



## Independent Vaping Industry Calls on FDA & States to Create Meaningful Market Reform

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## Executive Summary

We represent a group of broad industry stakeholders concerned with two false claims regarding our industry: (1) FDA regulated vapor products have caused acute pulmonary diseases and multiple fatalities, and (2) youth initiation is driven by flavored nicotine-containing e-liquids. Each claim will have significant negative public health and economic impacts. Further, the consequences of the political action taken in response to these two fabrications have not been duly taken into consideration. Together, our group represents multiple domestic and foreign hardware and e-liquid manufacturers and more than 600 vape retail stores in 35 states who serve approximately one million customers a year, of which over 85% have used vaping to quit or substantially reduce smoking combustible cigarettes. The companies described in the introduction below represent approximately 5% of the vape store market and employ approximately 2,700 employees who earn \$63 million in annual wages.

**Claim 1: Vaping creates acute pulmonary disease and has led to multiple fatalities.** There is no evidence that FDA regulated vapor products have resulted in any of the recent pulmonary disease-related deaths and the overwhelming majority of the patients suffering from respiratory illness have reported the use of only THC vaping products, with or without nicotine. CDC has failed to properly distinguish illegal black-market THC vaping cartridges from legally purchased nicotine-containing e-cigarettes. This oversight has caused significant consumer confusion, resulting in customers returning to cigarettes and economic hardship for vape retail store operators.

**Claim 2: Youth initiation is driven by flavored electronic nicotine delivery systems (otherwise known as ENDS, e-cigarettes, or nicotine-containing vapor products).** Flavored ENDS products have existed worldwide for more than a decade. The acceleration of youth consumption only became an epidemic in the last two years along with the increased popularity of high-nicotine, closed-pod systems. This youth initiation closely follows JUUL's growth and market penetration. Flavors are not the underlying cause of the increase in youth uptake.

These two claims are having significant negative impacts with respect to public health (sending people back to smoking and black markets), as well as significant economic (80,000+ potentially lost jobs and \$24 billion industry economic output) and political impacts (8 million upset, passionate vapers who feel vaping has improved their lives).

### Data-Driven Risk-Based Policy Recommendations

1. **Limit flavors to lower nicotine products sold through adult-only age-verified retailers.** As our research shows, flavors are not the underlying cause of the "youth epidemic." However, flavors combined with high nicotine strengths *and* discreet devices can increase youth initiation. We recommend limiting flavors to lower nicotine concentrations (30mg/ml and below) sold through adult-only age-verified retailers.
2. **Examine nicotine strength and risk profiles.** The acceleration of youth vaping is highly correlated to the growing popularity of high nicotine concentration products, particularly 50mg/ml. A nicotine-level restriction has proven lower youth adoption rates in other countries, where non-tobacco flavors remain available. The FDA should recognize this heightened risk profile with respect to the distribution and marketing of all ENDS.
3. **Encourage manufacturers to build age verification tools into all hardware.** Discreet devices are a powerful tool for adult consumers; however, when combined with high nicotine concentrations, they also have the youngest customer age demographic. For hardware devices commercially marketed prior to August 8, 2016, we recommend the FDA waive enforcement action to allow for the addition of age verification tools. Additionally, we recommend FDA waive

enforcement action for pre-August 8, 2016 closed pod systems marketed with a high nicotine-concentration, in order for the manufacturer to reduce the nicotine level. These devices should only be sold in adult-only, age-verified retailer establishments.

### **Pivot Current Crisis into a Positive Public Health Outcome**

Failing to clarify the difference between nicotine and black-market THC vaping has led to a significant public misconception regarding the risks associated with the use of ENDS products. Consumers have stopped vaping as an alternative to smoking cigarettes, and returned to their prior habits. To stop and reverse this trend, the CDC should:

1. **Clarify the role of nicotine vaping vs. illegal THC vaping in the reported cases:** The CDC should immediately release a public announcement clarifying that illegal THC vape cartridges are the underlying cause of the recent respiratory illnesses and not FDA regulated vapor products. CDC should immediately cease its recommendation that consumers refrain from use of e-cigarettes as e-cigarettes are regulated by FDA as electronic nicotine delivery systems and do not contain THC.
2. **Accept public health benefits of vaping products:** The CDC should publicly acknowledge Public Health England's well-researched and scientifically-reviewed statement that e-cigarettes are 95% safer than combustible cigarettes, and that all smokers (if they have failed to quit smoking through other FDA-approved methods) should transition to a reduced-harm product, such as ENDS. In addition, FDA announced that e-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products and onto nicotine delivery products that may not have the same level of risks associated with them<sup>1</sup>. Former Commissioner Scott Gottlieb noted, "if you could take every adult smoker and fully switch them to e-cigarettes, that would have a substantial public health impact."<sup>2</sup> The New England Journal of Medicine published a study in March 2019 stating that e-cigarettes are nearly twice as effective as nicotine-replacement therapy for smoking cessation.<sup>3</sup>

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<sup>1</sup> FDA. *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use.* September 12, 2018. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use>

<sup>2</sup> Vaping Scout. *Former FDA Gottlieb Admits Pods Help Smokers Quit but Should Be Pulled from Market.* May 21, 2019.

<https://vapingscout.com/vaping-news/former-fda-commissioner-gottlieb-says-fda-should-consider-pulling-vape-pods-market/>

<sup>3</sup>Stephens, Wallace. *e-Cigarettes Nearly Twice as Effective as Nicotine-Replacement Therapy for Smoking Cessation.* March 8, 2019. <https://www.ajmc.com/newsroom/ecigarettes-nearly-twice-as-effective-as-nicotinereplacement-therapy-for-smoking-cessation>

## Introduction

This paper is published on behalf of a group of leading vape store operators and supported by a number of independent vapor stores and vapor product manufacturers. Together, our group represents more than 600 vape stores which we estimate represent approximately 5% of the vape store market and employs approximately 2,700 employees who earn an estimated \$63 million in wages. None of these operators are owned by big tobacco companies.

Most importantly, our group serves approximately one million passionate customers of which an estimated 85% have quit or significantly decreased their consumption of combustible cigarettes. Of these former smokers, 97.8% feel that vaping has improved their lives.

**AMV Holdings, LLC (AMV):** AMV is engaged in the manufacturing, distribution and retail sale of vapor products. Subsidiaries of AMV own and operate one e-liquid manufacturing facility, multiple e-commerce platforms, and 105 vape stores in 17 states. The brick and mortar vape stores operate under the following brand names: Alohma, Electra Vapor, Madvapes, Maxx Electronic Cigarettes, and Select-a-Vapor.

**Aqueous Vapor, LLC:** Aqueous Vapor was founded on June 1st, 2013 in Columbia, MO with the intention of providing an alternative to traditional combustible cigarettes. Focusing on a well-trained staff, exemplary customer service, and superior product mix, it now operates 27 locations throughout Missouri, Kansas, Iowa, Illinois, and Arkansas.

**AVAIL Vapor, LLC:** Base in Richmond, Virginia, AVAIL is a leading premium U.S. e-liquid and CBD manufacturer, retailer, and provider of scientific industry services. It delivers on the promise of quality across its customer base through three divisions: retail, sciences and manufacturing, and research and development. AVAIL retail offers a broad array of products online and in their 99 stores across 12 states. The scientific services division promotes turnkey regulatory and scientific services to business customers across the industry.

**Create a Cig, LLC:** Create a Cig is a family-owned business that started in Austin, Texas in October 2012. Create A Cig was Austin's first dedicated vape and e-cig store and has since expanded to 27 locations in cities across Texas, Tennessee and Louisiana. They are dedicated and passionate about helping smokers become vapers and helping experienced vapers get the best of the growing number of vaping products on the market.

**ECIGCharleston, LLC:** Established in 2011, ECIG Charleston is South Carolina's largest vape company. It operates 20 retail stores as well as a manufacturing and distribution facility and employs over 60 full time employees with health benefits.

**Good Guy Vapes:** Good Guy Vapes aims to aid their customers in quitting conventional cigarettes by providing exceptional customer service and a repertoire of the best quality vapor products in the world. Based in New Jersey and founded in 2013, they currently maintain 40 stores and over 200 employees in six states.

**Joost Vapor, LLC:** Joost Vapor is the largest independently owned alternative nicotine retailer in Michigan with 17 locations. They have been named Veteran-Owned Enterprise of the Year (EPIC Awards-2018) and one of Michigan's Top 50 Companies to Watch (SBAM-2018). Joost Vapor focuses on brick and mortar business to consumer retail of alternative nicotine products. Their affiliate, Mod Fuel, is the largest manufacturer and distributor of e-liquids in Michigan. Mod Feul's manufacturing facility is ISO9001:2015 certified with a focus on business to business sale of e-liquids.

**Kure Vaporium:** KURE™ Vaporium is a premium, uniquely tailored vape shop and CBD retail store. Their products include their own line of high-end custom blend e-juices, as well as popular third-party

brands of advanced hardware, select e-liquids and CBD products. KURE™ operates 18 locations across four states and employs approximately 100 people.

