

POLICY PLAYBOOK FOR E-CIGARETTES Version 2.0







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<u>Vaping Prevention Resource</u> is a leading online destination for vaping prevention media, research, policy, and advocacy. A non-commercial, educational resource for communities, VPR was created by UNC-Chapel Hill researchers working on the front lines of tobacco control at the Lineberger Comprehensive Cancer Center, the Gillings School of Global Public Health, and the Hussman School of Journalism and Media. In addition to the media gallery featuring free, openaccess vaping prevention materials to download and use, VPR offers the latest vaping advocacy materials, research, news updates, and policy solutions.

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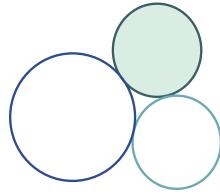
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PURPOSE OF THE POLICY PLAYBOOK

Since e-cigarettes were first introduced to the U.S. market in 2007,¹ the prevalence of vaping has soared, especially among youth and young adults.² Addressing the phenomenal growth of the U.S. vaping epidemic requires coordinated and evidence-based policy at local, state, and federal levels. In 2020, the UNC Lineberger Comprehensive Cancer Center partnered with the Public Health Law Center to create a Policy Playbook as a guide for public health practitioners and educators interested in adopting state and local policies to curb the vaping epidemic.

This 2022 update of our Policy Playbook for e-cigarettes provides policy and advocacy tools to help communities address and prevent the public health harms caused by the use of electronic nicotine delivery system (ENDS) products such as e-cigarettes. In addition to including new information on e-cigarette policies and legislation, the playbook features four case studies of effective policies that state or local communities across the country recently adopted to regulate e-cigarettes. These case studies illustrate the ways in which communities can overcome obstacles and secure public support for their policies and the tactics they use in enforcing them. For state and local health practitioners and educators, this refreshed Policy Playbook offers a framework to assist in deciding on policies and practices to pursue as well as policy implementation guidelines and examples.

NEED FOR E-CIGARETTE REGULATION

Prevalence

In recent years, e-cigarettes have become the tobacco product most commonly used by youth.³ As of 2021, an estimated 2 million U.S. youth reported using e-cigarettes within the past 30 days, including 11.3 percent of high school students and 2.3 percent of middle school students.⁴ One in four high school students and one in twelve middle school students who vaped in the past month reported vaping every day.

In 2021, disposable and flavored products were most popular with 53.7 percent of youth using disposables and 84.7 percent using flavored e-cigarettes.⁵ This 2021 prevalence data may also be an underestimate. Prior to 2020, data on student e-cigarette use was typically collected at school, but due to the COVID-19 pandemic, 2021 data was collected from students at home, school, or other locations. Tobacco use rates are typically lower when youth are surveyed at home compared to school, and the CDC urges caution when making comparisons between rates in 2021 and prior years.^{6,7}

Research shows that most habitual nicotine product use begins during youth and young adulthood. Among adults who smoke combustible cigarettes daily, nearly 90 percent began smoking by age 18.8 The high prevalence of e-cigarette use among youth can lead to continued addiction in young adulthood and contribute to a higher overall prevalence of nicotine and tobacco product use in the U.S. population. In fact, the prevalence of adult e-cigarette use is highest among 18 to 24 year olds,9 and has risen since 2014.10 A 2020 study found that more than a quarter (27.5 percent) of youth and young adults who started e-cigarette use in 2018 went on to try combustible cigarettes in 2019, compared to 2.4 percent of those who had never used an



e-cigarette.¹¹ An earlier study found that over 40 percent of youth who used e-cigarettes reported cigarette initiation approximately 16 months later in a follow-up survey.¹²

Health Inequities

Like other tobacco-product use, inequities exist related to youth e-cigarette use. Race/ethnicity, sexual orientation, gender identity, and ability, as well as the history of the tobacco industry's marketing towards certain communities, contribute to these inequities.

