

# ACTION NEEDED: E-CIGARETTES

Since their introduction in 2008, **e-cigarettes** have become both **ubiquitous** and an increasing source of public policy concern and debate. This concern stems primarily from **drastic increases in youth e-cigarette use**. The most recent data show that **27.5%** of high schoolers are using these products — a rate of youth tobacco product use not seen in nearly two decades. The public health community, parents and educators are shocked and worried to find their children and students using these products at home and even in class. **Young people are reporting severe signs of dependence**, including using e-cigarettes when they first wake up, inability to concentrate in the classroom without using an e-cigarette, and even waking in the night to get a nicotine fix.

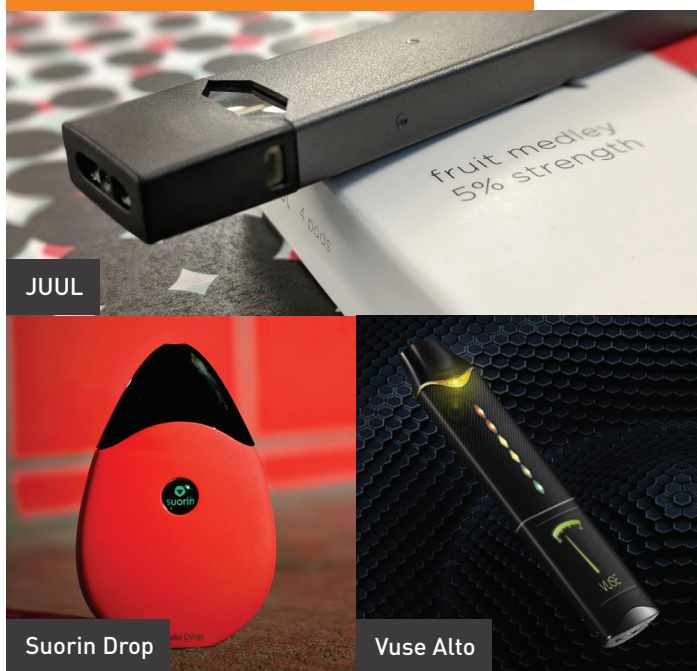
We have known for decades that **youth in particular should not be exposed to nicotine because it changes brain chemistry to create a stronger addiction**, can lead to memory and concentration problems, and can make youth who use it more susceptible to addiction to other substances. Research also suggests that young people who use e-cigarettes are four times more likely to go on to smoke combustible cigarettes.

**E-cigarettes are now threatening to undo all the progress that the public health community and government have made over decades to reduce cigarette smoking.** Indeed, the surgeon general raised the alarm by issuing an advisory declaring a youth e-cigarette **epidemic** in December 2018. Since then, data show that more and more youth continue to use e-cigarettes. And this isn't just experimental or occasional use — it's regular use likely driven by **addiction**. The most recent National Youth Tobacco Survey data show that **34.2%** of current **high school e-cigarette users** use them on 20 days or more per month.



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## Current generation of e-cigarettes



JUUL

Suorin Drop

Vuse Alto

Photo: Suorin USA

Photo: Vuse Vapor

Conversely, as the youth e-cigarette epidemic has continued unabated, we have seen adults, and especially older smokers, simply reject the product. In 2014, the first year that the National Health Interview Survey measured adult use of e-cigarettes, 3.7% of adults used the product in the last 30 days. In 2018, the adult usage remained low, at **3.2%**, and was largely driven by young adult users (7.6%), who have matured during the youth e-cigarette epidemic. While some adults have switched completely to e-cigarettes from combustible cigarettes, the **predominant pattern among adult users continues to be e-cigarette use in conjunction with smoking**. This “dual use,” however, provides no reduction in the harms associated with smoking.

As youth use continues to rise, the science around the potential harms of e-cigarettes has grown. Studies show that e-cigarettes produce lower amounts, but are not free from the toxins found in cigarettes. At the same time, **flavoring compounds and other ingredients may be producing their own unique harms**. Recent studies demonstrate **the harms e-cigarettes pose to the respiratory system**. Similarly, new studies show e-cigarettes may present unique threats to **cardiovascular health**. It continues to be nearly impossible to make generalized statements about the potential harms and benefits of the overall category of e-cigarettes due to the incredible variation in hardware design and ingredients. Moreover, as industry executives themselves have acknowledged, **we simply do not know the long-term health impacts of e-cigarette use**. It took us many decades to understand the toxicity of cigarettes, and, even today, we are discovering new ways in which they harm health.

Simply put, the data show that **e-cigarettes** as they are currently sold and regulated in the United States are overwhelmingly a **vehicle for youth initiation**, not adult cessation. **E-cigarettes expose kids — who otherwise never would have been — to nicotine** and put them at risk for both long- and short-term health consequences.



## Vaping-related illness outbreak

As of this writing (November 2019), the country is experiencing an outbreak of vaping related illnesses. More than 2,000 cases have been reported across 49 states with 39 deaths. Most of these cases were from users who reported use of THC, about 86% reported use of THC and 64% reported use of nicotine vaporizer products and 11% report exclusively using nicotine products. The Centers for Disease Control and Prevention continues to update this information on its [website](#). On November 8, 2019, the CDC identified vitamin E acetate as a significant concern in the outbreak, finding the chemical in all 29 samples it had analyzed from victims. The CDC states, “it is possible that more than one compound or ingredient could be a cause of lung injury, and evidence is not yet sufficient to rule out contribution of other toxicants.” It continues to advise non-smokers to avoid vaping of any variety and for everyone to avoid all vaping products purchased “off the street.”

## THE POSITION OF TRUTH INITIATIVE®

Truth Initiative has maintained that there may be some possible public health benefit from properly regulated e-cigarettes, provided manufacturers can demonstrate that the products can help adults quit smoking combustible cigarettes safely and completely. However, no e-cigarette has been approved for smoking cessation and no e-cigarette has gone through the rigorous scientific review necessary to determine whether it actually does help smokers to quit. Furthermore, **any public health benefit from e-cigarettes for smokers must be weighed against the incredibly high youth use of e-cigarettes** and the fact that there are currently no significant marketing restrictions on these products. **Without a significant change in regulatory approach, it is unlikely that e-cigarettes will contribute to the overall benefit of public health.**

While the industry was creating the e-cigarette problem, the federal government had the tools it needed to slow — if not prevent — this epidemic. Unfortunately, it failed to use them. The government must use those tools now to rein in and reverse this dangerous turn of events. It took the Food and Drug Administration until 2016 to assert authority over e-cigarettes, despite being given the ability to do so by Congress in 2009. Once they had the authority, the FDA could have ensured that products were reviewed to determine whether they provided any public health benefit, as required by the Tobacco Control Act, and that strong marketing restrictions were in place to protect youth. However, in 2017 the FDA chose to delay the due date for all e-cigarettes to submit their scientific public health review applications to 2022. This left products on the market about which the public (or the FDA for that matter) knew nothing — particularly in terms of their individual health effects, appeal to youth, and risks and benefits to smokers — unchecked for five additional years. It also **opened the door for the newest generation of high-nicotine content e-cigarette products, such as JUUL and Suorin Drop, to hit the market.**

These high tech “pod” or “pod mod” **products** are easily **concealable**, come in fruit and candy **flavors highly attractive to youth**, and some were introduced to the market with **advertising campaigns aimed directly at young people**. Although one of the manufacturers, market leader JUUL, has announced its plan to halt distribution of some flavors, it will continue to sell mint/menthol flavors, which nearly two-thirds of high school vapers use. In addition, other nicotine pod brands continue to sell a wide variety of fruit and candy flavors and market the products, featuring highly appealing advertising and social media campaigns directed at youth.

**As we find ourselves in the midst of another tobacco epidemic, many e-cigarette companies try to claim that they are not part of the tobacco industry. That is simply not true.** Tobacco companies either fully own or have significant vested interest in four of the top five e-cigarette companies. E-cigarette companies are emulating their Big Tobacco siblings in order to entice kids and increase their market share. Tactics

Photo: Stanford Research into the Impact of Tobacco Advertising



**E-cigarette companies are emulating their Big Tobacco siblings in order to entice kids and increase their market share.**

such as increasing their nicotine content; marketing their products with slick, colorful ads and using popular social media influencers; and claiming that their products are safer, despite no federal review of the products or these safety claims, come straight out of the **Big Tobacco playbook**.

As a result, we have a situation where **millions of youth are at risk of addiction to these products while no one, including the FDA or the e-cigarette companies themselves, knows the long-term or even all the potential short-term health effects.**

Truth Initiative, along with several other public health organizations, has sued the FDA to force the agency to take action much sooner than 2022 in order to get this epidemic under control. The court ruled that e-cigarette manufacturers must submit their scientific information on the public health impact of their products by May 2020. Additionally, in September 2019, the administration stated that it would pull all flavored e-cigarettes off the market until the manufacturers could show that a flavored e-cigarette has a public health benefit. As of this writing, the **administration has not moved forward** with this plan.

In the meantime, the public health community and all levels of government must help the millions of youth and young adults who are now being exposed to nicotine and prevent this generation from falling into the next trap set by the tobacco industry. The FDA has many tools at its disposal to address the



situation but it has chosen not to use them. **The time is long past for the FDA to take action and use its authority to correct this massive regulatory failure.** In addition, states and some localities can take action to protect their youngest citizens.

We outline **key actions** all levels of government should take below.

## FEDERAL ACTION NEEDED

- > **FDA review:** First and foremost, the FDA must enforce its authority to require a **full scientific review of all e-cigarette products** to determine their impact on public health. The agency must **adhere to the court-ordered date** of May 2020 and take products that do not comply off the market immediately. If the FDA had done this in the first place, many of the problems we're seeing now, including skyrocketing youth use, would have been significantly reduced.
- > **Extend marketing restrictions on cigarettes to e-cigarettes:** The FDA must restrict e-cigarette marketing so that it does not target or appeal to youth. Specifically, the agency must immediately **extend the marketing restrictions that apply to combustible cigarettes to e-cigarettes.**

The FDA must enforce its authority to require a full scientific review of all e-cigarette products to determine their impact on public health.

