

ACTION NEEDED: E-CIGARETTES

Following years of successful tobacco control efforts that achieved record low youth smoking, **e-cigarettes have driven total youth tobacco use to rates unseen in decades.** Current, or past 30-day, use of e-cigarettes among high school students increased from 11.7% to 27.5% between 2017 and 2019, driving overall tobacco use among high school students to 31.2%.¹⁻³ The most recent data from 2020 show that **high school students continue to use e-cigarettes at epidemic levels**, with 1 in 5 (19.6%) vaping in the past 30 days, and that the **intensity of use has increased** with 38.9% of current users reporting vaping on 20 or more days per month.^{2,3}

The Food and Drug Administration has taken only tentative steps to remove some youth-appealing products and flavors. In the absence of comprehensive federal regulation, many flavored e-cigarettes remain on the market and sales data indicate that young people simply switch to products that are still available. Meanwhile, evidence is mounting that links e-cigarette use among young people with subsequent cigarette use. A 2020 Truth Initiative study shows that **young Americans who had ever used e-cigarettes had seven times higher odds of becoming smokers one year later compared with those who had never vaped.**⁴

Despite the tobacco industry's insistence to regulators that e-cigarettes are intended for and marketed to adult smokers, the data show that youth and young adults continue to vape at the highest rates. While youth use of e-cigarettes reached 20.8% in 2018, the National Health Interview Survey found in the same year that only 3.2% of adults use e-cigarettes — much of that driven by young adults, who use at 7.6%.^{5,6} A recent Truth Initiative study also found that **very few adult smokers are using e-cigarettes to try to quit.** Among adult smokers who tried to quit in the last year, just 1.1% used JUUL



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alone and only 5.6% used other e-cigarettes alone.⁷ The study found that among former smokers who had quit in the past four years, just 2.2% reported using only JUUL and 6.9% used other e-cigarettes.⁷ While some adults have used e-cigarettes to switch completely from combustible cigarettes, the **FDA has not approved any e-cigarette as a cessation intervention, and nearly half of adults who use e-cigarettes also use cigarettes.** This “dual use” provides no reduction in the harms associated with smoking.

In an era when brand names of e-cigarettes have become verbs (e.g. “JUULing”), much work remains for federal, state and local governments to establish comprehensive policies to protect youth from highly addictive nicotine-containing products like e-cigarettes. Immediate action is needed, including **removing all non-tobacco flavors from the market**, ensuring a thorough and **transparent FDA review** of all products, and placing **restrictions on e-cigarette marketing**, among other regulatory measures that will help protect youth from a lifetime of nicotine addiction.



11 Years of Delays: A Brief Regulatory History of E-cigarettes

The 2009 Tobacco Control Act gave FDA the necessary tools to reduce society's toll from tobacco, including e-cigarettes.¹⁶ However, the agency has **repeatedly failed to use its powers to slow — or even prevent — the youth e-cigarette epidemic**. Indeed, until very recently, e-cigarette manufacturers enjoyed a market with few barriers.

While Congress expressly gave FDA the responsibility to regulate tobacco products in 2009, repeated **regulatory delays gave e-cigarette manufacturers 11 years to operate with minimal federal oversight**. First, FDA took seven years to officially bring e-cigarettes under its jurisdiction following the passage of the Tobacco Control Act in 2009. During that time, there were no federal regulations on e-cigarettes. In 2016, when FDA finally “deemed” e-cigarettes as part of its jurisdiction, it gave e-cigarettes that were currently on the market two years to prepare premarket applications (known as PMTAs).¹⁷ FDA requires these applications to determine whether new tobacco products are “appropriate for the protection of public health” before they are allowed on the market.¹⁸

The deadline for e-cigarette pre-market applications faced four additional years of delays.

In 2017, FDA extended the deadline for completed applications to August 2022.¹⁹ When several public health groups, including Truth Initiative, sued FDA, a federal court ordered the agency to require applications be submitted by May 2020.²⁰ The deadline changed again to September 9, 2020, following FDA and tobacco industry requests for more time due to the COVID-19 pandemic.²¹

At long last, after finally facing a deadline for e-cigarette manufacturers to submit applications, FDA has begun reviewing thousands of applications to determine if those products meet the public health standard set by the Tobacco Control Act. While the agency is supposed to conduct its review of those products in one year, FDA's Center for Tobacco Products director has admitted “the likelihood of FDA reviewing all of these applications during the one-year review period is low,”²² foreshadowing **yet more delays in necessary and urgent regulatory action**.

