

# E-CIGARETTES

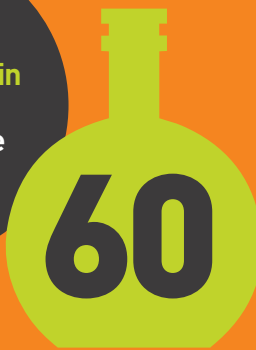
**E-cigarettes** operate by heating a liquid solution to produce an inhalable aerosol.



They are less toxic than cigarettes, but still contain harmful chemicals.



At least 60 chemical compounds are in e-liquids, and more are in the aerosol they produce.



Use of e-cigarettes among high school students



**E-cigarettes** are now the

# most popular tobacco product among youth.

**68%**

**E-cigarettes are rapidly evolving.**

The new high-nicotine product JUUL has become so popular with youth that it captured 68% of the e-cigarette market in 2 years.

E-cigarettes come in many youth-appealing flavors and food-like packaging, which has prompted FDA action.

## BACKGROUND

Electronic nicotine delivery systems go by many names. The most common name is “e-cigarettes,” but others such as **e-cigs, vapes, vape pens, mods and tanks are also common terms**. Most recently, new products, such as JUUL, have created brand-centric terms for product use (“JUULing”). For this resource, the entire category will be referred to 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, typically include nicotine, flavoring and a humectant, such as propylene glycol, to retain moisture and create an aerosol when heated.<sup>1,2</sup>
  - » 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> but **not for inhalation**, due to the lack of research regarding the safety of these compounds when inhaled.<sup>2</sup>
  - » Some newer e-cigarettes on the market have nicotine salts in e-liquids — prompting questions about the use, purpose and safety of this novel form of nicotine. The makers of JUUL claim that their nicotine salt formulation increases the rate and amount of nicotine delivered into the blood, compared with other formulations.<sup>3</sup>



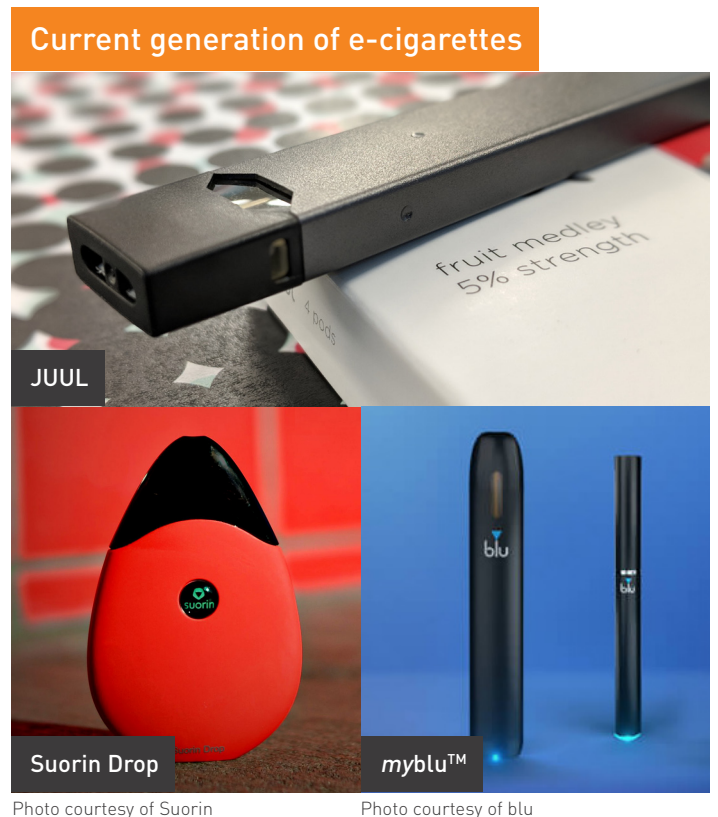
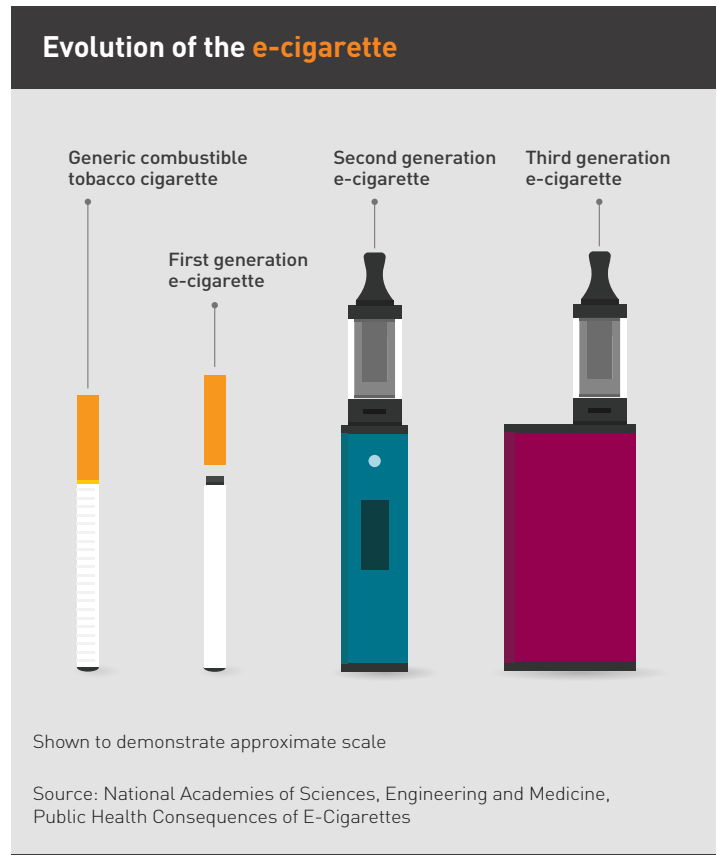
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- While using an e-cigarette is often called “vaping,” the devices produce an aerosol, not a vapor. Unlike vapor, which is simply a substance in gas form, the **aerosol from an e-cigarette can contain tiny chemical particles** from both the liquid solution and the device (e.g., metals from the heating coil).