**Lotus Vaping Technologies:** Lotus Vaping Technologies opened its manufacturing doors in 2011 and its first retail store in 2013 under the store name Lotus Vape Technologies. It currently operates 21 retail locations and employs over 110 employees through its retail and manufacturing companies. The company offers quality products for adults in the e-cigarette industry.

**Red Star Vapor:** RSV Holdings, LLC was founded in 2011 and is currently operating 50 retail store fronts under the name Red Star Vapor in Arizona and Colorado. Their e-liquid manufacturing/distribution centers operate under the name American Vapor Group and wholesale to over 300 independent vapor businesses around the United States.

**Saffire Vape:** Saffire Vapor is a chain of vapor stores that operates in Tennessee and Kentucky. The business was founded in 2012 and has grown to 24 retail locations and nearly 100 employees. From the beginning, it has operated with a focus on providing education and selection to adult consumers looking to switch from smoking to vapor in a friendly and welcoming environment.

**Vapor World and Vapor Maven:** Vapor Maven and Vapor World are dynamic and fast-growing companies specializing in vaping and CBD products. Vapor Maven was initially started as Vapor World in 2013 in Springdale, Arkansas. In order to expand the business, Vapor World transitioned to Vapor Maven at the end of 2016. To date, it has 130 corporate and franchise stores across the Midwest with over 800 employees.

## Claims

As a group, we are deeply concerned that two misleading claims circulating in the media and by public officials will have significant negative health, economic, and political impacts in this country. These two claims combined are driving legislation at the federal and state level to ban non-tobacco e-liquid flavors and go as far as banning the sale of vapor products all together.

### **Claim 1: Vaping creates acute pulmonary disease and has resulted in multiple fatalities.**

This claim is being widely published by the national media and is supported by statements made by the CDC. This claim does not differentiate between regulated nicotine vapor products and black-market THC vape cartridges. It has become overwhelmingly clear that the acute pulmonary diseases and multiple fatalities are the result of vaping illegal THC cartridges and other illicit products, not FDA regulated nicotine-containing products. E-cigarettes have been widely used for more than a decade and the current cases are focused on a very narrow epidemic, both in time and geography. This suggests that the respiratory illnesses are caused by specific batches of tainted black-market products and not FDA regulated vapor products.

On September 5, 2019, the New York Department of Health released an update on the pulmonary cases of New York patients. Laboratory test results showed very high levels of vitamin E acetate in nearly all cannabis-containing samples analyzed by the Wadsworth Center as part of this investigation. “At least one vitamin E acetate containing vape product has been linked to each patient who submitted a product for testing. Vitamin E acetate is not an approved additive for New York State Medical Marijuana Program-authorized vape products and was not seen in the nicotine-based products that were tested.”<sup>4</sup>

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<sup>4</sup>New York State Department of Health, *New York State Department of Health Announces Update on Investigation into Vaping-Associated Pulmonary Illnesses*, Sept 5, 2019. [https://health.ny.gov/press/releases/2019/2019-09-05\\_vaping.htm](https://health.ny.gov/press/releases/2019/2019-09-05_vaping.htm)

In reference to the lung illness fatality in Minnesota, State Epidemiologist Dr. Ruth Lynfield stated, “the patient had a history of underlying lung disease and was hospitalized with a severe lung injury that progressed to include other conditions. Investigators looking into the case after the patient died found the lung injury was associated with vaping illicit THC products.” It was also noted in the Minnesota Department of Health’s news release on September 6, 2019 that of the 32 cases of reported lung illnesses under investigation, those who were interviewed all disclosed that they were vaping illicit THC products.<sup>5</sup>

According to the recent New England Journal of Medicine report, 85% of patients’ lung-illness incidences were tied to black-market drugs (which assumes the causes of the other 15% are either yet to be determined or the affected individuals are reluctant to disclose a recent use of illicit THC products). This study, published on September 6, 2019 delved deeper into 53 pulmonary illness cases in Illinois and Wisconsin. Of those patients, 41 were extensively interviewed, and 80% reported using THC products. Furthermore, 24 patients reported using the same illicit THC oil marketed under the “Dank Vape” label.<sup>6</sup>

Illicit black-market drugs made from harmful substances such as vitamin E acetate are the root cause of the current panic. Vitamin E acetate is not a substance in nicotine-containing e-liquids, as it is widely known to be harmful during inhalation. Marc Fariss, Ph.D., President and Chief Scientific Officer at ToxSynergy states, “based on 25 years of experience conducting academic research on the toxicology of vitamin E, it is my opinion that repeated inhalation of vitamin E acetate may lead to an accumulation of this oil in the lung resulting in inflammation and the loss of lung function.” According to Damien Bove, the Chief Regulatory Officer at ADACT Medical, “ADACT has reviewed the formulations of 23,000+ products that we look after (for purposes of TPD registration in Europe) and vitamin E acetate is not in any of them, as you would expect.”

By linking nicotine-based vaping and illegal black-market THC vaping, CDC has caused widespread panic among consumers who have used vaping to quit smoking cigarettes. Further, they have discouraged current smokers from transitioning to the less harmful alternative of e-cigarettes. The recent CDC announcement on September 27, 2019, identified approximately 77 percent of the reported cases admitted to use THC-containing products (with or without nicotine), 36 percent reported exclusive use of THC-containing products, and 16 percent denied any criminal activity (use of illicit THC products) and only reported exclusive use of nicotine-containing products. Dr. Michael Siegel has accused CDC of violating basic principles of epidemiological outbreak investigations and causing immediate harm by failing to either recommend or demand that all case patients be screened (via urine drug testing) for THC.<sup>7</sup>

### **Claim 2: Youth initiation is driven by non-tobacco flavors.**

There is widespread belief that non-tobacco flavored e-liquids are driving underage youth to vape. The real story is more complex than this simple headline. Unlimited flavors have been available for more than a decade, not only in the United States, but also in other countries around the world. The accelerated youth consumption only became an epidemic in the last two years in the United States along with the increased popularity of high-nicotine containing closed-pod systems. This youth initiation closely follows JUUL’s growth and market penetration. As the preliminary data from the National Youth Tobacco Survey displays below, between 2015 and 2016, the youth initiation battle was being won with a decrease of reported use by youth from 16 percent to 11.3 percent. During this time, flavors were widely available and vape retail

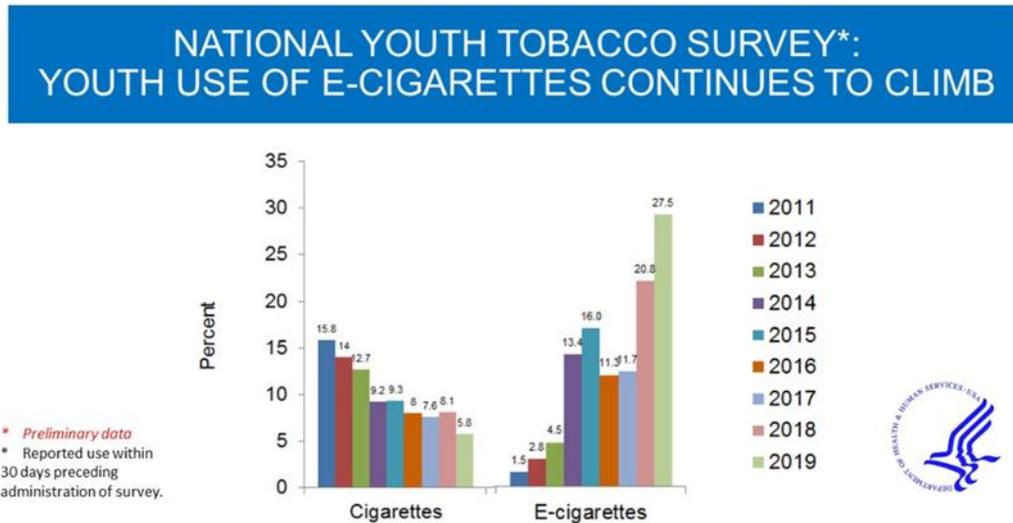
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<sup>5</sup> Minnesota Department of Health, *Health officials report death in a patient hospitalized for vaping-related lung injury*, Sept 6, 2019. <https://www.health.state.mn.us/news/pressrel/2019/lunginjury090619.html>

<sup>6</sup> Layden, Jennifer E. et al. *Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Preliminary Report*, Sept 6, 2019. <https://www.nejm.org/doi/full/10.1056/NEJMoa1911614>

<sup>7</sup> Siegel, Michael. *CDC’s Failure to Demand Urine THC Testing of All Outbreak Patients is Inexcusable and is Putting the Entire Nation at Risk*. September 27, 2019. <https://tobaccoanalysis.blogspot.com/2019/09/cdcs-failure-to-demand-urine-thc.html?m=1>

stores selling open systems owned a significant market share of the e-cigarette industry. From 2017 to present, convenience stores and closed systems have increased their market share substantially.