REMOVE ALL NON-TOBACCO FLAVORED E-CIGARETTES, INCLUDING MENTHOL

FDA must act to remove all non-tobacco flavored e-cigarettes, including menthol flavors, from the market. Federal actions to date to limit the marketing of e-cigarettes, including removing some pod-type flavored e-cigarette products,²³ have **proven insufficient to significantly reduce the alarming number of young people who use e-cigarettes.**

For example, FDA announced in January 2020 that it would remove all flavored, pod-based e-cigarettes except for menthol and tobacco flavors.²³ This **partial measure left not only menthol-flavored pods on the market, but all flavors of e-cigarette liquid, or “e-juice.”** It also **exempted disposable flavored e-cigarettes** — a relatively new sector within the category at the time. The tobacco industry quickly exploited these loopholes. By May 2020, menthol e-cigarettes accounted for more than half (51.6%) of e-cigarette sales and 37% of youth e-cigarette reported using menthol e-cigarettes.^{2,24} **Disposable e-cigarette sales increased from 10.3% of the market in August 2019 to 19.8% in May 2020,** and use of **disposable e-cigarettes among high school students increased an astounding 1000%** in that timeframe.^{2,24}

The policy simply moved young consumers from one product to another. It is clear that without a full removal of all flavored products from the market, reversing the youth e-cigarette epidemic will be stymied.

ENSURE A THOROUGH AND TRANSPARENT PRE-MARKET REVIEW PROCESS

After many years of delays (see sidebar: “A Brief Regulatory History of E-cigarettes”), e-cigarette manufacturers faced a deadline of September 9, 2020 to submit pre-market applications to FDA. The agency is now reviewing applications to determine whether the products can remain on the market. Only certain products that were on the market prior to August 2016 (before FDA had jurisdiction over

e-cigarettes) will be allowed to stay on the market for an additional year while FDA reviews these applications. All other products for which companies did not submit PMTAs are now on the market illegally and must be removed immediately.

FDA needs to be transparent about both the review process and its enforcement of the regulations against those products and companies who are operating outside of the existing regulatory structure. Specifically, **FDA should release on a regular and timely basis a list of those manufacturers who have filed PMTA applications** including the names of products submitted, status of their acceptance by FDA, and other information to keep the public informed about this critical review process. **Without such information, consumers, parents, retailers, lawmakers and the public health community have no way of knowing which products are even attempting to follow the regulatory process** and no way of holding FDA accountable for doing its job.

Product review is only the first step. FDA’s actions cannot and should not stop with the pre-market review process.

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RESTRICT E-CIGARETTE MARKETING TO ENSURE IT IS AIMED AT ADULTS

The marketing tactics of the tobacco industry have played a significant role in attracting youth to e-cigarettes. The products, which come in a wide variety of **fruit, candy and alcohol flavors that appeal to young people, are advertised with themes that the tobacco industry has successfully used to attract youth for decades**. The industry has also employed a variety of paid media efforts, such as extensive social media and experiential event campaigns featuring young influencers, to attract youth.⁸⁻¹⁵

FDA has indicated that it will impose restrictions on social media marketing and encourage e-cigarette advertising to be aimed at adults.²⁵ We urge FDA to move forward with imposing those restrictions expeditiously for all e-cigarettes so that the restriction is already in place prior to any product being authorized for sale in the U.S.

The need for this action is clear as there are numerous examples of e-cigarettes that are advertised and packaged in a manner that is clearly youth-appealing. FDA has taken action against some of the most blatant products, but this has

been a **piecemeal, reactive approach**. For example, in July 2020, FDA sent warning letters to seven manufacturers ordering them to remove their flavored disposable e-cigarettes from the market because their marketing was targeted to youth or likely to promote use by youth.²⁶ Egregious marketing examples cited in the letters included **using cartoon images or imitating food products that appeal to children, such as churros or other baked goods; popcorn and Cracker Jack; or breakfast cereals**.²⁷⁻³¹

These sporadic actions have not resulted in the removal of the myriad products that clearly target youth. For example, **despite its warning letter to the makers of Puff Bars, as well as that company's announcement that it would cease doing business in the U.S., sales data through October 2020 continue to show substantial sales** for the brand in monitored retail channels.

FDA must exert its considerable enforcement authority to protect youth and young adults from all nicotine containing products before they enter the market, and ensure swift and fulsome follow through in enforcement for those that flagrantly disregard the rules.

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COMPREHENSIVE ACTION NEEDED

Much more needs to be done to ensure that e-cigarettes do not attract youth, and are actually helping adult smokers switch from cigarettes completely. State and local governments also can further protect their residents from these products.

We have outlined a **comprehensive set of actions that are needed at the federal, state and local levels to best protect public health** and ensure that the tobacco industry does not continue to addict another generation of our nation's youth.