These include prohibitions on:

- > **Other marketing restrictions:** E-cigarette manufacturers have marketed their product as sleek and high tech using similarly high-tech marketing tactics in **digital and social media** as well as social media influencer campaigns. **The FDA must institute restrictions** on this type of marketing — particularly as it applies to **third parties who endorse products** on behalf of tobacco companies.
- >> Other federal agencies have a role to play as well. For example, the Federal Trade Commission (FTC) must also ensure that all industry-funded influencer endorsements clearly indicate that they are paid advertisements and clearly indicate the risks associated with nicotine use.
- >> The FTC must collect data from the e-cigarette industry on marketing spending just as they do for cigarettes and smokeless tobacco.
- > **Internet sales:** The FDA should **prohibit all non-face-to-face sales, along with internet sales**, of all tobacco products, including e-cigarettes.
- > **Product standards:** The FDA also has the ability to **institute product standards on e-cigarettes, preventing the sale and marketing of any product that does not adhere** to those standards. This is a powerful tool the agency needs to exercise in several areas:
  - >> **Flavor restrictions:** Truth Initiative has long supported the removal of flavors in cigarettes, cigars and smokeless tobacco products. We know that **flavors have overwhelmingly been used to attract**



those who have not previously used nicotine or tobacco products. Given the state of the youth e-cigarette epidemic, we strongly support **removing all flavored e-cigarettes from the market, including mint and menthol**, pending an FDA review. The burden should always have been on manufacturers to show that their products would not appeal to youth before going to market. Given what we now know about how dramatically flavors influence youth e-cigarette use, the burden should be high. We support a permanent ban on flavors unless a manufacturer can demonstrate three things to the FDA: 1) that a particular flavor helps current tobacco users to stop smoking, 2) it will not lead non-tobacco users, such as youth, to start, and 3) it does not increase the risk of harm from using the product.

Flavors have overwhelmingly been used to attract those who have not previously used nicotine or tobacco products.

- » **Product packaging:** E-cigarettes and e-liquid in particular should come only in **child-resistant packaging** to prevent young people from ingesting these products, which causes sickness and, in some cases, can be **fatal**.
- » **Restrictions on nicotine concentrations and delivery:** There are currently no restrictions on the concentrations of nicotine in e-cigarette products in the U.S. JUUL, the most popular e-cigarette in the U.S., contains 59mg/ml (or 5%) nicotine. Some of its competitors contain as much as 7% nicotine. This is in stark contrast to the European Union, where the highest nicotine concentration allowed is 20 mg/ml (2%). Truth Initiative supports **restricting not only the nicotine levels but also the mechanism by which nicotine is delivered** to reduce the level of nicotine actually delivered to the body in e-cigarettes. This will help reduce its addictiveness.
- » **Constituents** and are manufactured at the highest quality standards.
- » **Battery safety:** The FDA should ensure that battery and device quality are sufficient to **prevent explosions** and overheating.
- » **Enforcement:** The FDA must use its considerable enforcement authority to ensure that all aspects of the **Tobacco Control Act, as well as all subsequent regulations, are enforced to the full extent of the law**. Without enforcement, these measures will not protect youth. Additionally, other federal agencies, such as the FTC, should work with the FDA to protect against misleading marketing.
- » **Taxation:** Federal, state and local tax-writing authorities should set the **highest possible taxes on all tobacco products, including e-cigarettes, to discourage youth use**. Above that, combustible tobacco products should be taxed at the highest level, and the least harmful, well-regulated and FDA-reviewed noncombustible tobacco products should be taxed at lower levels.

- **Cessation:** Federal agencies such as the FDA and the National Institutes of Health must **redouble all efforts to develop nicotine cessation interventions for the millions of youth and young adults** who now find themselves addicted to nicotine from e-cigarette use. Additionally, the Centers for Medicaid and Medicare Services and insurance companies should make **quitting services** available for all those addicted to nicotine — whether from e-cigarettes or combustible tobacco products — with **no barriers to treatment, such as co-pays**.
- **Federal research:** The FDA and NIH should **fund research to better understand e-cigarette harms**, behavioral use patterns and impact on tobacco use cessation (separate from the research mentioned above).

States and local communities are often the incubators of strong tobacco control policies.



## STATE AND LOCAL ACTION NEEDED

**States and local communities are often the incubators of strong tobacco control policies.** They have an important role to play when it comes to protecting youth from e-cigarettes as well. Some examples include:

- **Licensing: Requiring all e-cigarette vendors to be licensed and registered** with the state or local (where allowed) government. Licensing, besides being an important way to keep track of who is selling tobacco products, can also be a tool to limit the density and location (i.e., not near schools) of tobacco retailers.
- **Flavor restrictions:** Many local jurisdictions have taken action to **restrict or prohibit the sale of flavored tobacco products**. Truth Initiative supports such actions because they limit the availability of such highly appealing tobacco products to youth.
- **Clean indoor air:** State and local governments should **require e-cigarette use to be subject to clean indoor air laws** and requirements.
- **Tobacco 21:** State and local jurisdictions should **limit sales of all tobacco products, including e-cigarettes and their components, to those age 21 and older**, with the onus lying with the retailer. We note that the tobacco industry has recently supported Tobacco 21 policies, selling the idea that this policy will take care of the youth tobacco problem. While Tobacco 21 is an important tool in the tobacco control toolbox, by itself it is not sufficient to keep tobacco out of the hands of young people. Tobacco 21 policies must be accompanied by complementary and strong policies, including but not limited to those listed above, to protect youth from tobacco.

# E-CIGARETTES

Among **youth who vape**, 97% used a **flavored e-cigarette** in the past month.

97%



E-liquids contain at least **60 chemical compounds**. E-cigarette aerosol contains even more.

60



16x

**15- to 17-year-olds** have more than **16x greater odds** to be current **JUUL** users vs. adults.

27.5%



In 2019, **e-cigarette use** among high schoolers **rose to 27.5%**.

For high school seniors, the rate has **doubled since 2017**.



2017



2019

Young people who use **e-cigarettes** are **4x times** more likely to start smoking tobacco **cigarettes** than their peers who don't vape.

4x



73%

**JUUL remains the top e-cigarette brand** and took **73.4% of the e-cigarette marketplace** by July 2019.



# E-CIGARETTES

## BACKGROUND

Electronic nicotine delivery systems (ENDS) go by many names. The most common name is “e-cigarette,” but others such as e-cigs, vapes, vape pens, mods and tanks are common terms. Recently, the e-cigarette brand **JUUL has become so ubiquitous among youth that “JUULing” is also used as a common verb** for all e-cigarette use. For the purposes of this resource we refer to the entire category as “e-cigarettes.”

## WHAT IS AN E-CIGARETTE?

- E-cigarettes are devices that operate by heating a liquid solution to a high enough temperature so that it produces an aerosol that is inhaled.<sup>1</sup>
- Solutions, sometimes called **e-liquids**, almost always include **nicotine**, **flavoring** and a humectant, such as propylene glycol, to retain moisture and create the aerosol when heated.<sup>1,2</sup>
  - » While many of the **flavorings** and humectants used in e-liquids have been approved by the Food and Drug Administration for oral consumption,<sup>2</sup> they **have not been approved for inhalation**. Thus, their health consequences are not well known when consumed in this manner.
  - » There is an ongoing outbreak of **significant lung illness and death (2,051 reported cases and 39 deaths as of November 5, 2019)** due to vaping. Most of these cases (over 80%), but not all, were from users who reported use of THC vaporizer products. On November 8, 2019, the CDC identified vitamin E acetate as a significant concern in the outbreak finding the chemical in all 29 samples it had analyzed from victims. The CDC states, “it is possible that more than one compound or ingredient could be a cause of lung



injury, and evidence is not yet sufficient to rule out contribution of other toxicants.” It continues to advise non-smokers to avoid vaping of any variety and especially products purchased “off the street.”

- Older generations of e-cigarettes used a form of nicotine called free-base nicotine. The most recent generation of e-cigarettes on the market, which include pre-filled pod systems like JUUL and refillable systems like Suorin Drop and Kandypens, use nicotine salts in the e-liquids.
  - » The **nicotine salt formulas allow for much higher levels and efficient delivery of nicotine** with less irritation compared to earlier generations of e-cigarettes — prompting questions about the use, purpose and safety of this novel form of nicotine.<sup>3</sup>

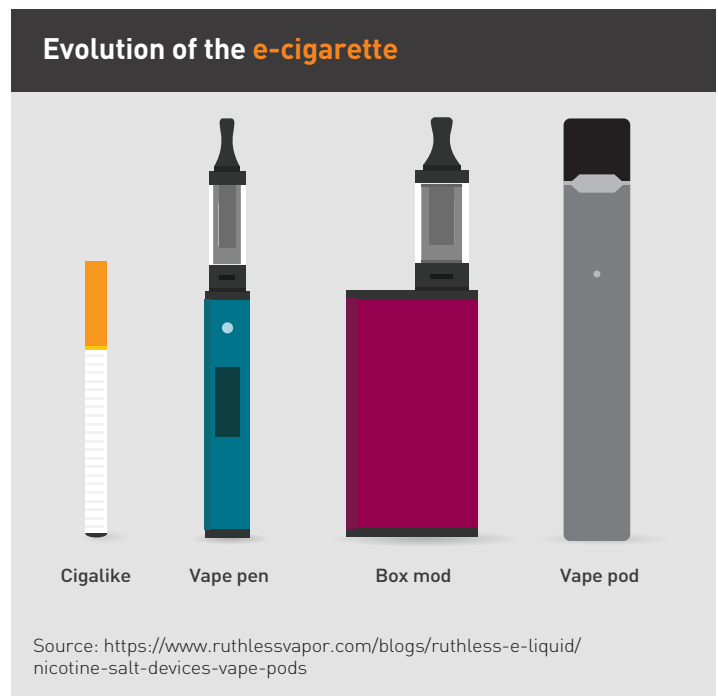
» **Higher nicotine e-cigarettes have driven the surge in e-cigarette sales** in recent years, with those containing at least 4% nicotine comprising nearly three-quarters of the e-cigarette market in 2018.<sup>4</sup> Unlike in Europe, where e-cigarette nicotine concentrations cannot exceed 2%, there are no nicotine concentration restrictions in the United States.<sup>5</sup>

➤ While using an e-cigarette is often called “vaping,” the devices produce an aerosol, not a vapor.

» **Unlike vapor, which is simply a substance in gas form, the aerosol from an e-cigarette contains tiny chemical particles from both the liquid solution and the device** (e.g., metals from the heating coil). There is evidence to suggest that these particles lead to **cardiovascular injury**, with links to negative effects on resting heart rate, blood pressure and the cells that line the blood vessels.<sup>6,7</sup>

## WHAT ARE THE TYPES OF E-CIGARETTES?

- When e-cigarettes first began entering the market around 2007, some devices were designed to resemble regular cigarettes, while others looked more like cigars, pipes, pens and even USB flash drives.<sup>1,8</sup>
- To account for the diversity in product design, some researchers have classified e-cigarettes as first, second or third generation devices.<sup>2</sup>
- A **first generation** e-cigarette is one that closely resembles a **cigarette** and is **disposable**.<sup>9</sup>
- A **second generation** e-cigarette is a larger, usually **pen-shaped** device, that can be **recharged**.<sup>9</sup>
- A **third generation** e-cigarette refers to devices that do **not resemble a combustible cigarette** and often have very large and sometimes customizable batteries. Some parts may be **replaceable**, which is why they are sometimes called “**mods**.” These devices are **refillable**.<sup>2,9</sup>



➤ More recently, e-cigarettes that have a **sleek, high-tech design** and easily rechargeable batteries have entered the market.