Transgender youth (40.2 percent) and female sexual minority youth (37.9 percent) are more likely to report ever using e-cigarettes compared with nontransgender (23.0 percent) youth and straight female youth (20.1 percent).¹³ Although non-Hispanic white youth are more likely to report frequent e-cigarette use and flavored e-cigarette use,¹⁴ Black and Hispanic youth initiate e-cigarettes significantly earlier than their white peers.¹⁵



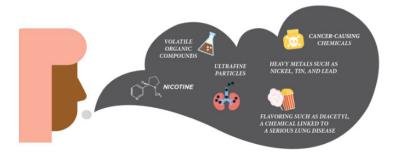
This is especially concerning since early initiation is linked to increased nicotine dependence and sustained e-cigarette use. 16 In one study, students with disabilities were more likely to use e-cigarettes in the last 30 days (18.3 percent) compared with their nondisabled peers (12.3 percent).¹⁷ In addition, a recent systematic review found that youth e-cigarette use is associated with greater mental health problems (compared with nonuse), particularly among adolescents. 18

E-cigarette Marketing and Advertising

From 2011 to 2019, e-cigarette marketing expenditures and internet advertising skyrocketed. As a result, one study showed that between November 2014 and June 2015, over 70 percent of youth reported exposure to e-cigarette marketing in the past month.¹⁹ The impact of marketing on youth has been significant. For instance, youth who report exposure to e-cigarette marketing are more likely to initiate the use of e-cigarettes.²⁰ Moreover, youth who recall internet e-cigarette advertisements are more than twice as likely to use e-cigarettes, and those who recall e-cigarette advertisements in retail stores are almost three times more likely to use e-cigarettes.^{21,22}

E-CIGARETTE USE & HEALTH RISKS

Various health risks and negative health outcomes are associated with vaping. The nicotine intake from e-cigarettes is comparable to intake from combustible tobacco cigarettes and can cause addiction.²³ Youth are at particular risk of developing nicotine addiction and can suffer related negative long-term impacts including impaired memory and reduced attention span.²⁴ The fine particulate matter emitted in e-cigarette vapor is known to cause cardiovascular and respiratory illnesses and can contain metals such as aluminum, nickel, chromium, and lead.²⁵ E-cigarette use in adolescents



is associated with an increased risk of asthma.²⁶ In addition, although most of the chemicals used to flavor e-liquids are designated as safe for **oral consumption**, they have not been approved for **inhalation** as aerosols.²⁷ The e-cigarette flavoring chemical diacetyl has been linked to lung disease, ²⁸ and another additive used to create cinnamon flavoring has been found to damage human cells. ²⁹ Recent research has found thousands of unknown compounds present in e-cigarette aerosol, many formed during the vaping process, including at least six potentially hazardous additives and contaminants.30

Yet another health risk posed by e-cigarettes is injury from defective battery explosions or accidental exposure to and ingestion of e-liquid.³¹ E-liquid ingested or exposed to the eyes or skin can result in vomiting, seizures, lactic acidosis, and anoxic brain injury.³² Between 2012 and 2015, the rate of child exposure to nicotine liquid increased rapidly and the odds of severe outcomes were 2.6 times higher for children exposed to nicotine liquid than for those exposed to combustible cigarettes.³³

E-cigarettes are also used to consume marijuana and other drugs. In 2019, a string of cases of e-cigarette or vaping use-associated lung injury (EVALI) were found to be linked to the presence of vitamin E acetate as an additive in some THC products used in e-cigarettes.³⁴ In the U.S. to date, 2,800 hospitalizations and 68 EVALI-related deaths have been confirmed.³⁵ The CDC reports that further research is needed to conclude

unequivocally that other chemicals in e-cigarettes are not associated

with EVALI.36

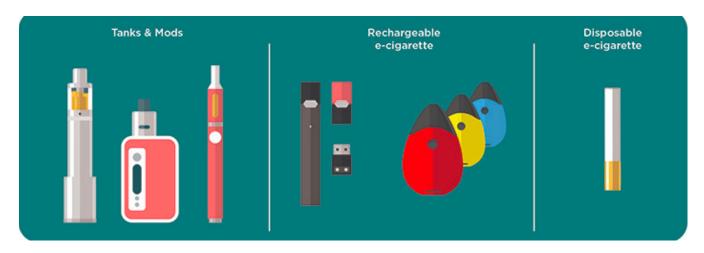
Although some public health experts advocate for e-cigarettes as a harm reduction tool, asserting that e-cigarette aerosol contains fewer toxicants than combustible tobacco cigarettes, 37 other experts disagree. These researchers point to the results of modeling studies that demonstrate that e-cigarettes reduce smoking cessation rates and increase the prevalence of smoking initiation by attracting youth.³⁸ In fact, a recent study found that youth aged 15 to 21 who use e-cigarettes or ever used the e-cigarette brand Juul have over three times higher odds of initiating use of cigars, little cigars, or cigarillos (CLCCs), compared with those who never vaped. 39 What remains clear is that e-cigarettes are not risk-free and that further research is needed to determine the long-term health effects of e-cigarettes.40