FEDERAL ACTION NEEDED

- Ensure illegal products that did not submit PMTA applications are *removed from the market immediately*. This process should be made public.
- FDA must promptly ensure that the **PMTA process is transparent** — and supply the public with information about industry compliance with, and FDA enforcement of the process. The FDA has indicated it will supply a list of products for which applications have been submitted. We strongly urge FDA to make that list available rapidly and to include public documentation of all actions FDA takes with regard to PMTA applications.
- **Marketing:** FDA must **restrict e-cigarette marketing** so that it does not target or appeal to youth.
 - Specifically, the agency must immediately impose the same marketing restrictions on e-cigarettes that it imposes on combustible cigarettes. These include prohibitions on:
 - Sponsorships of **sports and cultural events**
 - **Self-service access** to the products (i.e. keeping the products behind the counter)
 - **Free gifts** with purchase, other than tobacco products (i.e. no free branded t-shirts or hats with purchase)
- **Social media and influencer marketing restrictions:** FDA has indicated that it will review and institute **restrictions on social media and influencer marketing** (ensuring that marketing avoids images and themes that appeal to youth; that the marketing focuses on appealing to adults such as using “switching” themes, using older models; etc.) and restrictions on paid digital and social marketing and the use of influencers to limit youth exposure to advertising.²⁵ We urge FDA to follow through and apply such restrictions to all e-cigarette products immediately.
- **The Federal Trade Commission (FTC) monitoring:** 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 all marketing spending just as it does for cigarettes and smokeless tobacco.



➤ **Product standards:** FDA 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, including menthol, in cigarettes, cigars and smokeless tobacco. We know that flavors have overwhelming been used to attract youth and those who have not previously used nicotine or tobacco. Given the youth e-cigarette epidemic and the role that flavors play in influencing youth to use e-cigarettes, we strongly support **removing all flavored e-cigarettes from the market, including mint and menthol, as well as any “concept” flavors or other ambiguously named or packaged products that are flavored**. We support a permanent ban on flavored tobacco unless a manufacturer can demonstrate three things to the FDA: 1) that a particular flavor helps current tobacco users to switch completely to a substantially less hazardous product, 2) the flavor will not lead non-tobacco users, such as youth, to start, and 3) the flavor itself does not increase the risk of harm from using the product.

➤ **Product packaging:** FDA should issue product standards so that e-cigarettes, and e-liquid in particular, come **only in child-resistant packaging** to prevent young people from ingesting these products, which cause sickness and, in some cases, can be fatal.

➤ **Restrictions on nicotine concentrations and delivery:** Currently FDA does not impose 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 **59 mg/ml (or 5%) nicotine** and has recently introduced a 3% concentration. Other e-cigarette brands, such as popular disposable brand Puff Bar, claim to have just as much and other competitors claim to have 6-7% 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 nicotine levels, but also the mechanism by which nicotine is delivered** (e.g. restrictions on levels of nicotine salts), to reduce the amount of nicotine e-cigarettes deliver to the body. These restrictions will help reduce the addictiveness of the products.

➤ **Enforcement:** In addition to enforcing the PMTA requirements, the FDA must use its powerful enforcement authorities to **ensure that all aspects of the Tobacco Control Act, as well as all subsequent regulations, are enforced** in a timely manner to the full extent of the law. Without enforcement, these hard-fought measures are meaningless and will not protect youth. Additionally, other federal agencies, such as the FTC, should continue working with FDA to protect against misleading marketing.

➤ **Internet sales:** FDA should **prohibit all non-face-to-face sales**, along with internet sales of all tobacco products, including e-cigarettes.

➤ **Taxation:** Federal, state and local tax-writing authorities should set taxes on e-cigarettes at a level sufficient to discourage youth use.



- > **Cessation:** Federal agencies such as FDA and National Institutes of Health (NIH) 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 and interventions available for all those addicted to nicotine — whether from e-cigarettes or combustible tobacco products — with no barriers to treatment.
- > **Federal research:** FDA and NIH must **fund research to better understand harms associated with e-cigarettes**, behavioral use patterns, and impact on tobacco cessation (separate from the research mentioned above).

STATE AND LOCAL ACTION NEEDED

States and local communities are often the **incubators** of strong tobacco control policies and they have an important role to play in protecting youth from e-cigarettes. Some examples include:

- > **Licensing:** Requiring all e-cigarette vendors to be **licensed and registered with the state or local (where allowed) government**. Licensing is not only an important way to keep track of who is selling tobacco products, it can also be a tool to limit the density and location (i.e. not near schools) of tobacco retailers. For more information on the importance of tobacco retail licenses please see our [Point of Sale Policy Resource](#).
- > **Flavor restrictions:** Many local jurisdictions have taken action to **restrict or prohibit the sale of flavored tobacco products**.³² Truth Initiative supports such actions because they limit the availability of highly appealing tobacco products for youth.