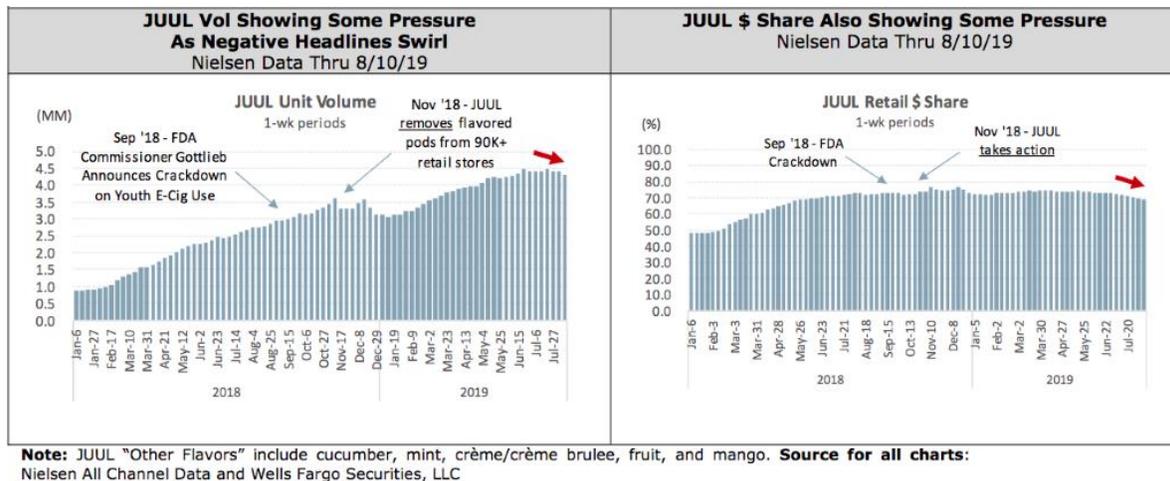
FDA. *Trump Administration Combating Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*. September 11, 2019. <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>

Nielsen data shows that JUUL monthly sales increased approximately five-fold from the beginning of 2018 through June of 2019.<sup>8</sup> This data is from traditional retail and c-stores and does not represent sales through the vape store channel. While this data indicates sales of JUUL are beginning to decline and the company is losing market share, we believe JUUL competitors are capitalizing on JUUL’s success and taking market share from the e-cigarette giant. As of September 2018, researchers had identified at least 39 JUUL “knock off” devices<sup>9</sup> and JUUL has filed patent infringement complaints against many of these companies.<sup>10</sup>

<sup>8</sup>Herzog, Bonnie. *Tobacco -E-Cig Flavor Ban Talk Heats Up With Mint/Menthol Now On The Table*. September 11, 2019.

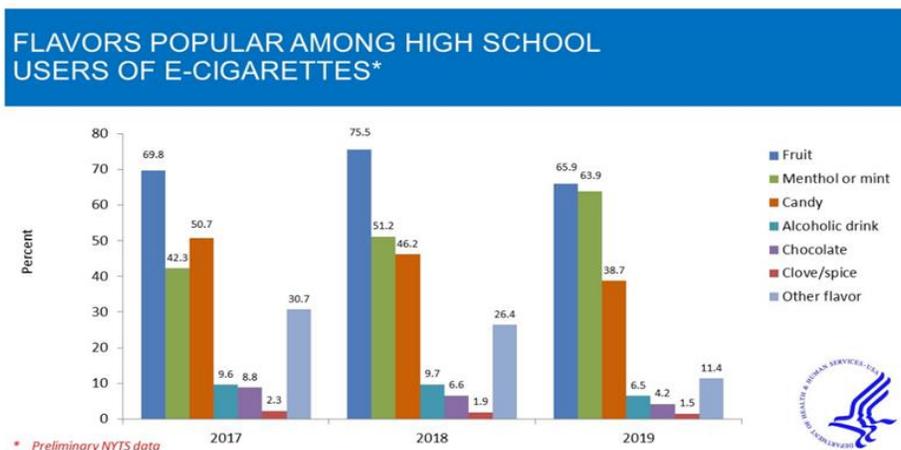
<sup>9</sup> Jackler, RK and Ramamurthi, D, “Nicotine arms race: JUUL and the high-nicotine product market,” *Tobacco Control*, published online February 6, 2019.

<sup>10</sup> Geller, M, “E-cigarette maker Juul files complaints against ‘copycat products,’” *Reuters*, October 4, 2018, <https://www.reuters.com/article/usjuul-ecigarettes-patents/e-cigarette-maker-juul-files-complaints-against-copycat-products-idUSKCN1ME127>.



From a product standpoint, we believe there is ample evidence that the underlying cause for youth initiation is a combination of nicotine salts that contain high levels of nicotine and discreet devices. The least important factor is non-tobacco flavors. Lastly, we believe that the distribution channels of c-stores and online purchases drives youth initiation rather than the vape store channel.

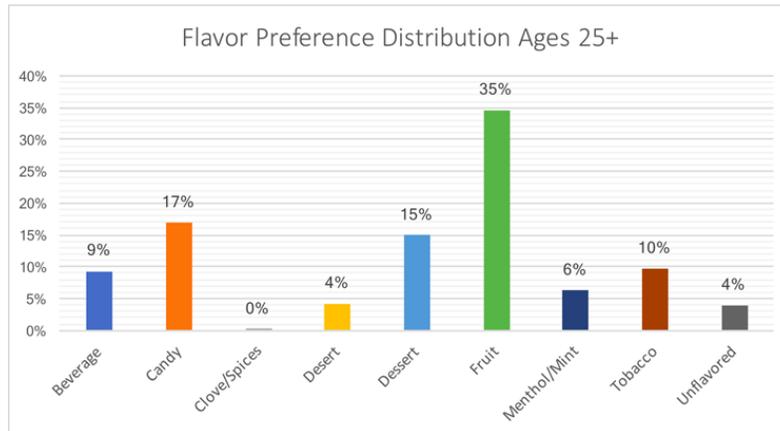
Preliminary data from the NYTS identifies youth popularity by flavor category. Since November 2018, when JUUL restricted its flavors in retail stores to tobacco, menthol and mint, the popularity of these flavors has risen substantially. If flavors were the primary motivation, we would expect to see a reduction in youth use and no change in the tobacco/menthol category. Instead, the data reveals an increase in youth use and an increase in popularity of tobacco, menthol and mint flavors. Acting FDA Commissioner Ned Sharpless, M.D. has also indicated that youth use may not be connected to non-tobacco flavors. When announcing FDA's flavor limitations, which suddenly included mint and menthol due to the increased popularity following JUUL's restriction of flavors, Sharpless stated that "if we see a migration to tobacco-flavored products by kids, we will take additional steps to address youth use of these products."<sup>11</sup>



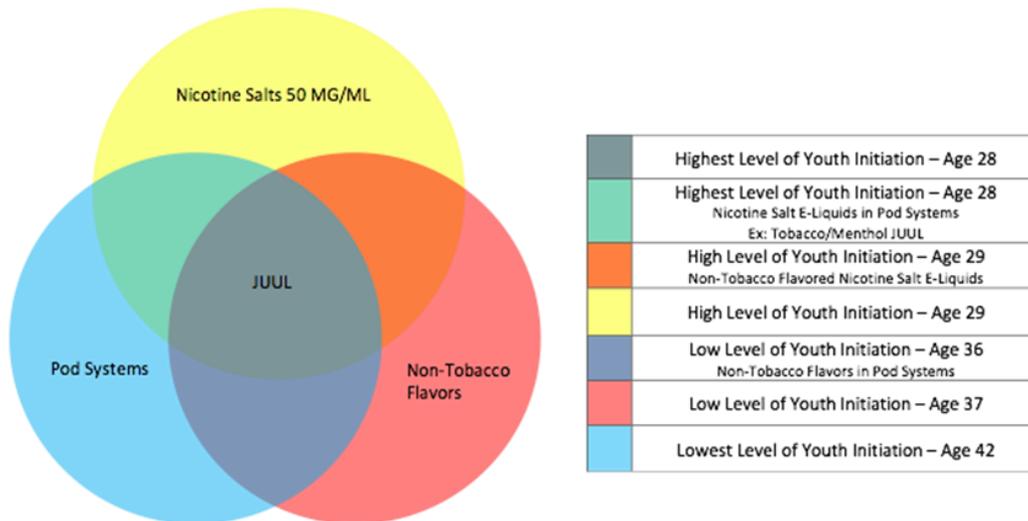
FDA. *Trump Administration Combating Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*. September 11, 2019. <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>

<sup>11</sup> FDA. *Trump Administration Combating Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*. September 11, 2019. <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>

Furthermore, adult flavor preferences reflect a lower popularity of tobacco, menthol and mint flavors as compared to youth. The graph published by the FDA above shows that 63.9% of youth have enjoyed mint/menthol flavors and 11.4% have enjoyed other flavors (which we assume include tobacco). In comparison, only 10% of adults over the age of 25 have bought tobacco flavors while 6% have bought menthol/mint flavors. This means that 84% of purchases by adult vapors in vape stores are non-tobacco flavors. This indicates that no one likes vaping tobacco flavors (not just young people).