- » The most popular, **JUUL**, emerged in 2015 and quickly established itself as a leading e-cigarette product, comprising nearly **three-quarters (73.4%) of the e-cigarette marketplace** by July 2019.<sup>10</sup>
- » “Copycat” products, such as Suorin Drop, myblu and Vuse Alto, follow JUUL’s blueprint of high-tech design and high nicotine delivery through the use of nicotine salt e-liquid formulations. These devices are all often referred to as “JUUL” due to the ubiquity of the brand, but they are also referred to as “**pod mods**” because the e-liquid is sold in self-contained disposable pods.
- » The enormous popularity of JUUL has encouraged copycat devices that are specifically compatible with JUUL, including Eonsmoke and Vapor4Life, that deliver similarly high amounts of nicotine in sleek, discreet devices or in devices that either use JUUL pods or have pods that can be used in JUUL devices.<sup>11</sup>



## Heated tobacco products

In addition to e-cigarette products, tobacco companies have begun introducing **tobacco heating systems** or, as the industry calls them, “heat-not-burn” tobacco products. These devices work by heating tobacco instead of burning it. Sometimes the tobacco is treated with a humectant like propylene glycol to produce an aerosol inhaled by the user. Manufacturers claim this delivery method is substantially less harmful than traditional cigarettes,<sup>12</sup> but **current data on health effects of these devices are sparse** and most of what has been published has been by tobacco industry scientists.

In 2019, the FDA allowed the first type of tobacco heating system to be marketed and sold in the U.S.<sup>13</sup> IQOS, produced by Philip Morris International (PMI), is now being sold in select test markets by Altria around the country.<sup>14</sup> Data in foreign markets submitted by PMI indicate that dual use of heated tobacco products along with cigarettes is, by far, the most dominant pattern of use, which raises substantial issues about what impact they might have on overall public health.<sup>15</sup> Notably, research has shown that **dual use is not associated with reduced cigarette use**, but rather increased exposure and poorer health outcomes than using cigarettes or e-cigarettes alone.<sup>16</sup> Read comments and potential concerns from Truth Initiative on the IQOS application. Truth Initiative will continue to monitor patterns of use as the product becomes more common in the U.S.

## HOW MUCH NICOTINE IS IN AN E-CIGARETTE?

Nicotine levels in e-cigarettes are highly **variable**, with some reaching or **exceeding** levels found in combustible **cigarettes**.<sup>2,17</sup>

- > **Labeling is not always a reliable indicator** of nicotine content, as studies have found mislabeling to be a common issue in the category.<sup>2,17</sup>
- > The way an e-cigarette is used or **modified** also affects the delivery of nicotine to an individual user.<sup>2,18</sup>
- > Some e-cigarette products deliver nicotine as efficiently as a cigarette. The use of nicotine salts also lowers the pH of e-liquids, which allows **higher concentrations of nicotine to be delivered with less irritation**.<sup>19</sup> For example, the maker of JUUL claims the product has a nicotine content like traditional cigarettes, and that it delivers the nicotine up to 2.7 times faster than other e-cigarettes.<sup>20</sup>
- > In the U.S., JUUL devices were originally introduced with a 5% nicotine salt pod.<sup>21</sup> Following suit, **JUUL competitors began offering nicotine salt concentrations as high as 7%** in what has been called a “nicotine arms race.”<sup>21</sup> However, in 2018, JUUL introduced a lower nicotine pod, with 3% nicotine strength.<sup>4</sup>
- > In addition to the rate of nicotine delivery, the nicotine content of products like JUUL also raises concerns about the potential for addiction. A 2018 Truth Initiative study published in Tobacco Control found that **among current youth and young adult JUUL users, the majority — 63% — did not know that the product always contains nicotine**.<sup>22</sup> Anecdotally, youth are reporting signs of **severe dependence**, such as inability to concentrate in class, using an e-cigarette upon waking, and using e-cigarettes at night after waking with a craving.<sup>23,24</sup>




## ARE E-CIGARETTES LESS HARMFUL THAN CIGARETTES?

It is generally accepted that e-cigarettes produce fewer of the toxins found in cigarette smoke.<sup>2</sup> However, it is becoming increasingly apparent that this frame is not adequate to tell the entire story regarding individual health impacts. The most recent evidence suggests that **e-cigarettes may pose their own unique health harms** and that comparison to cigarettes may not be the only relevant question for determining their impact on individual health.<sup>25-27</sup> Indeed, the growing evidence of potential health risks related to e-cigarette use has led some researchers to question whether e-cigarettes are safer than combustible cigarettes.<sup>27</sup> For more information see “Health Effects” on p. 17.

### The recent outbreak of vaping related lung injuries also supports caution with respect to e-cigarettes.

While a substantial number of cases in the recent outbreak of vaping related lung illness (see “Health Effects” on p. 18) appear to be related to THC vaping and the CDC recently identified vitamin E acetate as a chemical of significant concern, the agency has been cautious to say it has not found a single cause and continues to recommend caution with respect to all vaping as the investigation continues.<sup>95</sup> At minimum, this outbreak dramatically demonstrates the dangers of an unregulated market in inhaled substances with no premarket review for consumer safety.

We also note the frequently cited claim from **Public Health England** that e-cigarettes are definitively — 95% — safer than traditional cigarettes. First, this analysis was originally conducted in 2013, prior to recent research on health effects of vaping. Moreover, further analysis into the original research finds that the evidence for such a statistic remains unclear and not fully comprehensive, among other concerns about author and funding conflicts of interest.<sup>28</sup> The Public Health England claim also fails to acknowledge the reality of the potential for negative net public health impact among a population of users that have otherwise never used tobacco products or the lack of clinical and long-term evidence of these products’ safety in humans, regardless of current smoking status.<sup>28</sup>



Recent reports of lung illnesses related to vaping have raised questions about both the long- and short-term effects of vaping.

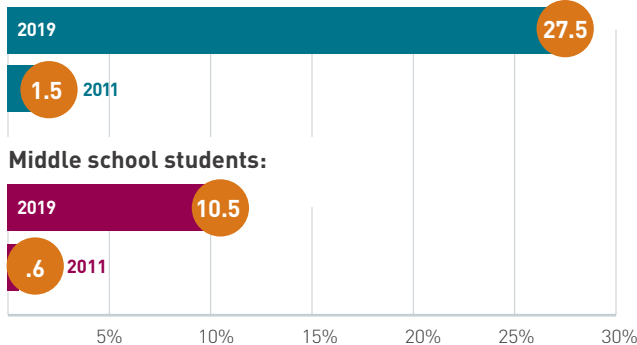
While a 2018 National Academies of Sciences, Engineering, and Medicine report found substantial evidence that exposure to toxic substances from e-cigarettes is significantly lower compared to combustible cigarettes, recent studies are showing that is not the end of the story on health impact. It now appears that **e-cigarettes may present their own unique health risks, including to the respiratory and cardiovascular systems**. Given the products’ relatively recent introduction to the marketplace, further research is needed to evaluate the short and long term health impacts of e-cigarettes.

**The evidence for e-cigarettes’ effectiveness as a cessation tool also remains inconclusive and, until an FDA review, the safest, most evidence-based cessation strategy should include a combination of counseling, nicotine replacement therapy, and/or cessation drugs like varenicline, approved by the FDA.**<sup>29</sup> Moreover, while the basic technology behind e-cigarettes is consistent, there is enormous variability within the product category and there is no typical e-cigarette. The products include different ingredients, different hardware and deliver highly variable amounts of nicotine and potentially **toxic chemicals**, including heavy metals such as cadmium, lead, nickel, tin and copper.<sup>30</sup> This variation makes it difficult to issue overall public health recommendations about the category and demonstrates the huge and long-standing need for pre-market review of these products.

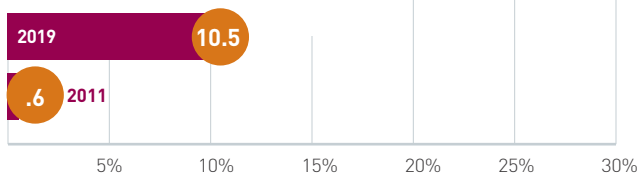
Consumers need to consistently know what they are getting and whether it is safe — particularly from a product designed to deliver chemicals by frequent inhalation. The growing evidence of potential health risks and lung injuries related to e-cigarette use has led researchers to question whether e-cigarettes are safer than combustible cigarettes.<sup>27</sup>

## Current e-cigarette use among middle and high school students

### High school students:



### Middle school students:



Source: 2019 National Youth Tobacco Survey

## PATTERNS OF USE

E-cigarette use has increased in recent years, especially among youth and young adults, who use e-cigarettes more than any other age group. **In 2018, the rapid rise of tobacco products led the U.S. surgeon general to issue an advisory about the youth e-cigarette “epidemic.”** In 2019, youth e-cigarette use increased to even higher levels. While the most recent studies show a decrease in youth use in 2020, the rate is still alarmingly high.<sup>31,32,175</sup>

### YOUTH

**The last five years have seen enormous spikes in youth e-cigarette use rates.**<sup>33</sup>

- > In **2017, 11.7% of high school students** had used an e-cigarette in the past 30 days.<sup>34</sup> By 2018, that number had risen to 21% and, by **2019, 27.5%** of high school students had used e-cigarettes in the past month.<sup>33,35</sup> That number dropped to 19.6% in 2020.<sup>175</sup>
- > The current use rate among middle schoolers rose from 0.6% in 2011 to 10.5% in 2019. The rate dropped to 4.7% in 2020.<sup>175</sup>
- > Using e-cigarettes has been shown to **increase the likelihood of smoking cigarettes among young people**, raising concerns that e-cigarettes are acting as **entry nicotine products** that may lead to use of more

dangerous nicotine products.<sup>32,40,41</sup> According to a recent study, young people in the U.S. who had ever used e-cigarettes in 2018 had **7X higher odds of ever using cigarettes and 8X higher odds** of currently using cigarettes one year later, compared with those who had never used an e-cigarette.<sup>176</sup> Another study estimated that e-cigarettes are likely responsible for **22% of new ever cigarette use** (trying a cigarette) and 15.3% of current cigarette use for the same group — totaling nearly **200,000 new cigarette initiators**.<sup>42</sup>