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E-CIGARETTE PRODUCTS AND FLAVORS

More than 460 different e-cigarette brands are currently on the market. The first e-cigarettes resembled cigarettes without rechargeable or refillable components, but over time products have evolved to be both reusable and adaptable to a user's preferences in terms of temperature and concentration of aerosol. These features affect the chemical composition and toxicity of the aerosol. Most e-cigarettes consist of four components: a cartridge or reservoir containing e-liquid, a power source (typically a battery), a heating element, and a mouthpiece used to inhale. The basic types of e-cigarette devices include tanks and mods, vape pens, rechargeable, and disposable e-cigarettes. Evolving products include e-cigars and e-pipes, and pod type devices such as Juul. Disposables are now the most popular e-cigarette devices used by current middle and high school e-cigarette users, followed by prefilled, refillable pods or cartridges, and tanks or mod systems. Although "pod mod" e-cigarettes such as Juul are commonly used by youth, fewer than half of parents of middle and high school students can recognize JUUL as a vaping device.



FLAVORED E-CIGARETTES

The prevalence and popularity of flavored e-cigarettes that attract young users are major public health concerns. More than 15,500 e-liquid flavors are on the market today. 47 Youth who use e-cigarettes prefer flavored products 48 and use flavored e-cigarettes more often than adults. 49 Among youth who used e-cigarettes in 2021, 84.7 percent used a flavored product. 50 Over 70 percent of youth report using e-cigarettes because they are available in flavors they like, 51 such as fruit, mint, candy, and dessert flavors. 52 In addition to attracting youth users, the chemicals used to create some e-cigarette flavors, such as diacetyl and acetyl propionyl, may be harmful when aerosolized and inhaled. 53

Because of these health risks and public health concerns related to flavored e-cigarettes, the U.S. Food and Drug Administration (FDA) issued a ban effective February 2020 of all flavors in cartridge e-cigarettes, with the exception of tobacco and menthol flavors. However, this ban makes significant exceptions and contains vague language that creates loopholes.⁵⁴ Disposable e-cigarettes, open-tank e-cigarettes, ⁵⁵ and menthol and tobacco flavored products⁵⁶ are not covered by the flavor ban. Notably, menthol-flavored Juul products continue to be available under the ban and remain popular among high school students.⁵⁷ In 2009, the FDA issued a similar ban on flavored combustible cigarettes that allowed for significant exceptions including menthol-flavored products.⁵⁸ When tobacco control policies have loopholes, they are often exploited by the industry and consumers.

Over 70 percent of youth report using e-cigarettes because they are available in flavors they like, such as fruit, mint, candy and dessert flavors. 51,52

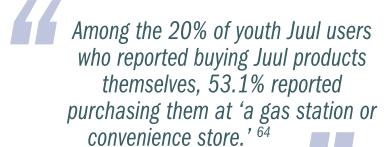
As a result, when cigarette flavor bans were implemented that still allowed menthol products on the market, many consumers switched to menthol products and the overall impact is fairly modest. ⁵⁹ Because of similar exceptions in the recent FDA flavor ban related to e-cigarettes, some state and localities have taken further action to restrict the sale of flavored e-cigarettes, discussed on page 20.



EASE OF ACCESS

The ease with which e-cigarettes can be obtained has contributed to the growth of the vaping epidemic in the United States. An estimated 53 percent of all e-cigarettes are sold at convenience stores or in food, drug, and retail outlets, 28 percent online or through other retail channels, and 19 percent at vape shops. The density of tobacco retailers is positively associated with smoking prevalence in an area. Moreover, many e-cigarette retailers (vape shops) are located in close proximity to schools and colleges. Youth often purchase e-cigarettes from these retail outlets and convenience stores. A 2019 survey found that among the 20 percent of youth Juul users who reported buying Juul products themselves, 53.1 percent reported purchasing them at "a gas station or convenience store."

In light of the concerning ease of access, the federal government recently restricted e-cigarette mail delivery. On December 27, 2020, the federal government passed an omnibus spending package and coronavirus relief law. Found in that 5,593-page piece of legislation was a short bill that added e-cigarettes to the 2009 Prevent All Cigarette Trafficking (PACT) Act. 65 This law requires online retailers to verify the age of customers for all purchases, requires an adult with identification to be present for delivery, requires packages to be labeled as containing tobacco products, and requires retailers to comply with all state and local tobacco tax requirements. It also requires the U.S. Postal Service to cease delivery of all e-cigarettes effective 2021.