- > **Clean Indoor Air:** State and local governments should **include e-cigarettes in their clean indoor air laws** and requirements.
- > **Tobacco 21:** While a federal Tobacco 21 law passed in 2019, state and local jurisdictions (where allowed) should **limit sales of all tobacco products, including e-cigarettes and their components, to those 21 and older, with the onus on the retailer to comply**. We note that the tobacco industry has 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.

Tobacco 21 policies must be accompanied by complementary and strong policies.



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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**.



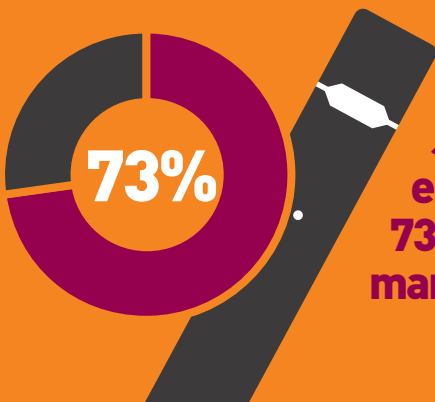
2017



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



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.¹
- 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.^{1,2}
 - » While many of the **flavorings** and humectants used in e-liquids have been approved by the Food and Drug Administration for oral consumption,² 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.³

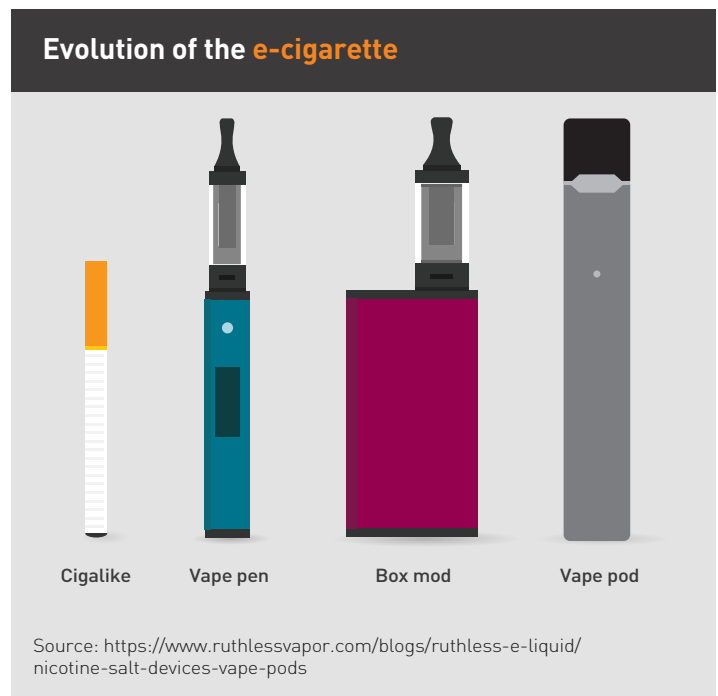
» **Higher nicotine e-cigarettes have driven the surge in e-cigarette sales** in recent years, with those containing at least 4% nicotine comprising nearly three-quarters of the e-cigarette market in 2018.⁴ Unlike in Europe, where e-cigarette nicotine concentrations cannot exceed 2%, there are no nicotine concentration restrictions in the United States.⁵

➤ 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.^{6,7}

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.^{1,8}
- To account for the diversity in product design, some researchers have classified e-cigarettes as first, second or third generation devices.²
- A **first generation** e-cigarette is one that closely resembles a **cigarette** and is **disposable**.⁹
- A **second generation** e-cigarette is a larger, usually **pen-shaped** device, that can be **recharged**.⁹
- 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**.^{2,9}



➤ 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 2019.¹⁰
- » “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.¹¹



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,¹² 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.¹³ IQOS, produced by Philip Morris International (PMI), is now being sold in select test markets by Altria around the country.¹⁴ 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.¹⁵ 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.¹⁶ 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**.^{2,17}

- > **Labeling is not always a reliable indicator** of nicotine content, as studies have found mislabeling to be a common issue in the category.^{2,17}
- > The way an e-cigarette is used or **modified** also affects the delivery of nicotine to an individual user.^{2,18}
- > 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**.¹⁹ 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.²⁰
- > In the U.S., JUUL devices were originally introduced with a 5% nicotine salt pod.²¹ Following suit, **JUUL competitors began offering nicotine salt concentrations as high as 7%** in what has been called a “nicotine arms race.”²¹ However, in 2018, JUUL introduced a lower nicotine pod, with 3% nicotine strength.⁴
- > 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**.²² 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.^{23,24}


ARE E-CIGARETTES LESS HARMFUL THAN CIGARETTES?