- > **Many young e-cigarette users do not know what is in the products they are using.** A recent study found that 99% of all e-cigarette products sold at convenience stores, supermarkets and similar outlets contain nicotine.<sup>43</sup> Yet, many young people **aren’t aware that the products they use, like JUUL, contain nicotine.**<sup>22</sup> In fact, a 2018 Truth Initiative study showed that nearly two-thirds of JUUL users aged 15-21 were not aware the product always contains nicotine.
- > As rates of use increase, we are also seeing the **frequency of use** (how many times a user vapes in a day) go up, indicating that users are not simply experimenting with e-cigarettes but are instead using them **habitually**. The 2020 National Youth Tobacco Survey data show that 38.9% of current high school e-cigarette users use e-cigarettes on 20 days or more per month up from 34.2% in 2019.<sup>175</sup>

## FLAVORED PRODUCTS

- > In 2020, 82.9% of youth e-cigarette users used flavored e-cigarettes, including 84.7% of high school users (2.53 million) and 73.9% of middle school users (400,000).<sup>175</sup>
- > Among high school students who currently used any type of flavored e-cigarettes, the most commonly used flavor types were fruit (73.1%); mint (55.8%); menthol (37.0%); and candy, desserts, or other sweets (36.4%). Among middle school students who currently used any type of flavored e-cigarettes, the most commonly used flavor types were fruit (75.6%); candy, desserts, or other sweets (47.2%); mint (46.5%); and menthol (23.5%).<sup>175</sup>

- **Youth e-cigarette users cite flavors as a top reason they began using e-cigarettes**, second only to use by a family member or friend.<sup>46</sup>
- A study that included middle and high school students reported that **43%** of young people who ever used e-cigarettes **tried them because of appealing flavors**.<sup>47</sup>
- The FDA has also reported that, among current youth users of e-cigarettes, **97%** used a **flavored e-cigarette** in the past month.<sup>48</sup>
- As much as **98.7%** of **flavored e-cigarette products** sold in convenience, dollar, drug and grocery stores contain **nicotine**.<sup>49</sup>
- While the most commonly used e-cigarette device type among youth was pre-filled pods, such as JUUL, disposable e-cigarettes saw huge increases. In fact, disposable e-cigarette use among current high school e-cigarette users increased by approximately 1000% during 2019-2020.<sup>175</sup>

For more information, see “Flavors” on pg. 25.

- JUUL continues to hold a majority of the U.S. e-cigarette sales market share, but the rise of disposable e-cigarettes and other brands are starting to erode that lead.
- The market share of disposable e-cigarettes nearly doubled in just 10 months from August 2019 to May 2020.<sup>177</sup> This is likely because disposable e-cigarettes are still being sold with youth appealing flavors such as candy and fruit.
- Research suggests that menthol, which remains available for sale, has continued to increase in popularity.
- By March 2020, menthol-flavored e-cigarette sales had risen to an all-time high of 57.7% market share.<sup>178</sup>
- 2020 NYTS data show that 37% of high school e-cigarette users use menthol flavored e-cigarettes.<sup>175</sup> In fact, following the FDA’s guidance around the removal of non-menthol-flavored cartridge-based e-cigarettes in

January 2020, menthol e-cigarette sales increased by \$59.5M and its market share shot up from 24% to 49% during the roughly eight-week period following the announcement. The market share of mint e-cigarettes decreased from 26% to 4% and sales declined by \$79.5M during this time, indicating that as other flavors were either voluntarily pulled or removed as a result of policy changes, users simply switched to menthol.<sup>178</sup>

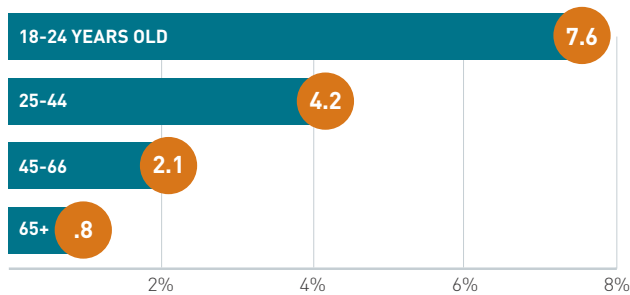
## YOUNG ADULTS

- **Like youth, young adults aged 18-24 are also using e-cigarettes at increasing rates.** Young adult use of e-cigarettes every day or some days increased from 2.4% in 2012 and 2013 to 5.2% in 2017, and increased again to **7.6% in 2018** based on a recent analysis.<sup>32,52,53</sup>
- A 2016 report from the Behavioral Risk Factor Surveillance System survey found that **44.3% of young adult current e-cigarette users were never smokers before trying e-cigarettes**.<sup>54</sup>
- Compared with adults aged 25 and older, **young adults are more likely to try e-cigarettes** and report having used e-cigarettes in the past 30 days.<sup>32</sup>
- A study in Mississippi suggests that using **JUUL leads to more sustained use than other e-cigarettes**. It concluded that the continued use of JUUL by Mississippi undergraduate students was more likely than the continued use of other e-cigarettes after an initial trial. The study found that 30-day use was **three times higher** among those who had tried JUUL than a different e-cigarette.<sup>55</sup>
- The growth in the popularity of e-cigarettes among young adults has caused concerns that use will lead to the **initiation of cigarettes** and other tobacco products.<sup>56-62</sup>

**44.3% of young adult current e-cigarette users were never smokers before trying e-cigarettes.**



## Adults who currently use e-cigarettes as of 2018



Source: 2018 National Health Interview Survey

### ADULTS

- E-cigarette use has remained relatively low and stable among adult users since around 2012. Between 2012 and 2013, 2.4% of adults aged 25-44 and 2% of adults aged 45-64 used e-cigarettes. By 2016, the rates had increased to 4.2% and 2.8%, respectively. The most recent data for the year 2018 show current use of e-cigarettes remaining at 4.2% among adults 25-44 and 2.1% among adults aged 45-64.<sup>52,63</sup>
- The overall adult rate of e-cigarette use in 2018 was 3.2%, down from 3.7% in 2014.<sup>52</sup>
- Those aged **45 and older** are **significantly less likely** to have ever tried an **e-cigarette** compared to young adults.<sup>64</sup>

### DUAL USE OF TOBACCO PRODUCTS

Among all age groups, e-cigarettes are most commonly used by **those who also use other tobacco products**, such as combustible **cigarettes**.<sup>52,54,65</sup> This pattern is commonly referred to as “dual use” or “poly tobacco use.”

Among **adult** users, this is a **troubling pattern** because it suggests that some **e-cigarette use may be supplementing smoking instead of replacing it**. Because there is no safe level of smoking, there are concerns that this behavior

suppresses efforts to completely quit smoking (i.e., people choosing to “cut down” instead of quitting smoking entirely). Some individuals using e-cigarettes to quit may experience a period of dual use as they transition between products, complicating the issue.

Among youth, the data tell a different narrative. A 2018 report from the NASEM concluded that there is **“substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,”** suggesting that e-cigarette use itself is a risk factor, not just a correlation with smoking.<sup>2,32</sup> More recent studies have suggested that **young e-cigarette users are four times more likely to begin smoking cigarettes** compared to their peers who do not use e-cigarettes.<sup>42,60,66</sup>

### DUAL USE PREVALENCE

- Among **adults** in 2016, **54.6%** of current e-cigarette users **also smoked cigarettes**.<sup>54</sup>
- Among adults who used more than one tobacco product in 2017, the most common combination was **cigarettes and e-cigarettes**.<sup>52</sup>
- Dual use** of e-cigarettes and cigarettes is **highly common** among **youth and young adults**.<sup>54,65,67,68</sup>
- A nationally representative survey in 2016 found that among youth and young adult e-cigarette users aged **13-25**, more than half (**55.9%**) **used another tobacco product in addition to e-cigarettes**.<sup>65</sup>
- Among **young adults** aged **18-35**, **e-cigarette** use was associated with **more frequent cigarette smoking** and more intensive cigarette use.<sup>69</sup>
- Young adults (18-35) who used e-cigarettes the previous year increased their odds of daily cigarette use by 1.67 and increased their odds of being diagnosed with tobacco use disorder by 2.58.<sup>69</sup>



# JUUL

Since 2016, the e-cigarette brand JUUL has surged in popularity among young people and, as of October 2019, holds 64.4% of the e-cigarette market share measured by Nielsen.<sup>50</sup> The traditional tobacco industry took notice of JUUL's rapid ascent. In 2018, Altria, the makers of Marlboro cigarettes, acquired a 35% stake in the company for \$12.8 billion. In September 2019, an Altria executive replaced the former head of JUUL as CEO.<sup>10,70,71</sup>

A 2017 study by Truth Initiative found 25% of survey respondents, aged 15-24, recognized a JUUL e-cigarette device when shown a photo of the product. And among those who recognized JUUL, 25% reported that use of this product is called "JUULing," indicating that this product is so distinctive, it's perceived as its own category.<sup>72</sup> However, it's likely that recognition is higher now given that JUUL's sales market share continued to rise throughout 2018 and top out at 75% among U.S. e-cigarette sales in July 2019.<sup>22,50</sup>

The most recent data from the CDC's 2019 National Youth Tobacco Survey confirms JUUL's grip on America's kids. More than 59% of high school e-cigarette users reported that JUUL was their "usual brand." Among middle school e-cigarette users, the number was more than 54%.<sup>39</sup> This equates to more than 3 million children reporting regular use of JUUL. Investigative reporting by Reuters shows that even early in its operations, JUUL was aware that its products were attracting unprecedented youth use, yet, in the face of enormous revenue growth, the company failed to take effective action to stem that trends.

### Flavors are a top reason why young people begin using e-cigarettes.

A 2018 Truth Initiative survey found that mint was among the top three favorite flavors among young JUUL users aged 12-24, meaning they chose it last time they vaped. New research shows that mint and menthol e-cigarette use among high school users rose from 16% in 2016 to 57.3% in 2019.<sup>39</sup> Among high school JUUL users, 67.5% reported that their preferred flavor was mint or menthol. Another study, conducted before JUUL pulled its other flavors from the market, found that mint was one of the most popular flavors among high school student JUUL users, but that menthol was less so.<sup>45</sup> However, study authors themselves caution that leaving both mint and menthol on the market undermines the purpose of removing flavors — which is to prevent kids from using e-cigarettes at all.

Promoted as a "satisfying alternative to cigarettes," **JUUL is putting a new generation of youth at risk of nicotine dependence and future cigarette use.**

- › JUUL has spent more than **\$1 million to market its products on the internet** and has paid for campaigns on Twitter, Instagram and YouTube.<sup>73</sup> However, recently JUUL announced that it would "suspend all broadcast, print and digital advertising in the U.S." It was not clear from the announcement how long that suspension would last.<sup>74</sup>
- › JUUL also **hired social media influencers** for product promotion.<sup>75</sup> The company had an entire department dedicated to influencer marketing and specifically looked for influencers under 30 and created a "VIP Portal" for celebrities.<sup>76,77</sup>

## QUITTING SMOKING

**There are substantial research gaps in proving the effectiveness of e-cigarettes as quit smoking aids.**

The 2018 NASEM report found limited evidence on the effectiveness of e-cigarettes to promote quitting.<sup>2,78-82</sup> Additionally, **e-cigarettes are not approved as quit aids** by the U.S. Preventative Service Task Force or the FDA.