THE FEDERAL GOVERNMENT AND E-CIGARETTES

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the FDA unprecedented authority to regulate tobacco products. ⁶⁶ While the law initially applied only to cigarettes, roll-your-own tobacco, and smokeless tobacco, the law also gives the FDA the authority to regulate any product made or derived from tobacco that is intended for human consumption. On August 8, 2016, the FDA's final "deeming rule" took effect, which deemed all tobacco products, including e-cigarettes, subject to its authority. ⁶⁷

FDA's Regulatory Tools

The FDA has several tools that it can use to regulate e-cigarettes, although to date it has taken only modest measures to regulate these products. Below are a few of the regulatory tools at the FDA's disposal.

Issuing Tobacco Product Standards. The Tobacco Control Act gives the FDA exclusive authority to issue "tobacco product standards," which are regulations affecting the design or safety of a product.⁶⁸ The FDA has broad authority to prohibit flavors in any tobacco product and to set standards relating to ingredients, additives, and characteristics, including nicotine content.⁶⁹ Congress included one product standard in the law itself that prohibits flavors such as strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee in cigarettes.⁷⁰ However, this specific product standard exempted menthol and tobacco flavors, leaving products on the market that are disproportionately marketed to, and impact, African American, LGBTQIA+, and Latinx populations, among others.⁷¹ On April 29, 2021, after being sued by the African American Tobacco Control Leadership Council and other public health groups over its inaction on menthol and its seven-year silence regarding a citizen petition filed by a coalition of public health





groups urging it to act, the FDA finally stated its intent to issue a rule prohibiting menthol in cigarettes by April 2022.⁷² However, as of today, the FDA has not issued any other tobacco product standards, and the list of prohibited "characterizing flavors" does not apply to e-cigarettes.⁷³

Requiring Warning Labels & Labeling. Beginning on August 10, 2018, e-cigarettes and advertisements for e-cigarettes are required to display the following text: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." According to the deeming rule, the text should fill a box that is 30 percent of the size of the package and use no less than 12-point font. The Tobacco Control Act preempts (or overrules) state labeling requirements that are different from the federal warning.

Prohibiting "Modified Risk" Claims. The Tobacco Control Act also prohibits manufacturers from making "modified risk" claims without prior authorization from the FDA. "Modified risk claims" are defined as claims that the product is less harmful than other tobacco products. For modified risk products, the manufacturer must show that marketing its product with modified risk claims would "benefit the health of the population as a whole." Though no e-cigarette has received authorization to market itself as a modified risk product, e-cigarette manufacturers have been marketing their products – both implicitly and explicitly – as presenting less harm to users than combustible products, prompting warning letters from the FDA.80

Ensuring Pre-Market Review of New Tobacco Products. The Tobacco Control Act is designed to prevent the introduction of new products — which are defined as those commercially marketed after February 15, 2007 — without prior marketing approval from the FDA. ⁸¹ Manufacturers must submit applications establishing that their products meet the requirements of one of three separate marketing pathways. ⁸² Generally speaking, the FDA must determine that the

marketing of a new product would be "appropriate for the protection" of the public health" before authorizing its sale. 83 As of September 9, 2020, the FDA requires e-cigarette manufacturers to submit applications for marketing authorization. According to the Tobacco Control Act, only products that have received affirmative marketing authorization from the FDA are allowed to be on the market. This means that the vast majority of e-cigarettes being sold are currently being illegally marketed to consumers in the U.S. The FDA, however. has chosen to use its enforcement discretion to not enforce these provisions against e-cigarette manufacturers who submitted applications by September 9, 2021. It has sent a handful of warning letters to manufacturers who failed to submit applications to the agency as required. As of the date of publication, eleven marketing orders have been issued for e-cigarette and heated tobacco products; however, none of these marketing orders cover the most popular devices used by youth and adults, meaning that the most widely used products have not received review or authorization for sale by the FDA.84

The FDA's Limited Action to Date

Limited Flavored E-cigarette Enforcement Efforts. As most e-cigarettes are "new" products (entering the market after February 15, 2007), they should have been subject to the FDA's premarket review process. 85 Unfortunately, as the e-cigarette epidemic demonstrates, the FDA allowed these products to remain on the market without regulatory oversight. 86 Only after a <u>lawsuit</u> brought by public health groups and a resulting <u>order</u> by a federal judge did the FDA set a deadline by which manufacturers must submit premarket review applications. 87