## WHAT ARE THE TYPES OF E-CIGARETTES?

- > Some e-cigarettes are designed to resemble regular cigarettes, while others look more like cigars, pipes, pens and even USB flash drives.<sup>1</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>4</sup>
- > A **second generation** e-cigarette is a larger, usually pen-shaped device that can be **recharged**.<sup>4</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>2,4</sup>
- > More recently, e-cigarettes that have a **sleek, high-tech design** and **easily rechargeable batteries** have entered the market. One device, **JUUL**, emerged in 2016 and quickly established itself as a leading e-cigarette product by early 2018. There has also been an emergence of copycat products, such as Suorin Drop and *myblu*<sup>™</sup>, that follow JUUL’s blueprint of a high-tech look and high nicotine delivery through the use of nicotine salt e-liquid formulations.

Some e-cigarettes are designed to resemble regular cigarettes, while others look more like cigars, pipes, pens and even USB flash drives.



# Heat-not-burn products

In addition to e-cigarette products, tobacco companies have introduced “**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, but **current data on the health effects of these devices are sparse** (and most of what has been published has been by tobacco industry scientists).

While these **products have not been approved by the FDA** for use in the U.S., a new product application for IQOS — a heat-not-burn product by Philip Morris International — is currently pending. Data in foreign markets submitted by Philip Morris indicate that **dual use of heat-not-burn 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**. Read [comments](#) from Truth Initiative® on the IQOS application.

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

- Nicotine levels in e-cigarettes are highly variable, with some reaching **levels near combustible cigarettes**.<sup>2,5</sup>
- Labeling is not always a reliable indicator of nicotine content, as studies have found **mislabeling** to be a **common** issue for e-cigarettes.<sup>2,5</sup>
- The way an e-cigarette is used or modified affects the delivery of nicotine to an individual user.<sup>2,6</sup>

- Some e-cigarette products deliver nicotine almost as efficiently as a cigarette. For example, the maker of **JUUL** e-cigarettes 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**. While that may make them more attractive to smokers as an alternative to cigarettes, it **increases the potential for youth addiction** and suggests such products should be carefully regulated to reduce youth access and use.
- A recently published Truth Initiative study found that among **current** youth and young adult **JUUL users**, only **37 percent knew that the product always contains nicotine**.<sup>7</sup>

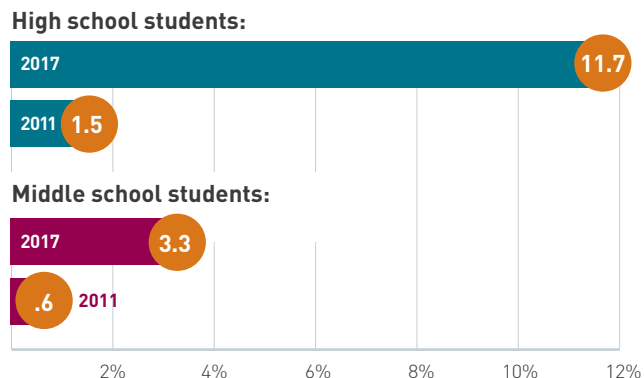
## ARE E-CIGARETTES AS HARMFUL AS CIGARETTES?