While some evidence supports the use of e-cigarettes as quit devices, recent research suggests that their efficacy for quitting is overstated.<sup>25</sup>

- > **A study published in 2016** reported that within two randomized control trials, **e-cigarettes with nicotine helped individuals quit better than non-nicotine e-cigarettes**.<sup>1,2,83</sup> The NASEM also reported that more frequent e-cigarette use may increase an individual's likelihood to quit smoking.<sup>2</sup>
- > **A 2019 study by the U.K. National Health Service published in the New England Journal of Medicine found e-cigarettes may help adults quit.** A group assigned to e-cigarettes as a combustible tobacco replacement were more likely to remain abstinent at one year compared with a group using nicotine replacement products (18% versus 9.9%). However, a majority of e-cigarette users were still using e-cigarettes at the one-year follow-up. Researchers noted the **study was based on a middle-aged adult population (median age of 41) actively seeking to quit smoking** and receiving at least four weeks of behavioral support.<sup>84</sup> Notably, the U.K. also places severe restrictions on the marketing of e-cigarettes.<sup>5</sup> **No similar study has replicated these results in the U.S.**
- > Another recent 2019 study exploring whether e-cigarettes' presence on the U.S. market has inspired more successful quit attempts found that users of e-cigarettes had 70% lower odds of quitting than non-users.<sup>85</sup>

**While some e-cigarettes may be an effective resource for quitting smoking, the diversity of**



**While some evidence supports the use of e-cigarettes as quit devices, recent research suggests that their efficacy for quitting is overstated.**

**products as well as the variations in quality and the lack of regulation make determining the potential of any particular product as a quit aid difficult.**<sup>2,25,27</sup>

Some smokers have switched to e-cigarettes or used them to quit tobacco completely; however, e-cigarettes, unlike FDA-approved cessation therapies, lack an evidence base that demonstrates their safety and efficacy.<sup>25</sup> Truth Initiative **supports regulation** that encourages the development of consistently **less harmful nicotine delivery alternatives** that allow smokers to **quit tobacco** altogether or **switch** completely to a much **less harmful, well-regulated product**.

One study shows that product appeal, including flavoring, is likely to encourage smokers to try to use e-cigarettes to quit or switch completely.<sup>86</sup> But, because the youth e-cigarette epidemic in the U.S. and the youth appeal of flavored e-cigarettes go hand in hand, **Truth Initiative strongly supports removing flavored e-cigarettes from the market**, pending an FDA review. Given what we now know about how dramatically flavors influence youth e-cigarette use, the burden should be high. We support a permanent ban on flavors unless a manufacturer can demonstrate three things to the FDA: 1) that a particular flavor helps current tobacco users to stop smoking, 2) it will not lead non-tobacco users (such as youth) to start, and 3) it does not increase the risk of harm from using the product. In addition to flavor restrictions, Truth Initiative supports **strong regulations** to keep all tobacco products, including e-cigarettes, away from youth. (See "Action Needed" on p. 1 for more information.)





## Age differences: Reasons for e-cigarette use

Analyses from the Population Assessment for Tobacco and Health study show that the leading reason for **youth and young adult e-cigarette use** is “**they come in flavors I like**” — with **77.9%** and **90.3%** selecting this as a reason, respectively. In comparison, only 66.4% of adults aged 25 and over selected this as a reason.<sup>87</sup>

The FDA has also reported that, among current **youth** users of e-cigarettes, **97% used a flavored e-cigarette** in the past month.<sup>48</sup> Youth and young adults had more than three times the odds of using fruit-flavored e-cigarettes compared to older adults.<sup>87</sup>

The leading reason for e-cigarette use among adults (25 and older) was the belief that e-cigarettes may be less harmful than combustible cigarettes both to themselves and others, with 79% selecting this as a reason. Additionally, 7 in 10 (71.5%) adults indicated that they believed e-cigarettes could facilitate quitting.<sup>87</sup>

## HEALTH EFFECTS

To date, no one knows the long-term effects of e-cigarette use, although **research continues to investigate some of the rapidly emerging evidence of adverse effects** on lung and cardiovascular health.

- > A recent and **robust research literature review** of **e-cigarette** health effects found that use of these products has been associated with increased odds of chronic **cough, phlegm and bronchitis**, as well as **asthma** diagnoses.<sup>27</sup>
- > Ongoing case studies and in vitro research that exposed human tissue to e-cigarette aerosol suggested that **e-cigarettes may be causing quantifiable injury to the small airways of the lungs** and were associated with a number of inflammatory diseases of the respiratory system, like pneumonia and interstitial lung disease.<sup>27</sup>
- > **Human cells exposed to vaped e-liquid have also been found to have decreased viability, with certain flavor compounds posing particular cell toxicity risks.** Other studies also showcased impaired immune cell function in the lungs, raising questions about e-cigarette users’ susceptibility to bacterial and viral infections of the respiratory system. There is uncertainty regarding the way these infections may manifest given the potential for other lung injury and inflammation in lung tissue from e-cigarette use.<sup>27</sup>
- > The first study to link e-cigarette use to cancer was published in October 2019. Researchers found that **mice exposed to e-cigarette aerosol for 54 weeks developed carcinomas of the lungs and abnormal bladder cell growth.**<sup>88</sup>
- > Research has also found that **some flavors are potentially more toxic** than others.
  - >> Researchers found that exposure to increased **cinnamon** flavoring caused significant **cell death** compared to other flavors.<sup>89</sup>

» Another concern related to flavoring stems from **pulegone** — a compound found in prepared oil extracts of certain **mint** plants. Pulegone is a **known carcinogen** and the tobacco industry has in the past reduced the amount of this compound in menthol tobacco products as a result of toxicity concerns. The **FDA banned pulegone as a food additive** in 2018, yet studies have identified that **substantial amounts of this additive are found in mint and menthol e-liquid** in the U.S. — raising concerns about the potential toxicity of these popular flavors.<sup>70</sup>

» Research also indicates that **mixing multiple flavors can be more toxic to cells** than exposure to just one flavor at a time.<sup>91</sup>

⊕ Research regarding the impact of e-cigarettes on cardiovascular health has yielded mixed results. Some studies have shown that short-term exposure to e-cigarette aerosol has no measurable harm on cardiovascular health. However, others suggest negative effects on resting heart rate, blood pressure and the cells that line the blood vessels. **More extensive research is needed to gain perspective on the long-term effects of e-cigarette use on heart health**, which have yet to be identified.<sup>6</sup>

⊕ Another pressing concern of e-cigarette use on cardiovascular health is the creation of **carbonyl compounds from e-cigarette aerosol**. Carbonyls are created when propylene glycol and glycerol — common solvents in e-liquid — are exposed to the high heat of an e-cigarette coil. Many of these carbonyl compounds have been previously associated with an increased risk of **blood clot and atherosclerosis** — a disease in which plaque builds on the walls of arteries, narrowing blood flow.<sup>6</sup>

More research over a longer time period is needed to understand the full breadth of health consequences associated with the use of e-cigarettes as well as how their use compares to the well-established negative effects of long-term combustible cigarette use.



## Federal investigations into vaping-related illnesses

The emergence of vaping-related illnesses, which have prompted federal health agencies' investigations and advisories, underscores the urgency of research.

As of November 5, 2019, more than **2,000 vaping-related illnesses and 39 deaths have been reported** to the CDC.<sup>26</sup> A review of some of the affected e-cigarette users in two states reported that a majority of patients were experiencing cough, labored breathing, reduced blood oxygen levels and elevated white blood cell counts.<sup>27</sup>

Research by Mayo Clinic of 17 patients with vaping related lung issues found that the injuries resembled “exposures to toxic chemical fumes, poisonous gases and toxic agents.”<sup>92</sup> Because a large proportion of the cases with specific substance use information available involved individuals who vaped THC (either exclusively or along with nicotine), the FDA has recommended that consumers not purchase vaping products of any kind on the street and avoid using THC oil or modifying store-bought products.<sup>93</sup> The CDC has also recently identified vitamin E acetate, a chemical found most often in illegal THC vaping products, as a primary chemical of concern in the outbreak.<sup>93</sup>

**The CDC has recommended that those who use vapes consider not using them** and that children and women who are pregnant should not use e-cigarettes regardless of the outcome of this investigation. For those who vape and experience similar symptoms, the CDC recommends seeking prompt medical care.<sup>94</sup> It is important to note, though, that the CDC continues to state, “it is possible that more than one compound or ingredient could be a cause of lung injury, and evidence is not yet sufficient to rule out contribution of other toxicants.”<sup>95</sup>

## ADDICTION AND BRAIN DEVELOPMENT

**Nicotine** is an addictive substance, but its **level of addictiveness can vary substantially depending on its mode of delivery**. Nicotine delivered by the combustion of tobacco is the most addictive form.<sup>96</sup> The rise in popularity of e-cigarettes that can deliver levels of nicotine similar to combustible cigarettes is causing concern about the potential risk for addiction.<sup>32</sup>

- > Exposure to nicotine among youth is particularly dangerous since it has been shown to have an effect on key brain receptors, making **young people more susceptible to nicotine addiction**.<sup>41</sup>
- > There is some evidence that the effect of nicotine on developing brains may prime not just nicotine addiction, but **greater vulnerability to addiction to other drugs** as well.<sup>97</sup>

In young people, the amount of nicotine needed to establish an addiction has been estimated at around 5 mg a day, or roughly one-quarter of an e-cigarette pod.<sup>21,98</sup> In recognition of these and other risks related to e-cigarettes, the U.S. surgeon general issued an advisory on e-cigarette use among youth, urging **parents, teachers, health professionals and states to take action to stop the epidemic among youth**.<sup>51</sup>

While e-cigarettes contain far fewer toxins than combustible cigarettes, they are not free of toxins and still deliver harmful chemicals.