The following diagram represents mean ages of vape store customers who purchase nicotine salts, discreet devices, and non-tobacco flavors. As the diagram will indicate, pod systems and non-tobacco flavors alone, or combined, have an average user age between 36 and 42. When further combined with nicotine salts, at high concentrations, the average age drops to 28. This is apparent in pod systems paired with high nicotine salts as well.



If non-tobacco flavors were the primary motivation of youth use, we would expect a similar age profile across all flavors regardless of nicotine type (salt versus free-base nicotine) and device type (closed pod systems such as JUUL versus open pod systems). However, we do not see this trend. Mango flavored e-liquid is sold in free-base nicotine to consumers. Customer data from one vape store company reveals the average age of customers who purchase Mango free-base nicotine e-liquid is 40 years of age. Customers

who purchased mango JUUL pods with salt nicotine in corresponding high nicotine concentrations were 28 years old, on average. This data further demonstrates that youths are not necessarily drawn to a flavor, but rather to the high nicotine concentration and device (discreet, closed pod system).

**Table (1) Mango Age Profile**

<b>Free-Base Nicotine, 0-24 mg/ml</b>				
	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	40	18	73	14
<b>18-24</b>	20%			
<b>25-34</b>	18%			
<b>35-44</b>	23%			
<b>45-54</b>	18%			
<b>55-64</b>	16%			
<b>65+</b>	5%			

**Table (2) Mango JUUL Pod Age Profile**

<b>Salt Nicotine 24-50mg/ml</b>				
	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	28	18	75	11.21
<b>18-24</b>	53%			
<b>25-34</b>	26%			
<b>35-44</b>	12%			
<b>45-54</b>	4%			
<b>55-64</b>	3%			
<b>65+</b>	2%			

The age distributions in the Table 1 and Table 2 show free-base mango e-liquid’s age profile to be in line with industry expectations while the distribution chart for JUUL is dominated by the age category of 18-24 years of age.

This trend is also evident when comparing the average age and age distribution of e-liquids that are available in both nicotine salts and free-base nicotine. As an example, the popular brand X of e-liquid has nicotine salts available in 30mg/ml and 50mg/ml, while its free-base nicotine flavors are offered in 0mg/ml, 3mg/ml, and 6mg/ml.

As Table 3 indicates, the average age for customers who purchased free-base nicotine e-liquid is 33 years of age, while the customers who purchased the same flavor in nicotine salt were 30 years of age on average. Further, 40% of the customers who purchased nicotine salts fell into the 18-24 age range.

**Table (3) Popular Brand X Age Profile**

<b>Free-Base Nicotine</b>					<b>Nicotine Salts</b>				
	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>		<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	33	18	71	10.74	<b>Age</b>	30	18	76	11.2
<b>18-24</b>	25%				<b>18-24</b>	40%			
<b>25-34</b>	38%				<b>25-34</b>	32%			
<b>35-44</b>	21%				<b>35-44</b>	16%			
<b>45-54</b>	10%				<b>45-54</b>	9%			
<b>55-64</b>	4%				<b>55-64</b>	1%			
<b>65+</b>	1%				<b>65+</b>	2%			

Table 4 compares the age profile of customers purchasing 30mg/ml nicotine salts and 50mg/ml nicotine salts of the same brand and flavor. The average age of customers who bought 30mg/ml nicotine salts is 32 years of age while that of 50mg/ml nicotine salts consumer is 29 years of age, with 50% of its consumers falling in the 18-24 age range.

**Table (4) Popular Brand X Age Profile**

<b>30mg/ml Nicotine Salts</b>					<b>50mg/ml Nicotine Salts</b>				
	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>		<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	32	18	80	11	<b>Age</b>	29	18	81	11
<b>18-24</b>	31.7%				<b>18-24</b>	49.9%			
<b>25-34</b>	33.6%				<b>25-34</b>	25.4%			
<b>35-44</b>	19.8%				<b>35-44</b>	13.9%			
<b>45-54</b>	10.5%				<b>45-54</b>	7.5%			
<b>55-64</b>	3.5%				<b>55-64</b>	2.7%			
<b>65+</b>	0.9%				<b>65+</b>	0.6%			

Tables 5 and 6 represent the average age and distributions of customers who purchased open system devices versus those who purchased discreet systems such as JUUL. Two-battery open system devices are not intended for nicotine salts because of the power they generate. The average customer age of those using two-battery open systems is 34.28 years, as compared to JUUL’s average of 28 years old.

**Table (5) Open System Device**

	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	34.28	18	73	12.15
<b>18-24</b>	27%			
<b>25-34</b>	30%			
<b>35-44</b>	23%			
<b>45-54</b>	11%			
<b>55-64</b>	8%			
<b>65+</b>	1%			

**Table (6) JUUL**

	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	28.02	18	71	11.67
<b>18-24</b>	58%			
<b>25-34</b>	20%			
<b>35-44</b>	11%			
<b>45-54</b>	6%			
<b>55-64</b>	3%			
<b>65+</b>	2%			

**Table (7) JUUL**

	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	28.02	18	71	11.67
<b>18-24</b>	58%			
<b>25-34</b>	20%			
<b>35-44</b>	11%			
<b>45-54</b>	6%			
<b>55-64</b>	3%			
<b>65+</b>	2%			

**Table (8) Brand X Closed Pod System**

	<b>Mean</b>	<b>Min</b>	<b>Max</b>	<b>Std Dev</b>
<b>Age</b>	36.96	18	76	13.93
<b>18-24</b>	22%			
<b>25-34</b>	23%			
<b>35-44</b>	22%			
<b>45-54</b>	19%			
<b>55-64</b>	9%			
<b>65+</b>	5%			

As evident in Tables 7 and 8, JUUL has an average customer age of 28 and 58% of its customers fall into the 18-24 age group as compared to another leading closed pod system brand which has an average consumer age of 37 years and only 22% fall into the 18-24 age range.

Europe adopted a 20mg/ml nicotine limit and has seen significantly lower youth initiation rates. In June 2019, Action on Smoking and Health (ASH) found that just 1.6% of 11-18 year-olds used e-cigarettes more

than once a week<sup>12</sup> as compared to nearly 27% of American high school students who have used an e-cigarette in the last 30 days.<sup>13</sup> This is despite unlimited flavor availability in the United Kingdom and the government in the UK actively promoting vaping/e-cigarettes as a healthier alternative to combustible cigarettes.

JUUL launched with a very high potency nicotine level at 50mg/ml, using nicotine salts. Nicotine salts are designed to smooth out the harsh and irritating puffs so users can get their nicotine fix quickly and mask the body's natural reaction to high nicotine levels.

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<sup>12</sup> Action on Smoking and Health. *Fact sheet: Use of e-cigarettes among young people in Great Britain*. June 2019. <http://ash.org.uk/wp-content/uploads/2019/06/ASH-Factsheet-Youth-E-cigarette-Use-2019>

<sup>13</sup> FDA. *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*. Sept 11, 2019. <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>

## Impacts of Misleading Claims- Health, Economic & Political

Claiming that vaping causes pulmonary illness and youth initiation is driven by non-tobacco flavors has potential to cause consumer confusion and bad policy implementation, leading to a negative public health impact and the potential loss of 80,000 jobs.

### **Public Health Impact**

Because the CDC has refused to differentiate between nicotine vaping and THC-based vaping, the agency has created massive confusion and panic among the 13 million consumers who vape nicotine-containing e-liquids. In addition, the CDC statement has emboldened knee-jerk state action which will be detrimental to public health.

At the critical period when negative opinions about e-cigarettes spread all over the country and people are panicking about the impact on youth and the harm of nicotine-based e-cigarette itself, the FDA has gone mute about their stance that the e-cigarette is less harmful than combustible cigarettes. The FDA has stated more than once that the e-cigarettes are actually beneficial to public health and especially to smokers.

Former FDA commissioner Scott Gottlieb stated last year that “e-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products and onto nicotine delivery products that may not have the same level of risks associated with them. So, we set out on a new rulemaking process that seeks to regulate the nicotine levels in combustible cigarettes to render them minimally or non-addictive. That process is well underway.”<sup>14</sup>

Both Gottlieb and FDA’s Tobacco Products Director, Mitch Zeller, have stated that if they can take every adult smoker and fully switch them to e-cigarettes, that it would be good for public health.<sup>15</sup> In addition, there are widespread claims that there is no proof that e-cigs help smokers quit, but rather those smokers become dual users. However, the study from the Massachusetts General Hospital’s (MGH) Tobacco Research and Treatment Center reviewed and analyzed data from 8,2000 participants of the Assessment of Tobacco and Health Study and provides critical population-level evidence demonstrating that using e-cigarettes daily helps U.S. smokers quit smoking combustible.