Using e-cigarettes is substantially less harmful to individual health than inhaling smoke from combustible tobacco, such as cigarettes and cigars. However, while **e-cigarettes** contain far fewer toxins than combustible cigarettes, they are **not free of toxins** and still **deliver harmful chemicals**.

While the basic technology behind e-cigarettes is consistent, there is an enormous variability within the product category and there is **no typical e-cigarette**. The products have different **ingredients** and different hardware, and deliver highly **variable amounts of nicotine** and potentially **toxic chemicals**. This variation makes it difficult to make overall public health recommendations about e-cigarettes and is a driver for the need for regulation. **Consumers need to consistently know what they are getting — particularly from a product designed to deliver chemicals by frequent inhalation.**

There is substantial confusion about the health effects of e-cigarettes. A recent 2015 study found that among adult smokers, 30.8 percent thought e-cigarettes were about as harmful as cigarettes, 4.3 percent thought they were more harmful, 28.9 percent didn't know and only 36 percent thought they were less harmful.<sup>81</sup> The variation in product characteristics and the current regulatory system — which has few barriers for selling e-cigarettes as recreational devices, but many barriers for marketing the products for quitting or complete switching — are likely contributing to this confusion. These misperceptions show that there is an opportunity to educate smokers on this issue, especially when public health authorities are confident particular products have been reviewed for issues such as toxicity, effectiveness in nicotine delivery, basic consumer safety and youth appeal.<sup>81</sup>

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



Source: 2017 National Youth Tobacco Survey

## 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.** This pattern is commonly referred to as “**dual use**” or “poly tobacco use.”

Among adult users, **dual use 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 **represses efforts to completely quit smoking** (i.e., people choose to “cut down” instead of quitting smoking entirely). This issue is somewhat complicated because some individuals who use e-cigarettes to quit may experience a period of dual use as they change products.

**Among youth, the data are more difficult to interpret.** Dual use may indicate that kids who use other nicotine products are also more likely to use e-cigarettes due to shared character traits — like sensation seeking and openness to risk (the “shared liability” theory) — and/or the fact that initial e-cigarette use is a cause of subsequent use of other nicotine products (the

“gateway” theory). A 2018 report from the National Academies of Sciences, Engineering, and Medicine addressed this issue and 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>2,9</sup>

- > Among **adults** in 2015, **58.8 percent of e-cigarette users also smoked cigarettes.**
- > Among **young adults** in 2015, **40 percent of e-cigarette users also smoked cigarettes.**<sup>10</sup>
- > In 2013 and 2014, just 6.1 percent of young adults and 1.6 percent of adults exclusively used e-cigarettes.<sup>9</sup>
- > In 2015, **65.2 percent of youth** who had **used an e-cigarette** in the last 30 days also reported **using another tobacco product** in the same time frame.<sup>11</sup>
- > In 2015, **5.9 percent of high school students were exclusive e-cigarette users**, while 25.3 percent currently used any tobacco product.<sup>9</sup>

## 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.

**E-cigarettes are now the most commonly used tobacco product among youth.**<sup>8,9</sup>

### YOUTH

- **Between 2011 and 2017, e-cigarette use significantly increased among youth in high school and middle school.** The 2017 National Youth Tobacco Survey found that 11.7 percent of high school students and 3.3 percent of middle school students used e-cigarettes in the last 30 days, compared with 1.5 percent of high school and 0.6 percent of middle school students who reported current use in 2011.<sup>8</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>9,12,13</sup> The 2018 NASEM report concluded that, “there is **substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”<sup>2</sup>

**60% of teens incorrectly reported e-cigarettes as being comprised of mostly flavoring.**

- Many young e-cigarette users do not know what is in the products they are using. A recent study found that 98.7 percent of all e-cigarette products sold at convenience stores, supermarkets and similar outlets contain nicotine. Yet, many young people aren't aware that the products they use contain nicotine. In fact, **60 percent of teens incorrectly reported e-cigarettes as being comprised of mostly flavoring.**<sup>14,15</sup>



## JUUL

Since 2016, the **e-cigarette brand JUUL** has surged in popularity among young people, and as of June 2018, has taken **68 percent of the e-cigarette market** share measured by Nielsen. JUUL's emergence into the e-cigarette market has been so rapid that national surveillance systems have yet to ask specifically about its use.<sup>7</sup>

A 2017 study by the Truth Initiative Schroeder Institute<sup>®</sup> found that 6 percent of youth and 10 percent of young adults have used a JUUL e-cigarette in the last 30 days. The study also found that while many young people are aware of JUUL, many are **unaware that the product always contains the addictive chemical nicotine.**<sup>7</sup>

- Twenty-five percent of survey respondents aged 15 to 24 recognized a JUUL e-cigarette device when shown a photo of the product.
- Among those who recognized JUUL, 25 percent reported that use of this product is called “JUULing,” indicating that this product is so distinctive, it is perceived as its own category.
- Sixty-three percent of JUUL users did not know that this product always contains nicotine.