## PREGNANCY

- > Because most e-cigarettes contain nicotine, which can alter nerve cell functioning in developing organisms, especially during fetal development, **they should not be used by youth or pregnant women**.<sup>99,100</sup>
- > **Pregnant women** who use nicotine are also at a greater risk for **stillbirth** and **preterm delivery**.<sup>32</sup>

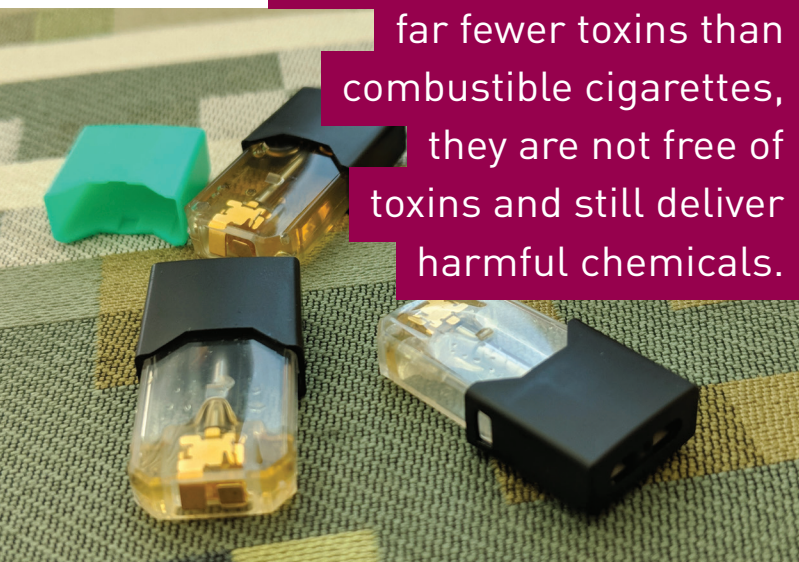
## CHEMICALS

While e-cigarettes may contain fewer toxins than combustible cigarettes, short and long-term effects of their use are unclear. What we do know is that they are not free of toxins and still **deliver harmful chemicals**.

- > **At least 60 chemical compounds** have been found in e-liquids, and still more are present in the aerosol produced by e-cigarettes.<sup>2</sup>
- > **Heavy metals** such as cadmium, lead, nickel, tin and copper have all been detected in aerosols produced by e-cigarettes.<sup>30</sup>
- > E-cigarettes produced fewer free-radicals than combustible cigarettes, however, even low levels of **repeated exposure to free-radicals** can cause oxidative stress, which increases the risk for cardiovascular and respiratory diseases.<sup>101</sup>
- > Researchers have identified several substances which are either harmful or potentially harmful to e-cigarette users, including **delivery solvents and propylene glycol**, which can cause dry mouth and **upper respiratory infections** as well as pulegone, a known **carcinogen**.<sup>2,90</sup>

## EXPOSURE TO E-LIQUID

- > Accidental exposure or ingestion of **e-liquids** can be very dangerous and, in the case of **accidental swallowing or injection**, even **fatal**.<sup>2</sup>
- > More than **8,000 accidental liquid nicotine exposures** were reported by U.S. poison control centers between 2012 and 2017 in **children aged 6 or younger**.<sup>102</sup>





- > Nearly 5,000 (4,745) children under the age of 5 were treated in U.S. emergency rooms for e-liquid nicotine exposure from 2013 to 2017. More than half (56.2%) of the children were aged 2 or younger.<sup>103</sup>

## EXPLOSIONS

- > Defective, poorly manufactured and improperly modified e-cigarettes have also been known to explode and cause injury. The rate of explosions is unknown, but both hospitals and burn centers have reported injuries from e-cigarettes.<sup>2</sup>

## SECONDHAND AEROSOL EXPOSURE

- > Exposure to aerosol from e-cigarettes may expose non-users to nicotine, but research indicates that secondhand aerosol results in substantially lower exposure to toxicants and carcinogens than cigarette smoke. However, exposure among vulnerable populations, including pregnant women and children, could still be dangerous.<sup>2</sup>

## LUNG ILLNESS AND SEIZURES

- > The FDA is investigating whether a direct relationship exists between the use of e-cigarettes and seizure risk or other neurological symptoms. As of August 2019, the agency had received 127 reports of seizure or other neurological symptoms that occurred between 2010 and 2019.<sup>104</sup>
- > The CDC, FDA and state and local health departments are investigating a multistate outbreak of severe lung injury associated with e-cigarette or vaping product use. As of November 5, 2019, more than 2000 cases of this disease, which CDC is calling “EVALI” (E-cigarette or Vaping product use-Associated Lung Injury) in 49 states, D.C. and the U.S. Virgin Islands. Thirty-nine deaths in 24 states have been confirmed.<sup>26</sup>

## INDUSTRY MARKETING AND YOUTH TARGETING

The introduction of e-cigarettes has allowed companies to advertise through traditional outlets that have been heavily regulated to reduce combustible cigarette marketing to children. For example, e-cigarette advertising appears on television and radio, despite the ban on cigarette advertising in both outlets since Congress passed the Public Health Cigarette Smoking Act in 1970. The FDA also banned flavors, except menthol, in combustible cigarettes in 2009 to curb youth appeal, whereas e-cigarettes capitalize on offering many kid-friendly flavors, such as mint, cotton candy and gummy bear.<sup>105</sup>

## MARKETING TACTICS

- > Individuals aware of e-cigarettes report that the most common platforms to hear about e-cigarettes are through in-person communications, by seeing them for sale and through online and television advertisements, in which some celebrities have endorsed the products.<sup>106-110</sup>
- > E-cigarettes are promoted heavily online<sup>111</sup> through e-cigarette company-sponsored advertisements,<sup>112</sup> and on YouTube<sup>112-115</sup> and Twitter.<sup>116</sup>

E-cigarettes capitalize on offering many kid-friendly food flavors, such as mint, cotton candy and gummy bear.



Photo: U.S. Food and Drug Administration

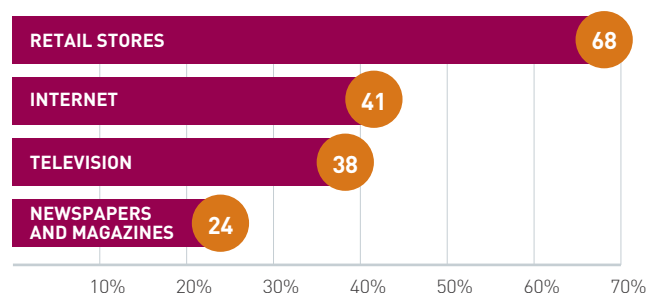


- > More recently, **mobile ads** have become a popular place to advertise e-cigarettes. Mobile ads, or **paid advertisements on smartphone applications** and websites optimized for mobile, have the potential to **reach millions of young people**.<sup>117</sup>
- > **Some e-liquids have been marketed to look like common food items — many of which appeal to kids.** Early examples included marketing e-liquids as “Thin Mints,” after the Girl Scouts’ cookie and “Tootsie Roll” after the iconic candy. Those were removed, or at least renamed, after the companies owning those copyrights took action to protect their intellectual property. Other food and candy flavors remained on the market.
  - >> Since May 2018, the FDA, often in conjunction with the FTC, has taken action against several **e-liquid companies that marketed their products to look like candy or other kid-friendly food items, such as Reddi-wip, Nilla wafers and Warheads candy**.<sup>118</sup> The FDA has also recently announced moves to restrict the sale of candy- or fruit-flavored e-cigarettes. For more, see “Policy Environment” on page 24.

## YOUTH EXPOSURE TO ADVERTISING

- > **Youth may be exposed to pro-tobacco content and advertising on social media** through various sources, including commercial **brands** as well as their own **peers** or **influential accounts** they follow. The nature of social sharing allows branded or promotional content to virally spread across platforms, which can increase youth exposure to overt marketing and pro-tobacco content posted by influential peer network members.<sup>75,119-121</sup>
- > By 2016, nearly **4 out of 5 middle and high school students**, or more than 20 million youth, **saw at least one e-cigarette advertisement**.<sup>122</sup>

## Where young people are most likely to see e-cigarette ads

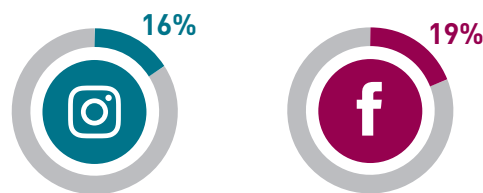


- > Young people were most likely to see ads at **retail stores** (68%), followed by the **internet** (41%), **television** (38%) and **newspapers and magazines** (24%).<sup>122</sup> Between 2014 and 2016, exposure to retail e-cigarette advertising among young people jumped nearly 20%.<sup>122</sup>
- > Mobile device ownership is most prevalent among young people, and research has shown that **mobile ads may attempt to capitalize on young audiences** by highlighting the product as “cool” or “high tech” and by featuring flavored ads.<sup>117</sup>
- > A recent study conducted by Stanford University School of Medicine found **JUUL advertisements strikingly similar to traditional tobacco advertising** in tone and imagery (smoking as pleasurable, relaxing, stylish or romantic).<sup>75</sup>
- > **JUUL has also targeted children as young as third grade by funding summer camps, visiting schools and paying community and church groups to distribute their materials**, according to recent **congressional testimony**.
- > On Oct. 17, 2019, JUUL announced that it would “suspend all broadcast, print and digital advertising in the U.S.” It was not clear from the announcement how long that suspension would last.<sup>74</sup>

## E-CIGARETTES ON SOCIAL MEDIA

- > JUUL spent more than \$1 million to market its products on the internet and has paid for campaigns on Twitter, Instagram and YouTube.<sup>73</sup>
- > Because JUUL relied heavily on social media advertising for its launch, unlike other e-cigarette brands who focused their marketing through traditional outlets (e.g., TV), **teen and young adults made up a significant majority of JUUL's social media audience.**<sup>123</sup>
- > JUUL also hired social media influencers for product promotion.<sup>75</sup> They had an entire department dedicated to influencer marketing and specifically looked for influencers under 30 and created a "VIP Portal" for celebrities.<sup>76</sup>
- > As of October 2018, 11 JUUL-centric YouTube videos from users had more than 1 million total views. In November 2018, JUUL's Instagram account had 77,600 followers and #juul had 260,866 postings. By January 2019, JUUL's hashtag had 336,308 posts.<sup>75</sup>
- > On Nov. 13, 2018, JUUL Labs announced they would be shutting down their U.S.-based Facebook and Instagram accounts in an effort to curb youth e-cigarette interest and use. The official Twitter account remains active.<sup>124</sup>
- > There were 366,786 JUUL-related tweets in 2017, 17 times more than the previous year. A 2018 study found the **surge of tweets mirrored JUUL's sizable growth in retail sales.**<sup>125</sup>
- > A 2018 study found that **exposure to e-cigarette advertisements on social media among young adults was strongly associated with positive expectations of e-cigarette use** — like the idea that using e-cigarettes would provide a pleasurable taste and smell and that it was safe and socially acceptable. These outcomes were also found to be directly correlated with current use.<sup>119</sup>
- > Even among non-smokers, exposure and marketing through social media linked e-cigarettes with increased perceptions of stylishness and popularity.<sup>119</sup> Of the study

### Non-smokers regularly saw e-cigarette ads on social media



Source: Lin X, Spence PR, Lachlan KAJCiHB. Social media and credibility indicators: The effect of influence cues. 2016;63:264-271.