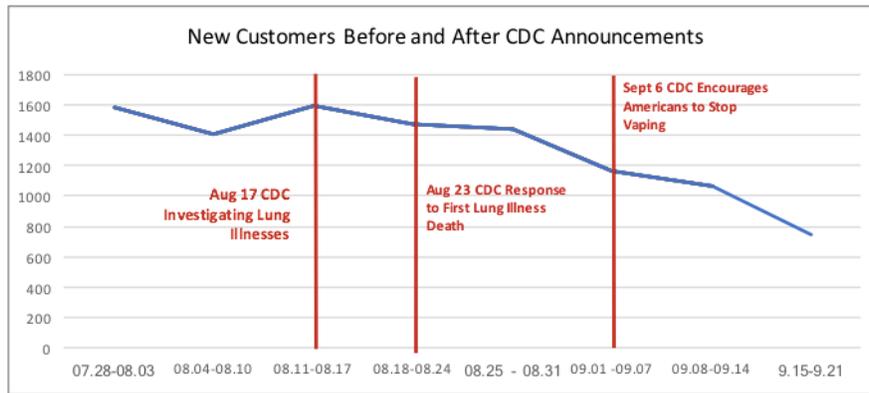
Since the public health announcement, daily sales for vape retail stores have decreased compared to previous month’s sales. Sadly, numerous consumers have informed us that they will return to smoking cigarettes as it is now viewed as a “safer alternative.”

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<sup>14</sup> FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use. September 11, 2018. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use>

<sup>15</sup> Senate Health, Education, Labor and Pensions Committee Hearing, May 15, 2014.

**Table (9)** New Customers in a 68 Store Chain



Based on surveys conducted in 2015, 2018 and 2019, between 85% and 92% of customers visiting vape retail stores were smokers prior to vaping. Since the first lung illness related death and the CDC announcement on August 23, in one vape store chain of 68 stores, new customer acquisition has dropped by 47% as seen in Table 9. This drop means a lost chance for this store to convert over 746 combustible cigarette smokers per week to a reduced harm product such as e-cigarettes. More importantly, 69.3% of these customers could reasonably be expected to be cigarette free after 12 months. Unless perceptions change, for a 68-store chain, this implies that 26,882 smokers will not be converted off of cigarettes.

Several states have taken the announcement by the CDC as a license to enact extreme vaping legislation or emergency declarations. For example, the following states have enacted emergency action:

- Michigan – Emergency action by the governor to ban non-tobacco flavors
- New York – Emergency action by the governor to ban non-tobacco flavors
- Massachusetts – Emergency action to ban the sale and display of all vapor products
- Rhode Island – Executive order banning the sale of flavored vapor products

Senators Mitt Romney (R) and Dick Durban (D) are proposing to sponsor a bill that would not only ban flavors, but also ban open system hardware so users wouldn't be able to add marijuana or other unregulated substances to their e-liquids.<sup>16</sup> In reality, the black-market products purchased are closed systems pods compatible with systems in the market. This proposed legislation would not solve the black-market problem.

The action of the CDC stands in sharp contradiction to that of Public Health England, which has actively encouraged smokers to switch to e-cigarettes and vaping. In their groundbreaking study in 2015, Public Health England determined that vaping was 95% less harmful than smoking cigarettes and that every smoker who has not been successful quitting combustible cigarettes should try to quit using e-cigarettes.<sup>17</sup> Public Health England has continued to review this statement on an annual basis and stands by their statement four years later.

<sup>16</sup> Siddons, Andrew. *Bipartisan group urges FDA to go beyond vaping flavor ban*. Sept 13, 2019.

<https://www.rollcall.com/news/bipartisan-group-urges-fda-to-go-beyond-vaping-flavor-ban>

<sup>17</sup> Public Health England. *E-cigarettes: and evidence update*. August 2015.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/733022/E-cigarettes\\_an\\_evidence\\_update\\_A\\_report\\_commissioned\\_by\\_Public\\_Health\\_England\\_FINAL.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf)

Not only has the UK seen a decline in the percentage of the population that smokes combustible cigarettes, but also a decline in their daily cigarette intake. In 2011, 20.2% of the population smoked combustible cigarettes and smoked 12.4 cigarettes per day on average, but today, only 14.7% of the population smokes combustible cigarettes and consumes an average of 10.6 cigarettes on a daily basis. Public Health England says vaping is now the most popular and effective way for smokers to quit.<sup>18</sup> This represents a 37.8% reduction in daily cigarette consumption in the UK.

### Banning Flavors

The vape store retail channel has proven very effective in helping adult cigarette users quit smoking combustible cigarettes. Adult smokers use a variety of flavors to help them make the transition away from combustible cigarettes. Adult customers receive personalized solutions in vape stores which is an effective method to converting cigarette smokers to non-smokers. Three separate surveys (conducted in 2015, 2018 and 2019) display the following results:

- Vape Stores Serve Former Smokers: Results of surveys indicate that approximately 88% of customers were previously smokers, or are attempting to quit.
- Flavors Are Important in Conversion: 73.35% of customers say flavors other than tobacco and menthol are very important or extremely important to in helping stop their use of traditional tobacco products.
- Success Rate High: In a 12-month longitudinal study, one vape store chain found that after 12 months, 69.3% of former smokers who had tried vaping had quit smoking cigarettes. Only 30.7% of these customers had returned to smoking, showing a very high success rate in cessation via vaping.
- Flavor Ban Impact: 37.19% of former smokers said a ban of flavors will likely result in them switching back to cigarettes, and 48.84% said they will either make their products at home or buy them illegally on the black market.
- Improved Quality of Life: In the 2015 survey conducted by a vape store chain, 99.08% of the respondents considered electronic cigarettes to be a healthier alternative to traditional tobacco products and in another retailer's survey in 2019, 97.84% of former smokers responded that vaping had improved their lives. According to population modeling conducted by David Levy and colleagues at Georgetown University Medical Center, replacement of cigarette with e-cigarette use over a 10-year period would yield 6.6 million fewer premature deaths, with 86.7 million fewer life years lost.

A ban on flavors will have a severe impact on the vape store retail channel's ability to serve its customer base. This inability will have a substantial negative public health impact for the lives of millions of vapers served by this channel.

### 2015 Survey

In Q4 of 2015, AMV conducted a survey of its customer base. In this survey, 92.77% of the customers were former cigarette smokers. These smokers had been using combustible cigarettes for 15.1 years on average before switching to vaping. In this survey, customers were asked specifically how important flavors were in their ability to quit smoking cigarettes.

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<sup>18</sup> Cancer Research UK. *Comparison of Trends in Self-Reported Cigarette Consumption and Sales in England, 2011 to 2018*. August 28, 2019. [https://jamanetwork.com/journals/jamanetworkopen/articlepdf/2749052/jackson\\_2019\\_oi\\_190397.pdf](https://jamanetwork.com/journals/jamanetworkopen/articlepdf/2749052/jackson_2019_oi_190397.pdf)

**How important were flavors other than tobacco/menthol in helping you stop your consumption of traditional tobacco products?**

NOT IMPORTANT AT ALL	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT	TOTAL	WEIGHTED AVERAGE
7.59%	5.69%	13.36%	31.83%	41.52%	6,939	3.94
527	395	927	2,209	2,881		

The importance of non-tobacco/menthol flavors in helping people to stop the consumption of traditional tobacco products with 73.35% of the respondents saying that flavors were very important or extremely important and only 7.59% saying that these flavors were not important at all.

Furthermore, the variety of flavors was found to be an important factor in people continuing to permanently stay away from combustible cigarettes.

**How important to you is a variety of e-liquid flavors to choose from?**

NOT IMPORTANT AT ALL	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT	TOTAL	WEIGHTED AVERAGE
2.64%	3.65%	12.19%	25.02%	56.50%	8,602	4.29
227	314	1,049	2,152	4,860		

For 81.52% of customers, a variety of flavors is very important or extremely important. Only 2.64% of customers said flavor variety is not important to them. This importance is reflected by the fact that 80% of sales to adults are non-tobacco flavored products denoting that they are more effective than tobacco flavors in helping people transition away from combustible cigarette products.

The 2015 survey found that open system vaping devices were extremely effective at lowering a person’s addiction to nicotine. In the survey, 85.25% of the respondents had lowered their nicotine level and among them, 7.6% had switched to 0mg products, cutting out their nicotine consumption completely.

