardless of their age. For example, a 2016 Cornell study revealed that teen use of traditional cigarettes increases following the enactment of age-limits on e-cigarette sales. This indicates that teen usage of e-cigarettes may be displacing traditional smoking.<sup>16</sup> Similarly, a 2017 study found that county-level bans on vaping indoors led to a 31 percent increase in the mean smoking rate

among pregnant women, a result the authors suspect came from both “added inconvenience of vaping, but also due to changed perceptions of the risks of ENDS.”<sup>17</sup>



**Do flavors attract children?** Despite claims that sweet and candy-like e-cigarette flavors attract non-smoking teenagers to initiate use of electronic cigarettes, the evidence indicates that e-cigarette flavors hold little appeal to nonsmoking adolescents. In small 2015 study (216 nonsmoking teenagers and 432 adult smoker), researchers with the University of Pittsburgh Department of Psychology found that there no significant variation among nonsmoking teens’ interest in e-cigarettes by flavor variation.<sup>18</sup>

Though nonsmoking teens expressed no significant variation in interest to various e-cigarette flavors, it is interesting to note that there was a non-significant preference in this group for the flavors ‘classic tobacco’ and ‘single malt scotch.’ This might indicate that where adolescents are interested in flavors, it is not the stereotypical “kid-friendly” varieties, but rather the more seemingly adult flavors that are most attractive to youth.<sup>19</sup>



Bars represent standard errors  
 \* Bubble gum, cotton candy, and gummy bear were included to represent flavors expected to be most appealing to youth, but are not being contemplated as flavors for future offerings.

**Do flavors help adult smokers?** While nonsmoking teens may not be interested in flavors, the Pittsburgh University study found that interest in flavor varieties was significantly higher among adult smokers and even more so among adult e-cigarette users. While these groups rated ‘classic tobacco’ as the most appealing, it was closely followed by ‘menthol’ and ‘vanilla bean.’ Though considered appealing only to children, the adults also reported a significant interest in the fruit and candy options, like butter crunch and cotton candy.

Earlier survey data indicates that the variety of available e-cigarette flavors plays an important role for adults, not only in their willingness to try e-cigarettes as a smoking-cessation tool, but in their ability to sustain their quit-attempt. A survey of e-cigarette users in 2014 found that only 22 percent used a single flavor and only 15 percent cited “tobacco” as their primary flavor choice.<sup>20</sup>

In the same year, researchers at the Onassis Cardiac Surgery Center in Greece and the Biological and Chemical Toxicology Research Laboratory in Italy published their results of their survey of more than 4,500 adults; of whom 91.1 percent self-identified as a ‘former smoker.’ The study, published in the International Journal of Environmental Research and Public Health, found that the tobacco flavor in e-cigarettes seemed to be preferred primarily by those in the earlier stages of smoking cessation, while longer-term ex-smokers preferred non-tobacco flavors. On average, respondents switched between three different flavors, with former smokers switching more frequently than those who self-identified as a ‘current smoker.’<sup>21</sup>

When asked about how flavor variety in e-cigarettes affected their experience, 73 percent reported that they ‘liked a variety of choices’ and 51.5 percent reported that only using one flavor caused the flavor to become “blunt.” A majority of the respondents noted that flavor

variety was “very important” to their efforts to quit or reduce smoking and eliminating flavors would make vaping less enjoyable (68.9%), more boring (45.7%), increase their cravings for cigarettes (48.5%) and make them less likely to reduce or quit smoking less likely (39.7%). Most importantly, the study found that the number of flavors regularly used by e-cigarette consumers was independently associated with complete smoking abstinence.<sup>22</sup>

It is possible that smokers who are most motivated to quit are also more likely to try many e-cigarette flavors. But, this study raises the important and, as yet, unanswered question of how e-cigarette flavor variety impacts smoking cessation rates. Given that former smokers that have switched to e-cigarettes themselves cite flavor variability as an important factor in their cessation attempts, that question must be answered before we can have an idea of how eliminating flavor options might impact public health.

**Reduced-Risk Products and Public Health:** The FDA is statutorily obligated to consider the net impact limiting e-cigarette flavors may have on public health. In order to adhere to this public health standard, however, the Agency must first answer the following questions about limiting or banning e-cigarette and e-liquid flavors:

- What effect will this have on nonsmoking adults?
- What effect will this have on nonsmoking adolescents?
- What effect will this have on smoking adults and adolescents?

As discussed above, the existing evidence indicate that limiting flavor variety in e-cigarettes will have no effect on the nonsmoking population. However, it would significantly reduce e-cigarettes’ attractiveness to existing smokers who might try such devices as a means of reducing or quitting smoking. As a result, we assert such action would have a net *negative* effect on public health and should be rejected.