According to the product website, a single JUUL cartridge is roughly equal to a pack of cigarettes, or 200 cigarette puffs. JUUL is promoted as a “satisfying alternative to cigarettes,” and may be **putting a new generation of youth at risk of nicotine dependence** and future cigarette use.

- > Youth e-cigarette users cite flavors as a reason they begin using e-cigarettes. A study that included middle and high school students found that **43 percent of young people who ever used e-cigarettes tried them because of appealing flavors.**<sup>13</sup>

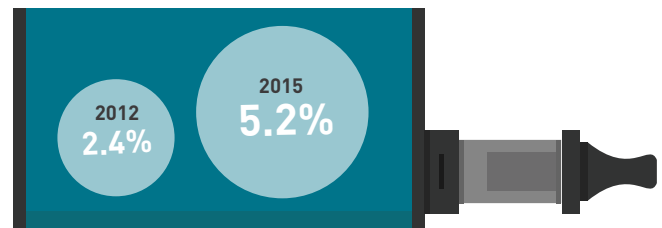
## YOUNG ADULTS

- > Like youth, **young adults** aged 18 to 24 are also **using e-cigarettes at increasing rates.** The amount of young adults who use e-cigarettes every day or some days increased from 2.4 percent in 2012 and 2013, to 5.2 percent in 2015.<sup>9</sup>
- > A 2015 report from the National Health Interview Survey states that 40 percent of young adults who use e-cigarettes every day or some days **were never smokers before trying e-cigarettes.**<sup>17</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>9</sup>
- > The growth in the popularity of e-cigarettes among young adults has caused concerns that use will **lead to the initiation of cigarette and other tobacco product use.**<sup>2,18,19,20,21,22,23,24</sup>

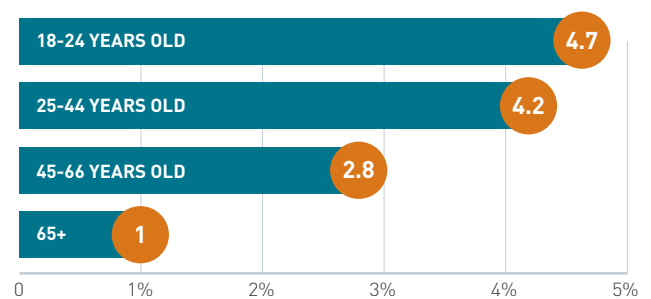
## ADULTS

- > **E-cigarette use has also increased among adults** in recent years, albeit much less dramatically than among youth. Between 2012 and 2013, 2.4 percent of adults aged 25 to 44 and 2 percent of adults aged 45 to 64 used e-cigarettes. By 2016, those rates increased to 4.2 percent and 2.8 percent, respectively.
- > Adults aged 45 and older are significantly less likely to have ever tried an e-cigarette compared with young adults.<sup>10</sup>
- > In 2015, among **adult e-cigarette users**, 29.8 percent were former regular smokers, **58.8 percent were current cigarette smokers** and 11.4 percent had never been cigarette smokers.<sup>17,25</sup>

### Young adults who use e-cigarettes every day or some days



### Adults who currently use e-cigarettes



The data indicate that patterns of use are the opposite of what they should be. Rates are highest among younger age groups and decrease with age. The pattern should be just the opposite, with higher rates of adult use consistent with higher rates of smoking prevalence.

Source: 2016 National Health Interview Survey



## 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>2,25,26,27,28,29</sup> Additionally, **e-cigarettes are not approved as quit aids** by the U.S. Preventative Service Task Force.


There is, however, some evidence that supports the use of e-cigarettes as quit devices.

- > A study published in 2016 reported that within two randomized control trials, **e-cigarettes with nicotine helped individuals quit better than e-cigarettes without nicotine**.<sup>1,2,30</sup>
- > The NASEM also reported that **more frequent e-cigarette use may increase an individual's likelihood to quit**.<sup>2</sup>

While some e-cigarettes may be an effective resource for quitting smoking, the **variation in product quality and the lack of regulation make determining the potential of any particular product as a quit aid difficult**.