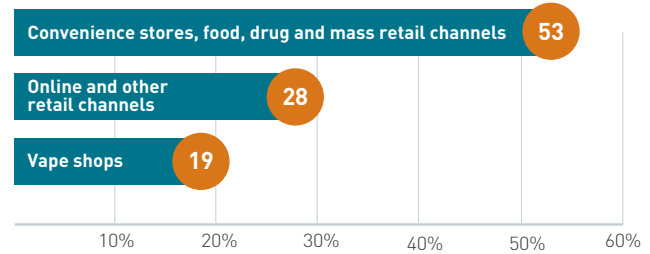
participants, 19% regularly saw e-cigarette ads on Facebook and 16% on Instagram. Even more reported seeing posts about e-cigarettes.<sup>119</sup>

- > The largest e-cigarette forum (/r/electronic\_cigarette) on reddit has **150,000 subscribers.**<sup>123</sup>
- > Another subreddit, titled /r/UnderageJUUL, at one point contained 844 members before it was shut down by reddit. Posts included discussions of flavors as well as methods of obtaining JUULs or pods. Most posts in this thread did not reference age, but those that did mentioned ages from 13 to over 21.<sup>127</sup>
- > A study found that **e-cigarette users who are male and younger** were the most likely to participate in **discussion forums online** related to e-cigarettes.<sup>126</sup>
- > Another study analyzed all public active profiles following JUUL's official Twitter account in April 2018. Of the 9,077 active individual followers, researchers estimated that **80.6% were aged 13-20**, despite the account stating that one must be 21+ to follow.<sup>128</sup>
- > Additional research has shown that **celebrity endorsements of e-cigarettes on social media** can have an impact on young adults. A study of college undergraduates found that the appearance of celebrities on an e-cigarette social media brand page **significantly increased intentions to use e-cigarettes** and positive attitudes towards the devices. This effect was not seen in those who saw non-celebrity endorsers or pages displaying only the product.<sup>129</sup>

## WHERE E-CIGARETTES ARE SOLD

- > It is difficult to monitor and analyze the market due to differences in the tracking of e-cigarette sales. Common **sales-tracking and retail measurement companies like Nielsen do not examine vape shop data**, which may constitute as much as 20% of the market.
- > E-cigarettes are sold at **conventional tobacco retailers**, such as convenience stores, gas stations, pharmacies and tobacco shops. They are also sold at **non-traditional retailers such as online retailers or vape shops**.
- > In 2018, the FDA contacted eBay and raised concerns about the site's continued sales of JUUL and other tobacco products — something that was against their company policy.<sup>130</sup> As a result, eBay agreed to work with the FDA and has tried to remove those listings from its website. It also published an explicit policy outlining the reasons why tobacco products cannot be sold on their site.<sup>131</sup> However, recent **reviews of eBay found the site still sells accessories for JUUL**, such as chargers and “skins” that wrap around JUULs to personalize them.
- > Because these non-traditional sources are not tracked by scanner data or other tracking, it is difficult to know how much of the market they represent. However, analysts have made some estimates. One paper noted that in 2014, traditional tobacco outlets accounted for less than one-third of the \$2.5 billion e-cigarette market. According to one recent estimate, the **breakdown of retail channels for the 2019 e-cigarette market** is:
  - » Vape shops: 19%<sup>132</sup>
  - » Convenience stores, food, drug and mass retail channels: 53%<sup>132</sup>
  - » Online and other retail channels: 28%<sup>132</sup>

## Retail channels of the e-cigarettes market



## POTENTIAL PUBLIC HEALTH IMPACT

The potential public health impact of e-cigarettes is a subject of hot debate. Despite inconclusiveness about their short- and long-term health effects, **e-cigarettes remain largely unregulated and their popularity among youth and young adults continues to rapidly escalate**. At the same time, serious illness and deaths have been linked to their use and recent research could not conclusively determine that they posed fewer health risks than combustible cigarettes.<sup>27</sup>

Moreover, their potential positive public health impact will be limited if they are not considered as part of comprehensive product regulation, including **actions such as reducing nicotine to non-addictive levels in the most dangerous products, such as cigarettes, and eliminating flavors and marketing practices that attract youth**. Continuous and rigorous implementation of traditional tobacco control measures, such as **taxation, clean indoor air policies** and public **education** is also essential. Additionally, an **overarching nicotine regulatory policy** is needed to help improve quitting drugs and to ensure that the FDA reviews tobacco products, including e-cigarettes, so that consumers better understand what can help them quit or completely switch from combustible cigarettes. Finally, the recent news of **vaping-related illnesses requires swift research** and effective guidance to protect the public's health.

## POLICY ENVIRONMENT

### FDA REGULATION

In May 2016, the FDA finalized its “deeming” regulation, asserting the agency’s authority to regulate e-cigarettes and any product meeting the definition of “tobacco product” under the Tobacco Control Act.<sup>133</sup> The **FDA can now establish product standards and regulate the manufacture, import, packaging, labeling, advertising, promotion, sale and distribution of e-cigarettes**, including components and parts of e-cigarettes.<sup>133</sup> Some of these regulations are outlined below.

- > The deeming regulation also includes **requirements for pre-market review for e-cigarettes as new tobacco products**. In order to receive marketing approval for a new product, a manufacturer would need to demonstrate that the new product would be “appropriate for the protection of the public health,” taking into account both the likelihood of new tobacco product initiation and the increased or decreased likelihood that existing users of current tobacco products would stop using such products.<sup>133</sup>
- > It is important to note that because virtually every e-cigarette on the market was introduced after Feb. 15, 2007, technically only those e-cigarettes that have gone through an FDA review to determine whether they benefit public health should be on the market now. However, when the agency finalized the deeming regulation, the FDA issued a “compliance policy” that would give e-cigarette manufacturers more time to prepare those submissions and still allow the products to be on the market. In other words, every e-cigarette on the market right now is illegal because it has not gone through an FDA review, and is only allowed to be sold because the FDA gave them a temporary pass.
- > Additionally, when the deeming regulation was finalized, the FDA indicated that no products could come on the market after

August 2016 without pre-market review and authorization by the FDA. Many companies have not complied with that and the FDA has sent warning letters to these companies. For example, in October 2019, the FDA sent a letter to Eonsmoke regarding nearly 100 flavored e-cigarette products that came on the market after August 2016 without pre-market review and authorization.<sup>134</sup>

- > In 2017, the **FDA pushed back the compliance date for e-cigarette manufacturers to submit pre-market applications even more to August 2022**. This delay in the compliance deadline enabled the proliferation of e-cigarettes that have never undergone an FDA review.
- > In March 2018, a group of public health organizations, including Truth Initiative, sued the FDA for unlawfully delaying the implementation of the deeming rule. In



## Legal challenges to e-cigarettes

A series of **lawsuits** in recent years have also been brought **against JUUL and other e-cigarette manufacturers** by young people who became addicted to JUUL, claiming **JUUL’s marketing was aimed at youth** and instigated these plaintiffs’ use. California, North Carolina, Illinois, Connecticut, Colorado, Massachusetts and the District of Columbia have announced either litigation or investigation into JUUL’s marketing practices and/or health claims.<sup>136-141</sup>



May 2019, a **federal judge ruled that the FDA had acted illegally** by allowing e-cigarettes, including those with flavors that appeal to youth, to remain on the market without formally reviewing their impact on public health.<sup>135</sup> The **judge ordered the FDA to commence the statutorily required review by May 2020**. The FDA appears to have accepted this timetable, although industry groups are still challenging the federal judge's decision.

- In addition, the **Trump administration has indicated it will take all flavored e-cigarettes off the market if they have not undergone premarket review**. By early November, the Administration had signaled it may walk back from that policy. As of November 8, 2019, no policy has been released.

## FLAVORS

- There are currently **no federal restrictions on flavored e-cigarettes**.
- In March 2018, the FDA issued an advance notice of proposed rulemaking to **request public comment to better understand the role that flavors in tobacco products play in attracting youth**, as well as the role they may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. However, this request for comment is not a guarantee of agency action on this issue and no further rule-making action on flavors has been taken or announced by the FDA as of this writing.
- In March 2019, the FDA proposed to **restrict the sales of flavored e-cigarettes, except mint, menthol and tobacco flavors**, to age-restricted locations and online retailers that place a limit on the quantity that a customer may purchase within a certain time period and have independent, third-party age-verification services.<sup>142</sup> As of October 2019, a final guidance had not yet been issued by the FDA.
- As of Aug. 28, 2019, **220 localities had prohibited the sale of flavored tobacco products, including flavored e-cigarettes**.



**220 localities have prohibited the sale of flavored tobacco products, including flavored e-cigarettes.**

These include Berkeley, Oakland, Sacramento and San Francisco, California; Aspen, Colorado; Chicago, Illinois; Boston, Massachusetts; Minneapolis and St. Paul, Minnesota; and Providence, Rhode Island.<sup>143</sup> However, a large majority of the U.S. population — more than 90% — is not covered by such restrictions.<sup>144</sup>

- In September and October 2019, **governors in several states (Michigan, Montana, New York, Oregon, Rhode Island and Washington) used their emergency executive powers or directed their state health departments to temporarily ban in-store and online sales of flavored e-cigarettes**, citing the youth e-cigarette epidemic and recent health concerns regarding seizures and lung illnesses.<sup>145-150</sup> As of late October 2019, however, the **New York, Michigan and Oregon bans had been temporarily suspended**.<sup>151-153</sup> In **Massachusetts**, the governor took the extraordinary step of **suspending the sale of all e-cigarettes**.<sup>154</sup> And while the ban has not been overturned, a judge recently ruled that it must be resubmitted with an opportunity for public comment.<sup>155</sup> Several other governors have ordered their legislatures to consider legislation to restrict e-cigarette sales. The Utah Department of Health also issued a temporary emergency rule to restrict the sale of flavored e-liquids to licensed specialty tobacco stores.<sup>156</sup>

- On Sept. 11, 2019, in light of significant signs of increased youth uptake of e-cigarettes and the lung illnesses and deaths associated with vaping, the **administration announced that it would not extend the compliance period described above to flavored e-cigarette products (other than tobacco flavor), effectively removing all but tobacco-flavored e-cigarettes from the market.**<sup>35</sup> Manufacturers would be able to submit flavored e-cigarette premarket applications to the FDA for review to determine whether they provide any public health benefit.<sup>35,157</sup> By early November, there were signs the Administration may water down that strong policy. At the time of this writing, the FDA has not yet finalized this action and flavored e-cigarettes remain on the market.