Since their introduction to the U.S. market, electronic cigarettes have been viewed by the U.S. public health community as being potentially as harmful as or even more harmful than cigarettes and characterized as a ploy by cigarette companies to lure non-smoking minors.<sup>23</sup>

While smokers initially embraced e-cigarettes, viewing them as a means of reducing their exposure to harmful chemicals, the messaging campaigns of health groups and certain government agencies has led to a decreasing public understanding of relative risk. Polls conducted by the researchers in the School of Public Health at Georgia State University found that while in 2012 only 13% of adults surveyed believed that e-cigarettes were as or more harmful than traditional cigarettes, by 2015 nearly 40% held this misguided belief.

Most disturbingly, the change in perception about e-cigarettes’ relative harm occurred in population most likely to benefit by using e-cigarettes as a method of cessation: between 2012 and 2015 the percentage of current smokers who said e-cigarettes were as or more harmful than cigarettes increased from under 12% to just over 35%.

Even as the evidence increasingly demonstrates the reduced risks of e-cigarettes compared to combustible tobacco, the emphasis on their unknown risks by government agencies and public health advocates has led to increased public misinformation. As a result, their well-intentioned efforts have stymied wider adoption of these demonstrably harm-reducing tobacco alternatives by the people who are most in need of such alternatives.

Reports from internationally respected health bodies like the National Academies of Science, Engineering, and Medicine have acknowledged that, based on the available evidence, electronic cigarettes emit significantly fewer harmful and potentially harmful chemicals than traditional cigarettes.<sup>24</sup> According to a recent study, the cancer risk of e-cigarettes is less than one percent of that posed by traditional smoking.<sup>25</sup> As such, the FDA should have the utmost concern about implementing any policies that might hamper smokers from switching to these demonstrably less harmful products. As discussed, we believe restricting e-cigarette flavors would do just that.

**Conclusion:** Adult consumers deserve access to a free market that provides them an array of nicotine-consumption choices. The fear that e-cigarette flavors attract non-smoking adolescents is utterly unsupported by the research literature and, as such, should not form the basis for stripping access to e-flavors for adults. We strongly urge the FDA to reject the exaggerated claims of anti-tobacco groups and to fulfill its obligation to support tobacco and tobacco-alternative technological innovations by allowing the market to do what decades of public health campaigns have failed to accomplish: provide smokers with satisfying alternatives to fully quit tobacco and eradicate tobacco-related harms.

Respectfully,  
Michelle Minton  
Senior Fellow  
Competitive Enterprise Institute

---

<sup>1</sup> World Health Organization, Tobacco Fact Sheet, updated May 2017, <http://www.who.int/mediacentre/factsheets/fs339/en>.

<sup>2</sup> Centers for Disease Control and Prevention, Fast Facts and Fact Sheets: Smoking and Tobacco Use, accessed September 8, 2017, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm).

<sup>3</sup> American Cancer Society, “Harmful Chemicals in Tobacco Products: Tobacco smoke,” <https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/carcinogens-found-in-tobacco-products.html>. Accessed June 8, 2018.

<sup>4</sup> René A. Arrazola, Tushar Singh, Catherine G. Corey, et al., “Tobacco Use Among Middle and High School Students — United States, 2011–2014,” Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, April 17, 2015, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm>.

<sup>5</sup> Singh T, Arrazola RA, Corey CG, et al., “Tobacco Use Among Middle and High School Students—United States, 2011–2015,” *MMWR Morbidity and Mortality Weekly Report*, 2016;65(14):361–7. doi: 10.15585/mmwr.mm6514a1.

<sup>6</sup> Ahmed Jamal, Andrea Gentzke, S. Sean Hu, Karen A. Cullen, Benjamin J. Apelberg, David M. Homa, Brian A. King, “Tobacco Use Among Middle and High School Students—United States, 2011–2016” Centers for Disease Control, Morbidity and Mortality Weekly Report, June 16, 2017, [https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1\\_down](https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1_down).

<sup>7</sup> Teresa W. Wang, Andrea Gentzke, Saida Sharapova, et al., “Tobacco Product Use Among Middle and High School Students—United States, 2011–2017,” Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, June 8, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>.

<sup>8</sup> Jeffrey G. Willett, Morgane Bennett, Elizabeth C. Hair, et al., “Recognition, use and perceptions of JUUL among youth and young adults,” *Tobacco Control*, Epub ahead of print, (April 18, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29669749>.

<sup>9</sup> Laura Bach, “JUUL and Youth: Rising E-Cigarette Popularity,” Campaign for Tobacco-Free Kids Fact Sheet, June 12, 2018, <https://www.tobaccofreekids.org/assets/factsheets/0394.pdf>.