**What answer most describes your nicotine intake over time with electronic cigarettes?**

ANSWER CHOICES	RESPONSES	
I use the same nicotine level as I did when I started using electronic cigarettes	11.43%	911
I use a lower nicotine level than I did when I started using electronic cigarettes	77.65%	6,191
I use a higher nicotine level than I did when I started using electronic cigarettes	2.62%	209
I have decreased my nicotine level and now use 0mg (no nicotine)	7.60%	606
I have always used 0mg (no nicotine)	0.70%	56
TOTAL		7,973

AMV’s 2018 Telephone Survey

In order to get a more complete picture of customers’ journeys through time, AMV conducted a 12-month longitudinal study of the Wilmington, NC market in 2017 and 2018. After analyzing point-of-sale data, 40% of customers who started shopping with AMV in Wilmington during May of 2017 and bought both a liquid and hardware were still purchasing their vape supplies from AMV 12 months later. AMV conducted a telephone survey of these customers. The following table displays this survey’s results. (It should be noted that this survey was conducted with customers who started vaping at the beginning of the rapid rise of JUUL popularity.)

Survey Data	AMV%	Corrected for 40% Retention	Non-AMV%	Corrected for 60% Attrition	Weighted Totals
Smoked, Vaped, Still Vaping	77%	31%	29%	17%	48%
Smoked, Vaped, Now Smoking	8%	3%	29%	17%	20%
Smoked, Vaped, Tobacco Free	4%	2%	29%	17%	19%
Didn't Smoke, Vaped, Not Vaping	0%	0%	14%	9%	9%
Didn't Smoke, Vaped, Vaping	12%	5%	0%	0%	5%
<b>Totals</b>	<b>100%</b>	<b>40%</b>	<b>100%</b>	<b>60%</b>	<b>100%</b>

Key takeaways from this survey:

1. Former Smokers: 87% of the customers interviewed in this survey were cigarette smokers prior to beginning their vaping journey.
2. High Quit Rate: The telephone survey found that after 12 months, 76% of the smokers had stopped smoking cigarettes, and 22% of the smokers had quit both smoking and vaping.
3. No Gateway Effect: None of the previous non-smokers interviewed had started to smoke cigarettes.
4. The Majority of Non-smokers Quit Vaping: 64% of the non-smokers who started vaping had quit vaping during the 12-month time frame.

The results of this survey clearly show the success rate that vape stores enjoy in converting cigarette smokers and further corroborate the news from Public Health England which states that vaping is the most effective and most popular smoking cessation tool. The key difference between the success rate experienced in vape stores and success rates overall is the individualization available in a vape store. Retail associates can fit the customer with the device and flavor that is most likely going to result in them quitting cigarettes and provide a supportive and encouraging environment.

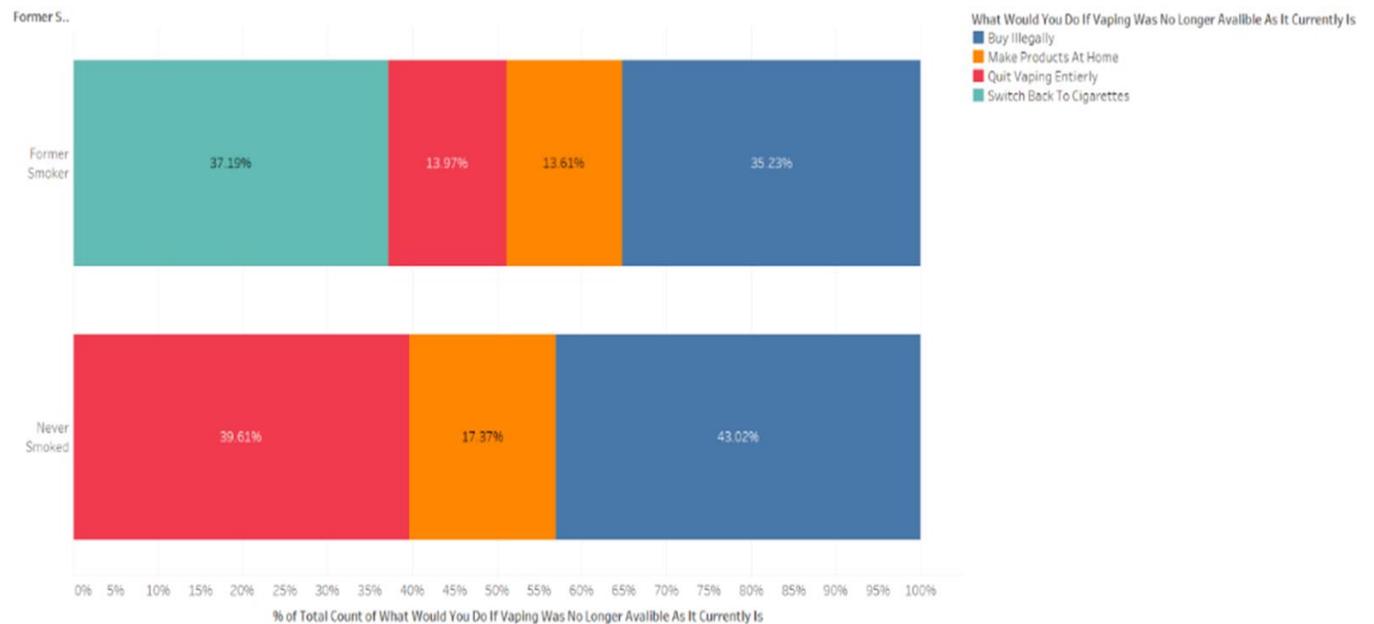
2019 Consumer Survey by Vape Store Retailer

A survey conducted by a vape store chain in 2019 of 6,000 customers shows similar results to the surveys conducted by AMV in 2015 and 2018. In this survey, 85% of the respondents classified themselves as Former Smokers.

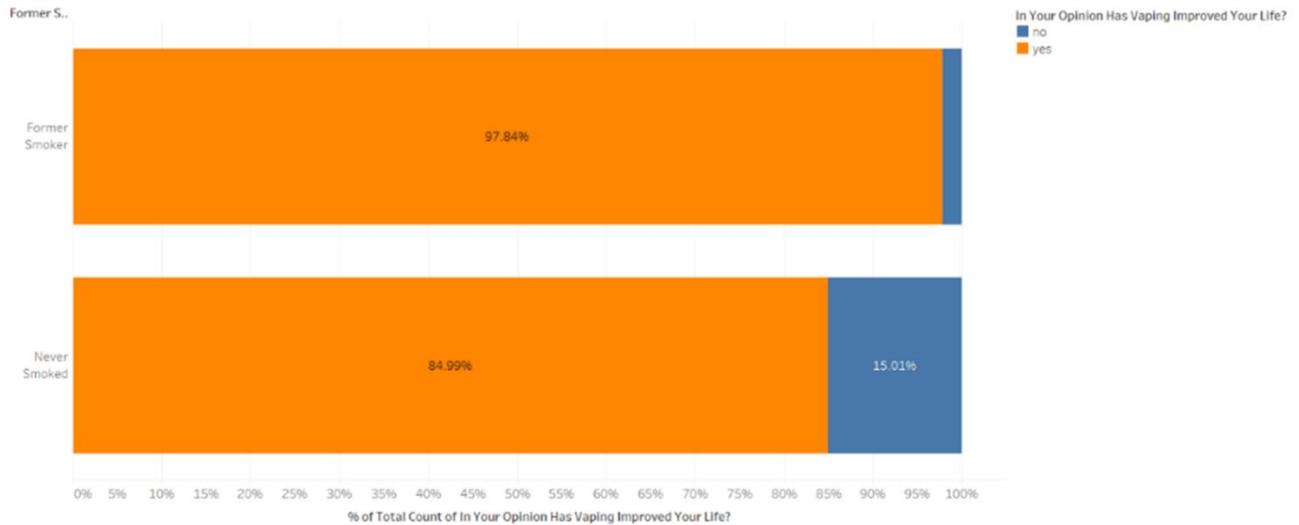
Of the 5,100 identified Former Smokers surveyed, only 16.7% preferred tobacco/menthol/mint flavors compared to 18.3% of Never Smokers. The fruity flavors were most attractive to both Former Smokers and Never Smokers who participated in this survey.



Banning non-tobacco flavors would have detrimental health impacts. The retailer asked its survey participants what they would do if vaping was no longer available at the level it currently is. Rather than pledging to quit smoking altogether, 86% of Former Smokers and 60.4% of Never Smokers disclosed that they would seek products elsewhere. Black market products pose extreme health risks, as they are not regulated. Returning to combustible cigarette use re-establishes well known health risks that were being combatted by e-cigarette use.



The retailer explicitly asked their participants if they believed that vaping has improved their lives. An overwhelming 97.8% of Former Smokers answered 'yes'.



### Health Impact Conclusion

The public health impact of a flavor ban will be severe. Susan Davis, a vaping industry customer, expressed this sentiment well in a Facebook post directed to CASAA: *“At least with vaping, I went from a 6-12 months shy of a COPD/Emphysema diagnosis almost seven years ago to a lung function test a couple of years ago with a result of a non-smoker, not former...non-smoker.”*

Flavors are not causing lung diseases. Flavors are not causing youth initiation. Flavors are helping adults quit smoking. Youth initiation is a result of (i) JUUL, (ii) high nicotine salts in discreet devices, and (iii) high concentration nicotine salts regardless of flavor. A flavor ban that includes free-base nicotine does not truly address youth initiation.