Although there is limited research currently supporting e-cigarette use for quitting, a smoker who switches completely to e-cigarettes from combustible cigarettes will substantially reduce exposure to toxic chemicals and health risks.<sup>2</sup> Some smokers have switched to e-cigarettes or used them to quit tobacco completely. **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 product**.

Product appeal, including flavoring, is likely to encourage smokers to try to use e-cigarettes to quit or switch completely.<sup>31</sup> But, because flavors also appeal to youth, **manufacturers should be prohibited from marketing flavored e-cigarettes unless they can show that the product helps adults switch and it is not attracting significant**



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**youth uptake** (as verified by careful postmarket surveillance). **Truth Initiative supports strong regulations to keep all tobacco products, including e-cigarettes, away from youth**.

## HEALTH EFFECTS

Using e-cigarettes is substantially less harmful than inhaling smoke from combustible tobacco, such as cigarettes and cigars. Much remains unknown, however, and it is **critical to continue to monitor the potential health effects, addictiveness and toxicity of e-cigarettes**.

## 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 tobacco combustion is the most addictive form.<sup>32</sup> The rise in the popularity of **e-cigarettes that can deliver levels of nicotine similar to combustible cigarettes is causing concern about the potential risk for addiction**.<sup>9</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>13</sup>



- There is some evidence that the **effect of nicotine on developing brains** may result in nicotine addiction and greater **vulnerability to addiction to other drugs** as well.<sup>33</sup>

## PREGNANCY

- Because many **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>34,35</sup>
- Pregnant women who use nicotine are at a **greater risk of stillbirth and preterm delivery**.<sup>9</sup>

## CHEMICALS

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

- At least **60 chemical compounds** have been found in e-liquids, and more are present in the aerosol produced by e-cigarettes.<sup>2</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.<sup>2</sup>

**E-cigarette flavors — even those approved for ingestion — have not been studied for toxicity if inhaled over long periods of time.** Many e-cigarette flavorings contain chemicals that are known to be **respiratory irritants**,<sup>2</sup> and research has found that some flavors are potentially more toxic than others. For example, researchers found that exposure to increased **cinnamon** flavoring caused significant **cell death**, compared with other flavors. Additionally, mixing multiple flavors can be more toxic to cells than exposure to just one flavor at a time.<sup>36</sup> The repercussions of long-term exposure to the chemicals found in e-liquids and produced by e-cigarettes are not yet known, since products have not been on the market long enough to conclusively study their effects.

## EXPOSURE TO E-LIQUID

- **Accidental exposure to or ingestion of e-liquids** can be very **dangerous** and, in the case of accidental swallowing or injection, even **fatal**.<sup>2</sup>

## EXPLOSIONS

- **Defective**, poorly manufactured and improperly modified **e-cigarettes** have 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 nonusers to nicotine**, but research indicates that secondhand aerosol results in substantially lower exposure to toxicants and carcinogens than secondhand cigarette smoke. However, exposure among **vulnerable populations**, including **pregnant women and children**, could still be **dangerous**.<sup>2</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 has appeared on TV and the radio, despite the ban on cigarette advertising on both outlets** since Congress passed the Public Health Cigarette Smoking Act in 1970. The FDA 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 cotton candy and gummi bear.<sup>37</sup>

### MARKETING TACTICS

- Recent reports have found that e-cigarette companies are **using scholarship offers** as a way to recruit youth users.<sup>79</sup>
- Individuals aware of e-cigarettes report that the most **common ways** to hear about e-cigarettes are through in-person communications, by seeing them for sale and by seeing them in **online** and **TV** ads, in which some celebrities have endorsed the products.<sup>38,39,40,41,42</sup>
- **E-cigarettes are promoted heavily online**<sup>43</sup> through e-cigarette company-sponsored advertisements,<sup>44</sup> and on **YouTube**<sup>44,45,46,47</sup> and **Twitter**.<sup>48</sup>
- 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>49</sup>
- **Some e-liquids have been marketed to look like common food items, many of which appeal to kids.** Examples include marketing e-liquids as “**Thin Mints**,” like the Girl Scout’s cookie, and “**Tootsie Roll**.” Those e-liquids were removed, or at least renamed, after the companies owning those copyrights took action to protect their intellectual property.



## The retail environment for e-cigarettes

E-cigarettes are sold in conventional tobacco retail outlets, such as convenience stores, gas stations, pharmacies and tobacco shops. They are also sold at nontraditional outlets, such as online retailers and vape shops.