## LICENSING

- Licensing and commercial zoning are areas of local concern. The federal government has **no regulations** affecting tobacco retailer licensing.
- As of June 15, 2019, **24 states and the District of Columbia require licenses for the retail sales of e-cigarettes.**<sup>158</sup> Delaware requires

Unlike traditional cigarettes, e-cigarettes can be advertised on television, radio, digital media and social media.

retailers to obtain a license to sell e-cigarette liquids, but not e-cigarette devices themselves. In North Carolina, e-cigarette retailers who buy their stock directly from a North Carolina distributor/wholesale dealer or manufacturer do not need to obtain a license, while those who obtain their stock directly from manufacturers outside of North Carolina do need a license.

## MARKETING

- There are **few federal restrictions on the marketing of e-cigarettes**, and, unlike traditional cigarettes, e-cigarettes can be advertised on television and radio, in print, and through digital and social media.
- Marketing materials of e-cigarettes cannot make claims that their product exposes users to fewer toxins or reduces harm unless the FDA grants an order allowing such claims.** In September 2019, the FDA sent JUUL a warning letter cautioning against unauthorized cessation claims and questioning recent marketing practices that appeared to be targeted to youth.<sup>159</sup> In October 2019, the FDA sent Eonsmoke a warning letter for, among other things, marketing their products with unauthorized claims of reduced harm of their products, and for advertisements through social media influencers that do not carry the required warning label.<sup>134</sup>
- E-cigarette products whose labeling or advertising is misleading can be considered to be misbranded under the Tobacco Control Act.** This includes e-cigarette marketing that imitates food or beverages, as mentioned above.
- States have the ability to regulate the time, place and manner of tobacco marketing, including e-cigarettes.**<sup>133,160</sup> For example, California and Delaware prohibit websites and online and mobile applications directed at minors from marketing or advertising e-cigarettes. California also prohibits advertisements of tobacco products, including e-cigarettes, on any outdoor billboard located within 1,000 feet of a school or public



playground.<sup>161</sup>

- Recently, the **FTC** announced it was requiring marketing data for the years 2015-2018 from six of the top-selling e-cigarettes in the U.S.

The companies will be required to provide data such as how much the companies spent on various types of advertising and promotions, product placement in media, as well as social media and influencer marketing. This is the first time such information will be collected by FTC.

## PRODUCT PACKAGING

- The FDA deeming regulation, effective Aug. 10, 2018, established a **nicotine warning label** that must appear on all tobacco products, including **e-cigarettes**:

**WARNING:** This product contains nicotine. Nicotine is an addictive chemical.<sup>162</sup>

The warning label must comprise 30% of the two principal display panels and be in a large,

legible font.

- > The Child Nicotine Poisoning Prevention Act of 2015 requires the Consumer Safety Product Commission to establish requirements for child-resistant packaging for e-cigarettes and e-liquids. The law,

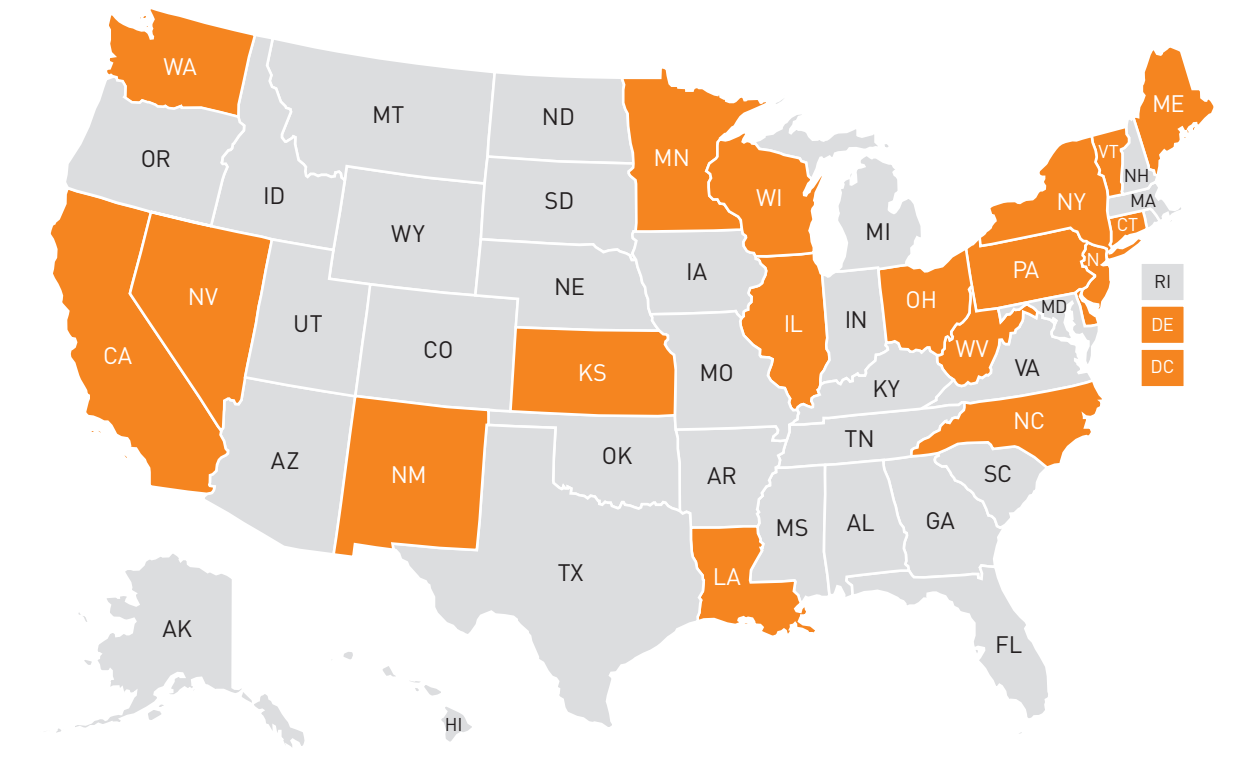
**for e-cigarettes and e-liquids.** The law, passed before the deeming regulation gave the FDA authority over e-cigarettes, maintains the FDA's ability to regulate such packaging. The FDA has indicated that it will also issue regulations requiring child-resistant packaging for e-cigarettes and e-liquids, but has not yet done so.

## TAXATION

- There is **no federal excise tax on e-cigarettes.**
- States have the authority to tax e-cigarettes. **Nineteen states and the District of Columbia have imposed a tax on e-cigarettes.**<sup>161</sup>

**Taxes** are a particularly **effective tool** for discouraging youth use of tobacco products. **Youth**

**Nineteen states and Washington, D.C., have imposed a tax on e-cigarettes.**



and young adults are two to three times more likely to respond to changes in prices than adults, and studies examining the effect of price increases on combustible cigarettes estimate that raising the cost of cigarettes to \$10 per pack nationwide would result in 4.8 million fewer smokers between the ages of 12 and 25.

## YOUTH ACCESS AND MINIMUM AGE OF SALE

- > **The FDA deeming regulation established a federal minimum age of 18 for the sale of all tobacco products, including e-cigarettes.** Retailers must check photo IDs of everyone under age 27 who attempts to purchase tobacco products, including e-cigarettes.
  - >> **Pennsylvania is the only state that does not have a law** restricting youth access to e-cigarettes.<sup>163</sup>
- > **Vending machine sales of e-cigarettes are prohibited**, except in facilities where only those over 18 are allowed.
- > **Free samples of e-cigarettes and their components are also prohibited** as of Aug. 8,

2016.<sup>133</sup>

- > The Tobacco Control Act required the FDA to issue regulations to **establish age verification requirements for the internet and other non-face-to-face purchases of any tobacco products**. However, the FDA has yet to implement this set of regulations.
  - >> A 2014 study of internet tobacco vendors selling e-cigarettes found that 52.3% of vendors had an age warning on the homepage of their website. However, **51.9% exclusively used age-verification methods that could not effectively verify the age of a consumer**. Additionally, 11.3% made no attempts to verify age at all.<sup>164</sup>
- > The Tobacco Control Act prohibits the FDA from further raising the federal minimum legal age of sale.<sup>165</sup> However, states and some localities have the ability to establish a higher age of sale for tobacco products beyond the federal requirement. As of Sept. 18, 2019, **18 states — Arkansas, California, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Jersey, New York, Ohio, Oregon, Texas, Utah, Vermont, Virginia and Washington — and at least 505 localities have established a minimum age of 21** for the sale of tobacco products.<sup>166</sup> As of this writing, the federal government is also considering proposals for adopting a nationwide minimum age of 21 for the sale of tobacco products, but those proposals are not yet law.
- > **Tobacco 21 laws**, which forbid the sale of tobacco to anyone under age 21, have **gained in popularity** in recent years. Tobacco companies have increasingly indicated their support for such laws, but they often simultaneously support and help to develop policies that weaken the impact of other



Tobacco 21 laws have gained in popularity in recent years.



effective tobacco control laws.

## INTERNATIONAL POLICIES

International regulation of e-cigarettes **varies widely**, and, due to the relatively recent introduction of the product category, is rapidly changing.

- > As of November 2018, 98 countries had national laws regulating e-cigarettes and 29 countries had banned the sale of e-cigarettes completely. **A significant portion of countries with e-cigarette policies (67) prohibit or regulate e-cigarette marketing.**<sup>167</sup> The European Union has enacted standards for e-cigarettes, including restricting the strength of nicotine fluids (2% maximum), limiting tank size on vaping devices (2 ml maximum), requiring child-resistant packaging and prohibiting cross-border advertising of e-cigarettes.<sup>168</sup> Some member states have further restrictions on the age of sale and taxes.<sup>169</sup>
- > The Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health keeps a database of international e-cigarette laws.<sup>170</sup> Notably, the **United Kingdom has been most active in promoting e-cigarettes as a reduced harm alternative to cigarettes.**<sup>171</sup> Public Health England has encouraged the National Health Service to make e-cigarettes available to smokers looking to quit or switch.<sup>171</sup> The U.K. allows for the licensing of e-cigarettes as medicinal quitting aids, but no manufacturer has yet taken this route to product approval.<sup>172</sup>
- > **The World Health Organization (WHO) recently warned governments, as well as the public, not to trust the tobacco industry's latest health claims regarding e-cigarettes.**<sup>173</sup> The WHO also released a set of recommendations around e-cigarettes to protect public health, including advertising and flavor restrictions to prevent youth sales, plain packaging policies, and awareness around the danger of tobacco use becoming re-normalized.<sup>174</sup>

Unlike in the U.S., a significant portion of countries with e-cigarette policies prohibit or regulate e-cigarette marketing.



Photo: Stanford Research into the Impact of Tobacco Advertising

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900 G Street, NW  
Fourth Floor  
Washington, DC 20001  
202.454.5555

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