### Economic Impact

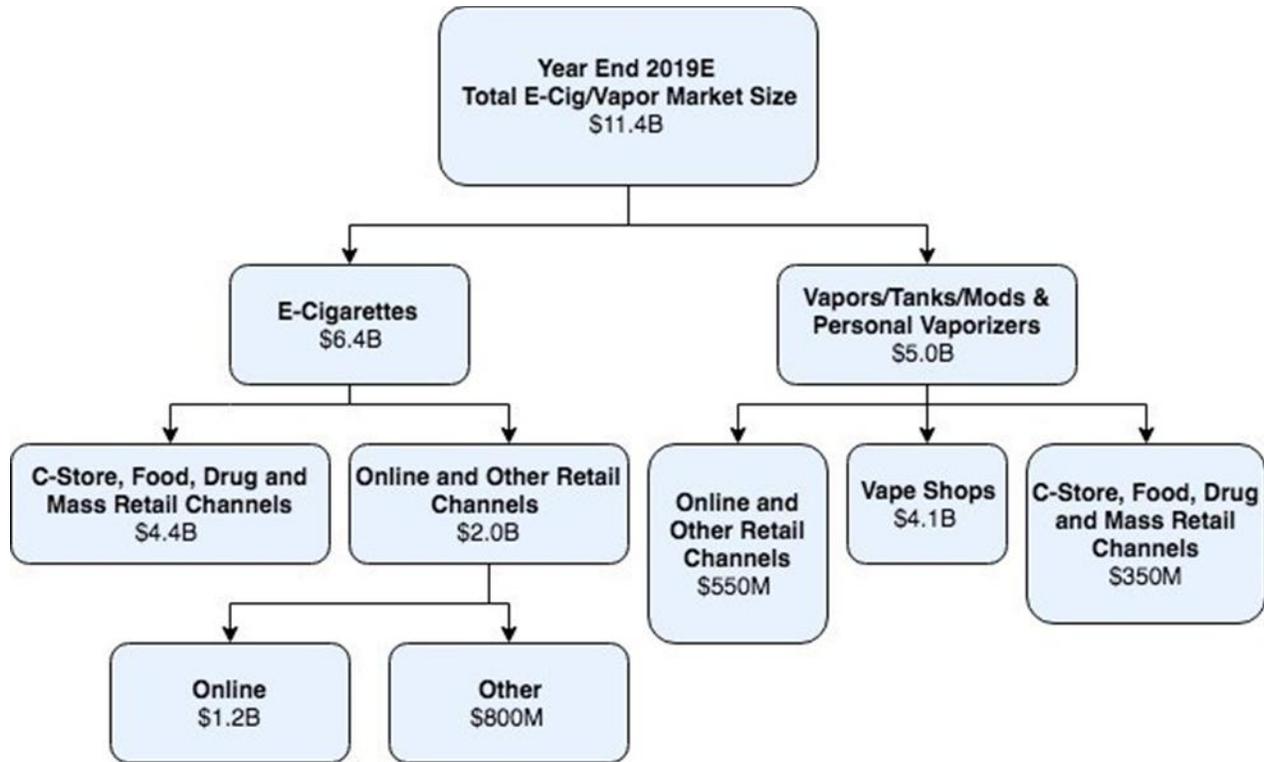
Claiming that vaping causes pulmonary illness and youth initiation is driven non-tobacco flavors has and will continue to have a significant economic impact on the open system market. The CDC announcement has already had a significant negative impact on revenue of vape stores and e-liquid manufacturers, and the flavor ban will:

- Devastate the independently owned and operated vape store market
- Devastate the independently owned and operated e-liquid industry
- Hand over the industry to Big Tobacco. Altria has recently acquired a 30% interest in Juul and RJ Reynolds has posted 12 job openings in September 2019 in their vapor product development group. As youth use is directly related to high nicotine concentration, Juul will continue to dominate the vapor market.
- Force adult consumers to pay more for their pods and systems compared to their current prices

To understand the economic impact of the two claims discussed above and the potential of a flavor ban, one must consider the vaping/e-cigarette market. The electronic cigarette and vaping industry can be broken down into two primary markets: (1) the traditional retail/c-store market and (2) vape store retail channel.

A February 11, 2019 report from Bonnie Herzog, Wells Fargo Analyst, estimates electronic cigarettes to bring ~\$4.5B annual retail sales through in Nielsen-tracked channels (vs \$3.3B in 2018 – 36%

growth).<sup>19</sup> Considering Nielsen underestimates and doesn't capture all channels where e-cigs/vapor products are sold (such as online, vape shops, etc.), we estimate the total category will reach approximately \$11.4B by the end of 2019.



**Traditional Retail:** Led by c-stores, this market is mostly made up of closed system devices dominated by traditional big-tobacco companies and includes JUUL, Njoy, MyBlu, and Vuse. The flavor selection is somewhat limited, the staff are generally uninformed, and this category is only a small portion of sales. While a flavor ban may have some impact on the revenue of these outlets, it would likely be small, and may even be offset by increased cigarette sales when vapers turn back to cigarette smoking.

**Vape Stores and Specialty Retail:** Vape stores offer a wide variety of flavors and products including tanks, mods, and pod systems. These stores generally have staff that are passionate about vaping and may have their own success stories about freeing themselves from cigarettes. This segment has been most effective in helping smokers quit (due to individualization, one-on-one instruction, etc.). On average, e-liquid sales is 50-60% of a vape store's revenue and non-tobacco flavors typically make up 80% of e-liquid sales. We estimate there are approximately 11,469 vape stores and 2,012 blending vape shops in the US, 80% being small store operators (under four stores). Based upon our knowledge of vape store economics, we believe that the average revenue for these stores is approximately \$30,000 per month or \$360,000 a year. We estimate that closed systems are approximately 7% of this segment of the market share. For the blended stores, we estimate \$15,000 in monthly revenue from nicotine vaping. As this market is much harder to track, we believe Wells Fargo's estimates are low for the vape store channel and have added our estimates to the Total 2019 Market Size hierarchy chart by Bonnie Herzog.

<sup>19</sup> Herzog, Bonnie. *Wall Street Update Slide Deck*. February 2019.  
[http://www.natocentral.org/uploads/Wall\\_Street\\_Update\\_Slide\\_Deck\\_February\\_2019.pdf](http://www.natocentral.org/uploads/Wall_Street_Update_Slide_Deck_February_2019.pdf)

**Table 11A Monthly Income before CDC Announcement**

**Table 11B Typical Monthly Income After CDC**

Typical Monthly 4-Wall Profile (Small Scale Operator - 80% of Industry)			
Total Revenue	\$	30,000	100%
Gross Profit	\$	15,000	50%
Payroll	\$	6,630	22.10%
Occupancy	\$	2,850	9.50%
Merchant	\$	540	1.80%
Marketing	\$	510	1.70%
Other	\$	1,590	5.30%
Total Expenses	\$	12,120	40%
EBITDA		2,880	10%

Typical Monthly 4-Wall Profile (Small Scale Operator - 80% of Industry)			
Total Revenue	\$	22,500	100%
Gross Profit	\$	11,250	50%
Payroll	\$	6,000	26.67%
Occupancy	\$	2,850	12.67%
Merchant	\$	405	1.80%
Marketing	\$	383	1.70%
Other	\$	1,590	7.07%
Total Expenses	\$	11,228	50%
EBITDA		23	0%

The CDC announcement has already had a significant impact on the operations and profitability of all vape store operators. A flavor ban would have an even more significant impact on the livelihood of these businesses and will force a large majority of these businesses to shut their doors. As a result, both the consumer and the operator will face economic impacts. Since the CDC announcement, five stores in Topeka, Kansas alone have closed their doors due to an abrupt slowdown in business. This trend will accelerate with the further uncertainty caused by the FDA and the proposed flavor bans.

Independently Owned E-Liquid Companies: Small, independently owned e-liquid companies are already struggling under the burden of the recently imposed PMTA deadlines. This struggle has been further exacerbated by the CDC announcement which has hurt vape store sales and, by extension, e-liquid sales. The uncertainty of the proposed flavor ban only makes it more difficult for these companies to invest in the vague and arduous PMTA process.

Total Job Losses: We estimate that the industry faces job losses of up to 80,000 in the United States and over \$2 billion in payroll. Of these wages, approximately \$1 billion are earned directly by retail employees and store owners, while the other \$1 billion are earned in the corporate oversight, supply chain management, and by the approximately 5,000 e-liquid brands/companies. Further, we estimate that more than \$500 million in profit earned by entrepreneurial Americans will be lost. Again, 80% of the both 11,469 vape stores and 2,012 blending vape shops are owned by operators who own/control less than four stores. Most of the e-liquid companies are also smaller operators with sales below \$5 million a year. The chart below shows the economic breakdown of the industry.