- It is difficult to monitor and analyze the market due to differences in how e-cigarette sales are tracked. **Common sales-tracking and retail measurement companies, like Nielsen, do not examine vape shop data**, which constitute a large portion of the market.
- Because nontraditional 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,<sup>78</sup> the **breakdown of retail channels for the 2018 e-cigarette market** is:
  - » **Vape shops: 36.4 percent**
  - » Convenience **stores**, food, drug and **mass retail channels: 31.8 percent**
  - » **Online** and other retail channels: **31.8 percent**
- **Recently, the FDA reprimanded eBay for allowing JUUL** and other tobacco products on the site in apparent violation of company policy. As a result, eBay removed listings, and took voluntary steps to prevent future sales, according to the FDA. However, recent reviews of eBay found not only JUUL devices for sale, but also accessories for JUUL, such as chargers and “skins” that wrap around JUULs to personalize them.

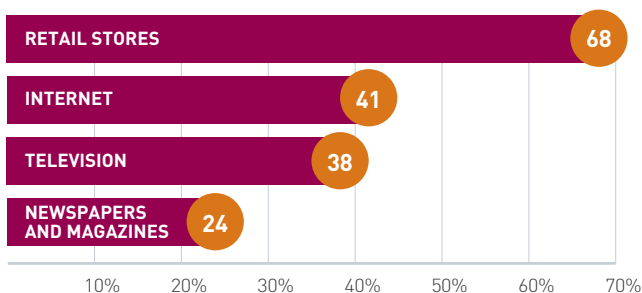
Other food and candy flavors remain on the market. In May 2018, **the FDA and the Federal Trade Commission took joint action against several e-liquid companies that marketed their products to look like candy** or other kid-friendly food items, such as Reddi-wip, Nilla Wafers and Warheads candy.

## YOUTH EXPOSURE TO ADVERTISING

Youth and young adults are widely exposed to e-cigarette marketing and have high awareness of e-cigarettes.

- > 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>15</sup>
- > Young people are most likely to see ads at retail stores (68 percent), followed by the internet (41 percent), television (38 percent) and newspapers and magazines (24 percent).<sup>15</sup> Between 2014 and 2016, **exposure to retail e-cigarette advertising among young people jumped nearly 20 percent**.<sup>15</sup>
- > One study found that, among **adolescents who had never used e-cigarettes**, those who were **exposed to four e-cigarette television ads reported a greater intention to use e-cigarettes** in the future, compared with those who did not view the e-cigarette ads. Additionally, current cigarette smoking was highly associated with likelihood of future e-cigarette use.<sup>50</sup>

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



- > A randomized controlled trial among young adults showed that **brief exposure to four e-cigarette print ads** increased **curiosity about e-cigarettes**, and ad exposure was associated with subsequent trial of e-cigarettes in a small proportion of the young adults who had never used an e-cigarette or cigarette.<sup>51</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 flavors.<sup>49</sup>

## SOCIAL MEDIA

**Emerging e-cigarette products make frequent appearances on social media.** As these products gain users and popularity, their likelihood of appearing on newsfeeds and timelines may be increasing.

- > Among **adults** in 2013, **8.6 percent** had seen or heard **content related to e-cigarettes on Facebook** and **3.8 percent on YouTube**. These numbers were higher for current users of e-cigarettes.
- > Those who were looking to **share information with their peers about e-cigarettes** were most likely to use **word of mouth** (53.9 percent) and **Facebook** (33.2 percent). Nearly half (48.5 percent) of adult e-cigarette users sharing information related to these devices used Facebook to do so.<sup>52</sup>
- > In 2013, researchers analyzed e-cigarette content on **YouTube** and found that there were nearly **30,000 videos** posted to the site related to **e-cigarettes**. These videos came from 10,000 unique accounts and had more than 100 million views.<sup>53</sup>

## POTENTIAL PUBLIC HEALTH IMPACT

There are varying estimates of the potential public health impact of e-cigarettes.

The recent review of the health impact of e-cigarettes from the 2018 NASEM report is instructive. It found that, if three conditions are assumed about **e-cigarettes** — that they are 90 percent less harmful than cigarettes, that they increase cigarette quitting rates by 15 percent and that they result in no increase in cigarette initiation by youth — they would contribute to a **1.5 percent decrease in expected smoking-related deaths** in 50 years. If the assumptions are changed to show only a 5 percent increase in quitting and a 10 percent increase in initiation, the result is a 0.2 percent decrease.<sup>2</sup> In contrast, the first 50 years of traditional tobacco control measures in the U.S. after the 1964 surgeon general's report on smoking resulted in a more than **35 percent decrease in expected deaths due to tobacco**.<sup>54</sup>

While **e-cigarettes** may have a role to play in curbing the tobacco epidemic, **potential positive effects will be limited if they are not considered as part of comprehensive product regulation**, like 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.