It is generally accepted that e-cigarettes produce fewer of the toxins found in cigarette smoke.² 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.²⁵⁻²⁷ 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.²⁷ 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.⁹⁵ 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.²⁸ 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.²⁸



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

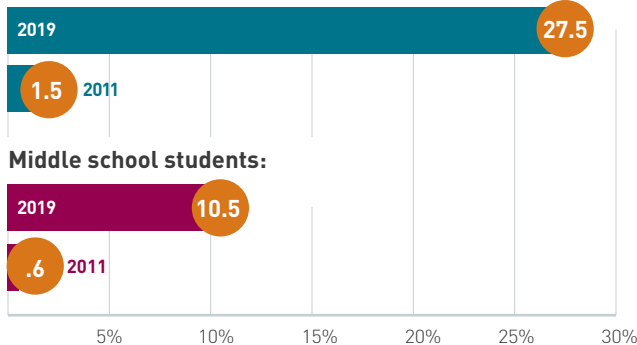
While a 2018 National Academies of Sciences, Engineering, and Medicine report found substantial evidence that exposure to toxic substances from e-cigarettes is significantly lower compared to combustible cigarettes, recent studies are showing that is not the end of the story on health impact. It now 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.²⁹ 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.³⁰ 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.

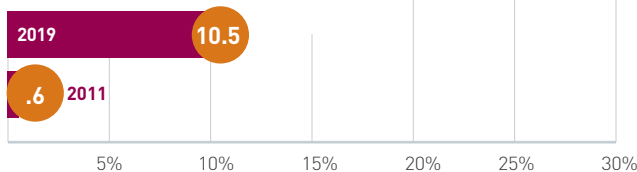
Consumers need to consistently know what they are getting and whether it is safe — particularly from a product designed to deliver chemicals by frequent inhalation. The growing evidence of potential health risks and lung injuries related to e-cigarette use has led researchers to question whether e-cigarettes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

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.^{31,32,175}

YOUTH

The last five years have seen enormous spikes in youth e-cigarette use rates.³³

- > In **2017, 11.7% of high school students** had used an e-cigarette in the past 30 days.³⁴ 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.^{33,35} That number dropped to 19.6% in 2020.¹⁷⁵
- > 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 2020.¹⁷⁵
- > 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.^{32,40,41} 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.¹⁷⁶ 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**.⁴²

- > **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.⁴³ Yet, many young people **aren’t aware that the products they use, like JUUL, contain nicotine.**²² 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 2019.¹⁷⁵

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).¹⁷⁵
- > 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%).¹⁷⁵

- **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.⁴⁶
- 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**.⁴⁷
- The FDA has also reported that, among current youth users of e-cigarettes, **97%** used a **flavored e-cigarette** in the past month.⁴⁸
- As much as **98.7%** of **flavored e-cigarette products** sold in convenience, dollar, drug and grocery stores contain **nicotine**.⁴⁹
- 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 2019-2020.¹⁷⁵

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 2020.¹⁷⁷ 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.¹⁷⁸
- 2020 NYTS data show that 37% of high school e-cigarette users use menthol flavored e-cigarettes.¹⁷⁵ In fact, following the FDA’s guidance around the removal of non-menthol-flavored cartridge-based e-cigarettes in

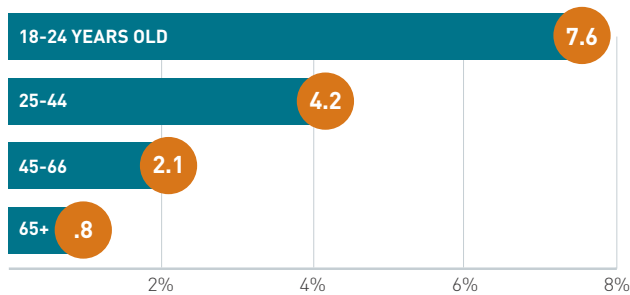
January 2020, menthol e-cigarette sales increased by \$59.5M and its market share shot up from 24% to 49% during the roughly eight-week period following the announcement. The market share of mint e-cigarettes decreased from 26% to 4% and sales declined by \$79.5M during this time, indicating that as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

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.^{32,52,53}
- 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**.⁵⁴
- 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.³²
- 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.⁵⁵
- 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.⁵⁶⁻⁶²

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.^{52,63}
- The overall adult rate of e-cigarette use in 2018 was 3.2%, down from 3.7% in 2014.⁵²
- Those aged **45 and older** are **significantly less likely** to have ever tried an **e-cigarette** compared to young adults.⁶⁴

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**.^{52,54,65} 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.^{2,32} 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.^{42,60,66}