<sup>10</sup> Thomas A. Wills, Rebecca Knight, Rebecca J. Williams, et al, “Risk Factors for Exclusive E-Cigarette Use and Dual E-Cigarette Use and Tobacco Use in Adolescents,” *Pediatrics* 2015 135(1):e43–51. doi: 10.1542/peds.2014-0760.

- 
- <sup>11</sup> Richard Miech, Megan E. Patrick, Patrick M. O'Malley, and Lloyd D. Johnston, "What Are Kids Vaping? Results from a National Survey of U.S. Adolescents," *Tobacco Control*, Vol. 26, Issue 4 (2017), pp. 386–391, <http://tobaccocontrol.bmj.com/content/26/4/386>.
- <sup>12</sup> Carl V. Phillips, "Gateway Effects: Why the Cited Evidence Does Not Support Their Existence for Low-Risk Tobacco Products (and What Evidence Would)," *International Journal of Environmental Research and Public Health*, Vol. 12, No. 5 (May 2015), pp. 5439–5464, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4454978>.
- <sup>13</sup> Ahmed Jamal, Andrea Gentzke, S. Sean Hu, Karen A. Cullen, Benjamin J. Apelberg, David M. Homa, Brian A. King, "Tobacco Use Among Middle and High School Students—United States, 2011–2016" Centers for Disease Control, Morbidity and Mortality Weekly Report, June 16, 2017, [https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1\\_down](https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1_down).
- <sup>14</sup> Centers for Disease Control and Prevention, "Smoking is the leading cause of preventable death," December 14, 2017, <https://www.cdc.gov/winnablebattles/report/tobacco.html>.
- <sup>15</sup> Shu-Hong Zhu, Yue-Lin Zhuang, Shiushing Wong, Sharon E Cummins, Gary J Tedeschi, "E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys," *BMJ*, Vol. 358, No. j3262 (July 26, 2017), <https://www.bmj.com/content/358/bmj.j3262>.
- <sup>16</sup> Michael F. Pesko, Jenna M. Hughes, Fatima S. Faisal, "The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use," *Preventative Medicine*, Vol. 87, pp. 207-212 (June 2016), <https://www.sciencedirect.com/une.idm.oclc.org/science/article/pii/S0091743516000396>.
- <sup>17</sup> Michael T. Cooper and Michael F. Pesko, "The effect of e-cigarette indoor vaping restrictions on adult prenatal smoking and birth outcomes," *Journal of Health Economics*, Vol. 56, pp. 178-190 (December 2017), <https://www.sciencedirect.com/science/article/abs/pii/S0167629617304988>.
- <sup>18</sup> Saul Shiffman, Mark A. Sembower, Janine L. Pillitteri, Karen K. Gerlach, and Joseph G. Gitchell, "The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes," *Nicotine & Tobacco Research*, Vol. 17, No. 10, pp. 1255-1262 (October 2015), <https://academic.oup.com/ntr/article-abstract/17/10/1255/1028251?redirectedFrom=fulltext>.
- <sup>19</sup> Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. "The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes," *Nicotine & Tobacco Research*, 2015; 17(10):1255-1262. doi: 10.1093/ntr/ntu333.
- <sup>20</sup> Niel McLaren, "The Big Survey 2014 - Initial Findings Eliquid," *Vaping.com*, July 17, 2014, <https://vaping.com/blog/data/big-survey-2014-initial-findings-liquid>.
- <sup>21</sup> Konstantinos Farsalinos, Giorgio Romagna, Dimitris Tsiapras, Stamatis Kyrzopoulos, Alketa Spyrou, and Vassilis Voudris, "Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey," *International Journal of Environmental Research and Public Health*, Vol. 10, No. 12, pp. 7272-7282 (December 2013), <https://europepmc.org/abstract/med/24351746>.
- <sup>22</sup> Ibid.
- <sup>23</sup> American Academy of Pediatrics, "Booming Market of Candy-Flavored E-Cigarettes and Cigars Threatens to Hook a New Generation of Kids, New Report Warns," news release, March 15, 2017, <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Booming-Market-of-Candy-Flavored-E-Cigarettes-and-Cigars-Threatens-to-Hook-a-New-Generation-of-Kids,-New-Report-Warns.aspx>.
- <sup>24</sup> National Academies of Sciences, Engineering, and Medicine, "Public Health Consequences of E-Cigarettes," Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>.
- <sup>25</sup> William E Stephens, "Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke," *Tobacco Control*, Vol. 27 (2018) pp. 10-17, <http://tobaccocontrol.bmj.com/content/27/1/10.info>.