## 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 Family Smoking Prevention and Tobacco Control Act.<sup>55</sup>

The FDA can now establish product standards and regulate the manufacturing, importing, packaging, labeling, advertising, promotion, sale and distribution of e-cigarettes, including components and parts of e-cigarettes.<sup>55</sup>

The deeming regulation includes **requirements for premarket review of e-cigarettes as new tobacco products**. In order to receive marketing approval for a new product, a manufacturer would need to demonstrate that the marketing of 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>55</sup> In July 2017, the FDA announced that it would extend the timeline to submit tobacco product review applications to market newly-regulated noncombustible products, including e-cigarettes, to Aug. 8, 2022.<sup>56</sup> This means that **more than 13 years will have passed from the passage of the Tobacco Control Act to the full regulation of e-cigarettes**. Said another way, an **entire generation of young people will have passed through their teen years during this time frame**. This is noteworthy given that 90 percent of all tobacco users start using tobacco before age 19.



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## MODIFIED RISK TOBACCO PRODUCTS

- > Under FDA rules, before an e-cigarette manufacturer can market a product as having lower risk of exposure to toxins or lower risk of adverse health effects, it must **submit the proposed marketing to the FDA for approval** to assess veracity of the claim and whether the marketing of the product would benefit the health of individuals and the population as a whole, considering factors such as new initiation of tobacco use or suppression of quitting of more harmful products like cigarettes. **To date, no e-cigarette manufacturer has requested such permission from the FDA.**

## CLEAN INDOOR AIR POLICIES

- > There are **no federal policies restricting indoor use of e-cigarettes** other than policies in individual federal buildings or properties.
- > Thirteen states and 752 municipalities have expanded their smoke-free air laws to also prohibit e-cigarette use in places where cigarette smoking is prohibited.<sup>57</sup> However, there are **no clean air restrictions covering e-cigarettes in the majority of the U.S.**

## 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 and no date has been set for action by the FDA on this issue.
- > More than **100 localities have prohibited the sale of flavored tobacco products, including flavored e-cigarettes.** These include San Francisco, Berkeley, Contra



Costa County, El Cerrito, Los Gatos, Manhattan Beach, Oakland, Palo Alto, San Leandro, Santa Clara, Sonoma and Yolo County, California; Chicago, Illinois; Boston and 105 other municipalities in Massachusetts; Duluth, Minneapolis, Robbinsdale, Shoreview, St. Louis Park and St. Paul, Minnesota; and Barrington, Central Falls, Johnston, Middletown and Providence, Rhode Island.<sup>58,59,60,61,62,63,64,65,66,67,68,69,70,80</sup> However, a **large majority of the U.S. population is not covered by such restrictions.**

## 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.**
- > Marketing materials for e-cigarettes cannot make claims that the product exposes users to fewer toxins or reduces harm unless the FDA grants an order allowing such claims.
- > E-cigarette products with misleading labeling or advertising can be considered misbranded under the Tobacco Control Act. This includes e-cigarette marketing that imitates food or beverages.

> **States have the ability to regulate the time, place and manner of tobacco marketing, including e-cigarettes.**<sup>55,71</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 ads for tobacco products, including e-cigarettes, on any outdoor billboard located within 1,000 feet of a school or public playground.<sup>72</sup>

> 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, passed before the deeming regulation gave the FDA authority over e-cigarettes, maintains the agency’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.**