DUAL USE PREVALENCE

- Among **adults** in 2016, **54.6%** of current e-cigarette users **also smoked cigarettes**.⁵⁴
- Among adults who used more than one tobacco product in 2017, the most common combination was **cigarettes and e-cigarettes**.⁵²
- Dual use** of e-cigarettes and cigarettes is **highly common** among **youth and young adults**.^{54,65,67,68}
- 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**.⁶⁵
- Among **young adults** aged **18-35**, **e-cigarette** use was associated with **more frequent cigarette smoking** and more intensive cigarette use.⁶⁹
- 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 2.58.⁶⁹



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.⁵⁰ 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.^{10,70,71}

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.⁷² 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.^{22,50}

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%.³⁹ 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 2019.³⁹ 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.⁴⁵ 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.⁷³ 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.⁷⁴
- › JUUL also **hired social media influencers** for product promotion.⁷⁵ The company had an entire department dedicated to influencer marketing and specifically looked for influencers under 30 and created a "VIP Portal" for celebrities.^{76,77}

QUITTING SMOKING

There are substantial research gaps in proving the effectiveness of e-cigarettes as quit smoking aids. The 2020 Surgeon General's Report on smoking cessation found that there is "inadequate evidence" to conclude that e-cigarettes increase smoking cessation.¹⁷⁹ Similarly, the 2018 National Academies (NASEM) report found limited evidence on the effectiveness of e-cigarettes to promote quitting.^{2,78,79,80,81,82}

E-cigarettes are also not approved as quit aids by the FDA or the U.S. Preventative Service Task Force.

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

- > The 2020 **U.S. Surgeon General's report** on smoking cessation found **insufficient evidence** to conclude that e-cigarette use increases smoking cessation, citing the variable components of e-cigarettes, the different ways in which they are used and a dearth of evaluative studies.¹⁷⁹ The report suggested that **e-cigarettes may help some adult users reduce their risk of smoking-related diseases if users avoid prolonged dual use.**
- > **Some evidence** suggests that, compared to e-cigarettes that don't contain nicotine, **e-cigarettes with nicotine are associated with increased smoking cessation**.¹⁷⁹ A 2020 systematic **review of 50 studies** that included adult smokers in the U.S. and other countries found moderate evidence that e-cigarettes with nicotine increase quit rates compared to those using nicotine replacement therapy or nicotine-free e-cigarettes. Nicotine e-cigarettes **may also help more people to stop smoking than no support or behavioral support alone**.¹⁸⁰ The NASEM report also reported that more frequent e-cigarette use may increase an individual's likelihood to quit smoking.²⁹



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

- > A **2018 study** among U.S. adults that explored whether e-cigarettes inspired more successful quit attempts found that **users of e-cigarettes had 70% lower odds of quitting than non-users**.⁸⁵
- > A **2019 study by the U.K. National Health Service and 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% vs. 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.⁸⁴ Notably, the U.K. also places severe restrictions on the marketing of e-cigarettes.⁵ **No similar study has replicated these results in the U.S.**

- **One study shows that product appeal, including flavoring, is likely to encourage smokers to try to use e-cigarettes to quit.**⁸⁶

A 2020 study published in JAMA Network Open found that among adults, use of flavored e-cigarettes was more likely to be associated with quitting smoking than use of unflavored e-cigarettes, with more than double the odds of increased adult smoking cessation.¹⁸¹ Given that flavored e-cigarettes constitute an overwhelming majority of the e-cigarette market in the U.S., **stronger empirical evidence is needed** to understand if and how flavors factor into smoking cessation.

While some e-cigarettes may help some people quit, the diversity of 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.^{2,25,27} 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.²⁵ 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**.

Because the youth e-cigarette epidemic in the United States and the youth appeal of flavored e-cigarettes go hand in hand, **Truth Initiative strongly supports removing all flavored e-cigarettes from the market**, regardless of device type. At a minimum, an e-cigarette manufacturer must show that the flavor itself is safe, helps smokers switch completely from combustible cigarettes, and does not attract youth before a product is allowed on the market. 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 page 1 for more information.)

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



QUITTING VAPING

After a smoker switches completely to e-cigarettes, they should also stop using e-cigarettes to achieve the maximum health benefit.¹ Many youth and young adult e-cigarette users, many of whom never previously used tobacco, are also in need of support to quit (see sidebar This is Quitting). Evidence from multiple sources indicate that both youth and young adult e-cigarette users want to quit and have made a quit attempt. Nearly two-thirds of adult e-cigarette users plan to quit vaping¹⁸² and almost a quarter of adolescents attempted to quit vaping in the past year.¹⁸³ Here is what we know about **reasons for quitting vaping**:

- > A 2020 Truth Initiative study published in Addictive Behaviors found that teens and young adults enrolled in the Truth Initiative quit vaping program This is Quitting said they were driven to quit because of concerns about **health (50.9%)**, **cost (21.7%)**, the desire to be **free from addiction (16%)** and social factors such as others' impressions of them (10.1%).¹⁸⁴
- > Nearly **two-thirds of adult e-cigarette users (62%) reported plans to quit e-cigarettes for good**, according to research published in Nicotine & Tobacco Research in 2020.¹⁸² Trends in **adolescents were slightly lower** with **44.5%** of youth aged 12-17 reporting that they seriously thought about quitting vaping, half of whom reported thinking about quitting within the next 30 days (50.2%).¹⁸³
- > A 2015 study in the International Journal of Environmental Research and Public Health found that reasons for quitting e-cigarettes varied by smoker status. **Never smokers** cited e-cigarettes being **bad for their health** and **tasting bad** as their reasons for quitting. **Former smokers** who gave up e-cigarettes were most likely to endorse that it was bad for their **health**, made them feel **sick**, and that they **preferred another form of tobacco**. **Current smokers** who quit e-cigarettes said that e-cigarettes were too **expensive**, they **liked another form of tobacco** better, and that e-cigarettes were **not strong enough**.¹⁸⁵



This Is Quitting

This is Quitting, Truth Initiative's first-of-its-kind, free and anonymous text message quit vaping program for teens and young adults, is helping more than 200,000 young people quit using e-cigarettes. The program first launched in January 2019, created with input from teens, college students and young adults who have attempted to, or successfully, quit e-cigarettes.

Preliminary data published in Nicotine & Tobacco Research showed that after just two weeks of using This is Quitting, more than half of participants — 60.8% — reported that they had reduced or stopped using e-cigarettes.

Teens and young adults can text "DITCHVAPE" to 88709 and get immediate help. Parents of young people who vape can get support at [BecomeAnEX.org](https://www.becomeanex.org).

- > A 2014 study published in Nicotine & Tobacco Research found that young people cited **losing interest (23.6%)**, perceiving e-cigarettes as **"uncool" (16.3%)**, and **health concerns (12.1%)** as their top reasons for quitting vaping.⁴⁷

Recent research has also shown that the E-cigarette, or Vaping, product use **Associated Lung Injury (EVALI) outbreak** in 2019 and 2020 drove increased coverage about the dangers of vaping and internet searches for vaping cessation. A 2020 study published in Tobacco Control found 130% **more news articles covering the dangers of vaping during the EVALI outbreak**, and searches for vaping cessation were 76% higher than expected levels for the days during the period when the sources of the outbreak were unknown.¹⁸⁶



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.⁸⁷

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

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.⁸⁷

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.²⁷
- > 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.²⁷
- > **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.²⁷
- > 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.**⁸⁸
- > 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.⁸⁹

» 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.⁷⁰

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

⊕ 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.⁶

⊕ 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.⁶

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.²⁶ 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.²⁷

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.”⁹² 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.⁹³ 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.⁹³

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.⁹⁴ 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.”⁹⁵

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.⁹⁶ 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.³²

- > 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**.⁴¹
- > 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.⁹⁷

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.^{21,98} 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**.⁵¹

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**.^{99,100}
- > **Pregnant women** who use nicotine are also at a greater risk for **stillbirth** and **preterm delivery**.³²

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.²
- > **Heavy metals** such as cadmium, lead, nickel, tin and copper have all been detected in aerosols produced by e-cigarettes.³⁰
- > 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.¹⁰¹
- > 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**.^{2,90}

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**.²
- > 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**.¹⁰²



- > 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.¹⁰³

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.²

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.²

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 2019.¹⁰⁴
- > 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.²⁶

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.¹⁰⁵

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.¹⁰⁶⁻¹¹⁰
- > E-cigarettes are promoted heavily online¹¹¹ through e-cigarette company-sponsored advertisements,¹¹² and on YouTube¹¹²⁻¹¹⁵ and Twitter.¹¹⁶

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



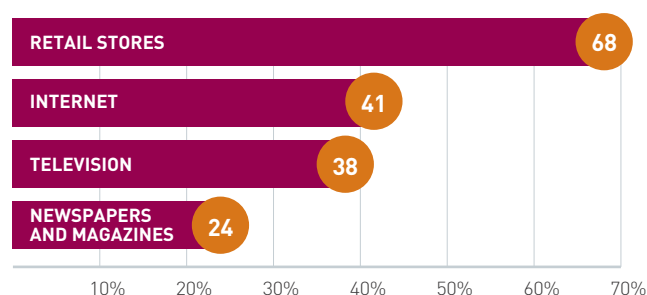
Photo: U.S. Food and Drug Administration

- 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**.¹¹⁷
- **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**.¹¹⁸ 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.^{75,119-121}
- 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**.¹²²