Open System Industry Economics			
<b>Revenue</b>			
Hardware Revenue	\$	2,000	
Liquid Revenue	\$	3,000	
<b>Total Revenue (Liquid and Hardware)</b>	<b>\$</b>	<b>5,000</b>	<b>100%</b>
<b>Hardware Cost</b>			
US Distributor	\$	313	6%
Chinese Manufacturer	\$	938	19%
<b>Total Hardware Expenses</b>	<b>\$</b>	<b>1,250</b>	<b>25%</b>
<b>Liquid Cost</b>			
Total Revenue Earned by Liquid Manufacturer	\$	1,000	20%
Extract/Bottling/Labeling	\$	300	6%
Payroll	\$	500	10%
Other	\$	100	2%
	\$		0%
<b>Total Liquid Expenses</b>	<b>\$</b>	<b>900</b>	<b>18%</b>
<b>EBITDA - Liquid Manufacturers</b>		<b>100</b>	<b>2%</b>
<b>Retail Level Economics for Industry</b>			
Gross Margin from Hardware	\$	750	15%
Gross Margin from Liquid	\$	2,000	40%
Occupancy Costs	\$	475	10%
Other	\$	440	9%
Payroll (includes non-four wall overhead)	\$	1,500	30%
<b>Store Profit</b>	<b>\$</b>	<b>335</b>	<b>7%</b>
<b>Total Payroll</b>	<b>\$</b>	<b>2,000</b>	
<b>Total Estimated profit</b>	<b>\$</b>	<b>497.50</b>	

The 80,000 estimate is based on (1) analysis directly tied to vape retailers and (2) estimates on 5,000 e-liquid companies, distributors and online sellers. This does not include all the ancillary jobs that support the industry.

Impact on the Consumer: The annual costs of vaping using an open pod system is significantly lower than using a JUUL (or other closed-pod system) or smoking cigarettes. To demonstrate this point, we show the costs incurred by an adult consumer who smokes two packs of cigarettes per day. This is compared to the equivalent JUUL use of two pods per day and equivalent 1.5 milliliters of 50 mg/ml nicotine-salt e-liquid using an open pod vape device purchased from a vape store.

	Cigarettes	JUUL	Open Pod
Consumption/day	2 Packs	2 Pods	1.5ml
Price/unit	\$ 6.50	\$ 4.00	\$ 1.00
Hardware	\$ -	\$ 34.99	\$ 45.00
Other Cost/month	\$ -	\$ -	\$ 10.00
Total Daily Spend	\$ 13.00	\$ 8.00	\$ 1.00
Total Monthly Spend	\$ 390.00	\$ 240.00	\$ 40.00
Total Annual Spend	\$ 4,745.00	\$ 2,989.98	\$ 620.00
<p>*Assumption: People smoke 2 packs of cigarettes, 2 pods of JUUL or 1.5ml Open Pod liquid everyday (given that they contain the same nicotine content). For JUUL, hardware should be replaced twice per year. For Open Pod systems, hardware should be replaced three times a year and coil replacements are required, estimated at \$10 per month.</p>			

Based upon this analysis, the consumer must spend 4.8 times more on JUUL products as compared to an open pod system. The increased cost will hurt other industries as the consumer will have less discretionary income to spend. These policies will increase sales of big tobacco companies/JUUL and hurt the sales of other consumer industries.

**Black Market:** A ban of flavors will result in a thriving black market. We have already seen this black market in action in Illinois, which recently increased the vaping age to 21. One individual reported selling \$8,000 worth of products per week to consumers under the age of 21.

### **Political Impact**

There are 13 million adult nicotine vapers in the United States. Of these, we estimate eight million buy their open systems vaping/e-cigarette supplies through the online and vape store channel (\$5 billion market with an average annual spending of \$620 per consumer). Of these vapers, (using the 85% - 92.7% range from previously discussed surveys) 7.4-6.8 million are former cigarette smokers.

As shown in the 2019 vape retail store survey, 97.8% agree that nicotine vaping has improved their lives. Not only do they feel better, but as the table above would show, they have also experienced a significant economic benefit by switching from smoking to vaping. The White House has already received a petition signed by 117,000 individuals who are against the proposed flavor ban. Given how passionate these consumers are about vaping, it is reasonable to expect that they will vote based on who they see is defending their right and access to vaping products.

## **Policy Recommendations to Curb Youth Initiation**

The youth epidemic is tragic and concerning for the public and vaping industry alike, but we believe there are legislative solutions that can help address this quickly and effectively:

1. **Limit flavors to lower nicotine products sold through age-verified retailers.**  
As our research shows, flavors are not the underlying cause of the respiratory illnesses. However, flavors combined with high nicotine strength *and* discreet devices can cause youth initiation. Therefore, we recommend limiting flavors to lower nicotine products (30mg/ml and below) sold through adult-only age-verified retailers.
2. **Examine nicotine strength and risk profiles.**  
The acceleration of youth vaping is highly correlated to the growing popularity of high nicotine concentration products, particularly 50mg/ml. A nicotine-level restriction has proven lower youth adoption rates in other countries, where non-tobacco flavors remain available. The FDA should recognize this heightened risk profile with respect to the distribution and marketing of all ENDS.
3. **Encourage manufacturers to build age verification tools into all hardware.**  
Discreet devices are a powerful tool for adult consumers; however, when combined with high nicotine concentrations, they also have the youngest customer age demographic. For hardware devices commercially marketed prior to August 8, 2016, we recommend the FDA waive enforcement action to allow for the addition of age verification tools. Additionally, we recommend FDA waive enforcement action for pre-August 8, 2016 closed pod systems marketed with a high nicotine-concentration, in order for the manufacturer to reduce the nicotine level. These devices should only be sold in adult-only, age-verified retailer establishments.

## Public Information Recommendations

The CDC's announcements, which failed to clarify the difference between regulated nicotine and black-market THC vaping, have led to a significant public misperception about the risks of legal nicotine vaping. This public misperception has stopped consumers from using vaping as an alternative to smoking cigarettes and will lead to negative public health outcomes. There have been countless studies on the effectiveness and safety of e-cigarettes use as it relates to combustible cigarette cessation. The New England Journal of Medicine concludes that "E-cigarettes are almost twice as effective as nicotine replacement treatments, such as patches and gum, at helping smokers to quit."<sup>20</sup> To prevent continued misinformation, the CDC should:

1. **Publish a Public Announcement:** The CDC should immediately release a public announcement further clarifying FDA regulated vapor products are not the cause of the respiratory illnesses and deaths that it is investigating.
2. **Accept Public Health England's Statement:** The CDC should publicly acknowledge Public Health England's well-researched and scientifically-reviewed statement that e-cigarettes are 95% safer than combustible cigarettes and that all smokers (if they have failed to quit smoking through other FDA-approved methods) should try vaping to transition away from combustible cigarettes.

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<sup>20</sup> Borrelli, Belinda. *E-Cigarettes to Assist with Smoking Cessation*. February 14, 2019. <https://www.nejm.org/doi/full/10.1056/NEJMe1816406>.

## Appendix A

List of vapor product companies that support these market reform recommendations.

1. ALD Group Limited
2. Alohma
3. Aqueous Vapor
4. Asheville Vapor
5. Avail
6. Big D Vapor
7. Boosted Dreamz Glass
8. BreezEsmokes, LLC
9. California Grown E-liquids
10. City Vapors, LLC
11. Colonial Vapes
12. Create a Cig
13. D&A Vapor
14. DC Vapor
15. ECig Charleston
16. E-cigs Depot LLC
17. E-liquid Brands
18. Envy Vapes
19. Foggy Bottom Vapes
20. Good Guy Vapes
21. High Times Vape
22. i59 Vapes
23. Icabod's, LLC
24. Innokin
25. Joost Vapor
26. Kangertech
27. Kure
28. 3L Vapor
29. Legends Smoke
30. Liquivana Vape Shop LLC
31. Lotus Vaping Technologies
32. Macon Vapor Trail
33. Madvapes
34. The Mamasan
35. Marlin Steam Co.
36. MAXX Electronic Cigarettes
37. Misty Vapor Emporium
38. Mt Vapors, LLC
39. OG Vapors
40. Puffs of Elkin
41. Puffs Vaping
42. The Rabbit Hole Vaporium
43. RVA Vapes
44. Red Star Vapor
45. Saffire
46. The Smokers' Den
47. Smoky Mountain Vapors
48. Select-a-Vapor
49. Smoke Stop Vape Shop
50. Smokin Legal Vaperz
51. SmokTech
52. Straight Line Vapors
53. UVape, LLC
54. V & A Vapor
55. VapaMotive
56. Vape Air
57. Vape Crypto
58. Vape Guys
59. Vape King Inc.
60. VapeZone Inc.
61. Vapor Bound
62. Vapor City
63. Vapor in Depew
64. Vapor Maven
65. The Vapor Shoppe
66. Vapor World
67. Vaporized of Gray
68. Voltage Vaping
69. World's Finest Vapeshop