## PRODUCT PACKAGING

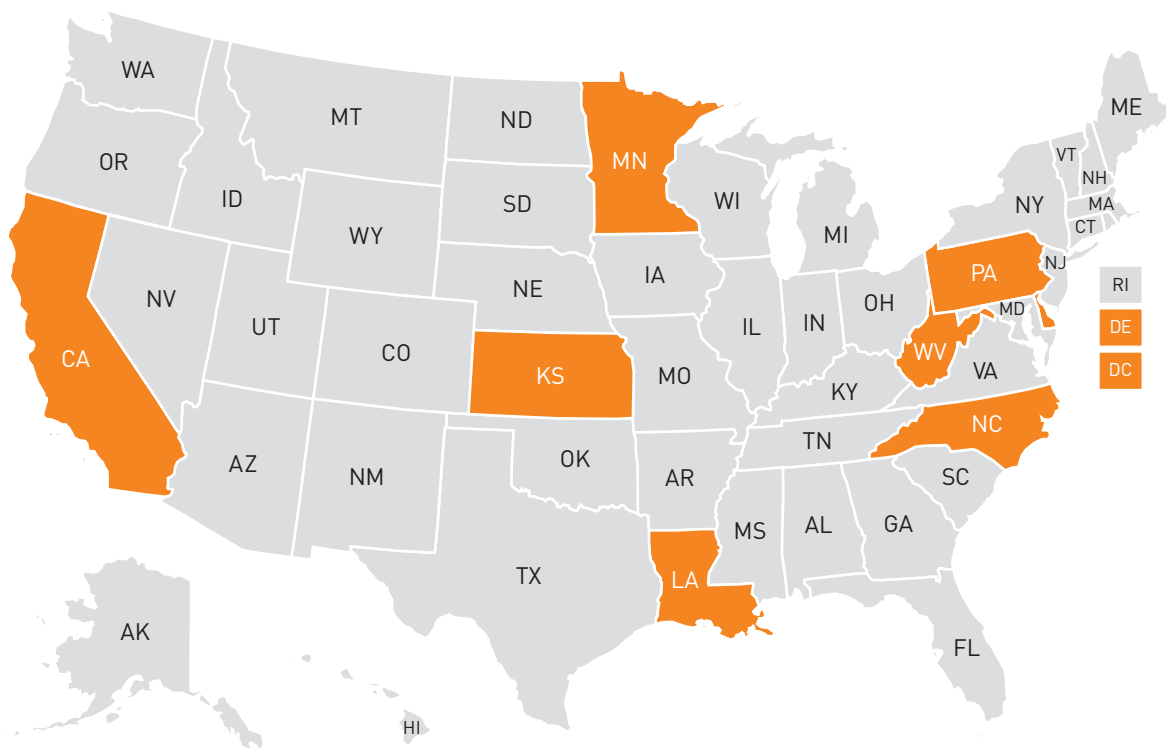
> The FDA deeming regulation, effective Aug. 10, 2018, established a **nicotine warning label that must appear on all tobacco products, including e-cigarettes**: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”<sup>56</sup> The warning label must comprise 30 percent of the two principal display panels and be in a large, legible font.

## TAXATION

> There is **no federal excise tax on e-cigarettes**.

> **States have the authority to tax e-cigarettes.** Eight states and Washington, D.C., have imposed a tax on e-cigarettes.<sup>72</sup>

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



## 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.
- > **Vending machine sales of e-cigarettes are prohibited**, except in facilities where only those over age 18 are allowed.
- > **Free samples of e-cigarettes and their components are prohibited**, as of Aug. 8, 2016.<sup>55</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 percent of them had an **age warning** on the homepage of their website. However, **51.9 percent** exclusively **used age-verification methods that could not effectively verify the age of a consumer**. Additionally, 11.3 percent made no attempts to verify age at all.
- > The Tobacco Control Act prohibits the FDA from further raising the federal minimum legal age of sale.<sup>73</sup> However, **states and some localities have the ability to establish a higher age of sale for tobacco products beyond the federal requirement**. Five states (California, Hawaii, Maine, New Jersey and Oregon) and at least 290 localities have established a minimum age of 21 for the sale of tobacco products.<sup>74</sup>

## INTERNATIONAL POLICIES

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

- > A 2016 study found that, of **90 countries surveyed, 25 banned e-cigarettes completely and 17 required premarket authorization** before an e-cigarette could be sold. Thirty-five countries that allowed e-cigarettes to be sold prohibited them from being advertised.<sup>17</sup>
- > The **European Union has enacted standards for e-cigarettes**, including **restricting the strength** of nicotine fluids (2 percent maximum), **limiting tank size** on vaping devices (2 mL maximum), requiring **child-resistant packaging** and **prohibiting cross-border advertising** of e-cigarettes.<sup>75</sup> Some member states have further restrictions on the age of sale and taxes.<sup>17</sup>
- > **The landscape of international e-cigarette regulation is quickly developing**. The Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health keeps a database of international e-cigarette laws.<sup>14</sup> Notably, the **United Kingdom has been most active in promoting e-cigarettes as a reduced harm alternative to cigarettes**.<sup>76</sup> Public Health England has encouraged the National Health Service to make e-cigarettes available to smokers looking to quit or switch.<sup>76</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>77</sup>

25 countries have banned e-cigarettes completely and 17 required pre-market authorization.

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