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

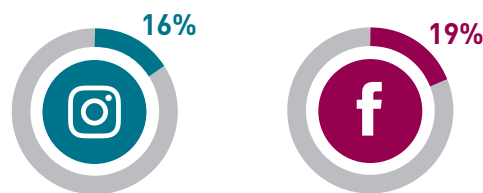


- Young people were most likely to see ads at **retail stores** (68%), followed by the **internet** (41%), **television** (38%) and **newspapers and magazines** (24%).¹²² Between 2014 and 2016, exposure to retail e-cigarette advertising among young people jumped nearly 20%.¹²²
- Mobile device ownership 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.¹¹⁷
- 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).⁷⁵
- **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.⁷⁴

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.⁷³
- > 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.**¹²³
- > JUUL also hired social media influencers for product promotion.⁷⁵ They had an entire department dedicated to influencer marketing and specifically looked for influencers under 30 and created a "VIP Portal" for celebrities.⁷⁶
- > 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.⁷⁵
- > 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.¹²⁴
- > 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.**¹²⁵
- > 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.¹¹⁹
- > Even among non-smokers, exposure and marketing through social media linked e-cigarettes with increased perceptions of stylishness and popularity.¹¹⁹ 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.

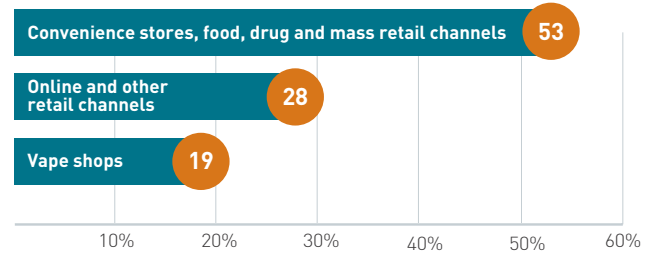
participants, 19% regularly saw e-cigarette ads on Facebook and 16% on Instagram. Even more reported seeing posts about e-cigarettes.¹¹⁹

- > The largest e-cigarette forum (/r/electronic_cigarette) on reddit has **150,000 subscribers.**¹²³
- > 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 21.¹²⁷
- > 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.¹²⁶
- > 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.¹²⁸
- > 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.¹²⁹

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.¹³⁰ 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.¹³¹ 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%¹³²
 - » Convenience stores, food, drug and mass retail channels: 53%¹³²
 - » Online and other retail channels: 28%¹³²

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.²⁷

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.¹³³ 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.¹³³ 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.¹³³
- > 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.¹³⁴

- > 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.¹³⁶⁻¹⁴¹

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.¹³⁵ 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.¹⁴² 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.¹⁴³ However, a large majority of the U.S. population — more than 90% — is not covered by such restrictions.¹⁴⁴

- 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.¹⁴⁵⁻¹⁵⁰ As of late October 2019, however, the **New York, Michigan and Oregon bans had been temporarily suspended**.¹⁵¹⁻¹⁵³ In **Massachusetts**, the governor took the extraordinary step of **suspending the sale of all e-cigarettes**.¹⁵⁴ And while the ban has not been overturned, a judge recently ruled that it must be resubmitted with an opportunity for public comment.¹⁵⁵ 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.¹⁵⁶

- 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.**³⁵ 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.^{35,157} 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.**¹⁵⁸ Delaware requires

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.¹⁵⁹ 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.¹³⁴
- 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.**^{133,160} 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.¹⁶¹

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



- 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.

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

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, 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.

- 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.**¹⁶¹

Taxes are a particularly **effective tool** for discouraging youth use of tobacco products. **Youth and young adults are two to three times more**

A map of the United States with states colored in orange or light gray. The orange states are WA, CA, NV, NM, KS, MN, WI, IL, OH, WV, PA, NY, CT, ME, and NC. The light gray states are OR, ID, MT, ND, SD, NE, IA, MO, AR, TX, OK, CO, WY, UT, AZ, AK, HI, MI, IN, KY, TN, MS, AL, GA, SC, VA, MD, DE, RI, NH, MA, VT, and FL.

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.¹⁶³
- 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, 2016.¹³³



- 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.¹⁶⁴
- The Tobacco Control Act prohibits the FDA from further raising the federal minimum legal age of sale.¹⁶⁵ 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.¹⁶⁶ 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 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.**¹⁶⁷ 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.¹⁶⁸ Some member states have further restrictions on the age of sale and taxes.¹⁶⁹
- The Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health keeps a database of international e-cigarette laws.¹⁷⁰ Notably, the **United Kingdom has been most active in promoting e-cigarettes as a reduced harm alternative to cigarettes.**¹⁷¹ Public Health England has encouraged the National Health Service to make e-cigarettes available to smokers looking to quit or switch.¹⁷¹ 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.¹⁷²
- **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.**¹⁷³ 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.¹⁷⁴

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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