Limited Flavored E-cigarette Enforcement Guidance. In light of the FDA's inaction in regulating e-cigarettes, coupled with aggressive marketing by e-cigarette companies, the U.S. experienced





a proliferation of flavored products, resulting in the e-cigarette epidemic among youth. In response to this health crisis, many states, public health professionals, and advocates called upon the FDA to remove flavored e-cigarettes from the market. However, when the FDA did release a guidance document describing its intent to remove certain products from the market, the guidance only addressed pod or cartridge-based products (such as Juul) and exempted menthol flavors entirely.⁸⁸ This effectively left all "disposable" products – as well as refillable products – on the market, in addition to many other flavored products that have been shown to lead to youth initiation. As a result, the popularity of these products soared, eventually overtaking the popularity of cartridge based products among youth.⁸⁹ This "whack-a-mole" approach to regulation is ineffective in reducing youth uptake.



Limited Follow-up on Other Flavored E-cigarette Products.

One popular, so-called "disposable" product left out of the FDA's e-cigarette enforcement guidance was "Puff Bar" - a self-contained product that comes in a variety of kid-friendly flavors, including Lychee Ice and O.M.G. (Orange, Mango, Guava). This product, and many of its imitators, became popular after the FDA released its guidance. In July 2020, the FDA issued warning letters to ten companies, including the company doing business as Puff Bar, notifying them that their products lack the required premarket authorization and must be removed from the market. 90 Moreover, the FDA has tended to use warning letters as its primary mode of enforcement to date, 91 even though it has broad authority to issue civil monetary penalties and no-tobacco sale orders, seize products, and even impose criminal penalties. 92 To our knowledge, no civil monetary penalties have been issued to manufacturers of tobacco products, underscoring the lack of robust enforcement action on the part of the FDA.

Synthetic Nicotine. After the FDA issued warning letters to the manufacturer of Puff Bar, the company began advertising its products as containing "<u>synthetic nicotine</u>," or nicotine that is not derived from tobacco, thus evading regulation by the FDA as tobacco products. ⁹³ While this may seem like a potentially large and problematic

loophole, the FDA had been limited because the Tobacco Control Act specifically restricted the FDA's authority to tobacco products made or derived from tobacco. 94 On March 15, 2022, President Biden signed into law the 2022 omnibus spending bill, which grants the FDA authority to regulate synthetic nicotine products as tobacco products. 95 Under the new law, an FDA-regulated "tobacco product" will now include "any product made or derived from tobacco or containing nicotine from any source that is intended for human consumption, including any component, part, or accessory of a tobacco product." 96

Role of State and Local Governments

Given the FDA's anemic response to e-cigarette regulation, states and many local jurisdictions, as well as several U.S. territories, have taken steps to restrict the sale, marketing, and use of e-cigarettes to protect the health of users, reduce youth initiation to nicotine and tobacco products, and promote enforcement of smoke-free laws. Tate and local jurisdictions have the authority to enact public health and safety laws that protect community members from health risks related to the sale or use of products such as e-cigarettes. This authority is well within the government's policymaking powers and represents its legitimate and primary obligation to protect the health and safety of its citizens.

Over the last five years, states and territories have amended many smoke-free laws, clean indoor air acts, and other tobacco-related laws to prohibit the use of e-cigarettes and related electronic smoking, as well as conventional tobacco products, in certain areas. States have also levied taxes on e-cigarettes, added point-of-sale retail requirements (including youth access restrictions), imposed product packaging requirements on e-cigarette and e-liquid products, and required licenses or permits for retail sales of e-cigarettes. 99



State and local jurisdictions have the authority to enact public health and safety laws that protect community members from health risks related to the sale or use of products such as e-cigarettes.



In addition, in light of the 2019 multi-state outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI) which resulted in over 2,800 hospitalizations, 100 several states and tribes have taken temporary or emergency action to ban sales of (typically flavored) e-cigarette products. 101 The EVALI epidemic was likely driven by the use of THC-containing products from informal and illicit sources, while the current youth e-cigarette epidemic is driven by the use of nicotine-containing products obtained mainly from formal sources such as authorized retailers. In either case, short-term state action to address the harms of e-cigarette use is not a substitute for bold, comprehensive, and permanent local and state policy.

Featured Case Studies

This playbook features four case studies of effective policies that state or local communities across the country adopted to regulate and address the rising use of e-cigarettes. The case studies highlight policies regulating e-cigarette retail density in San Francisco, California; e-cigarette taxes in Anchorage, Alaska; e-cigarette retail licensing in Santa Barbara, California; and e-cigarette waste in Boulder County, Colorado. These case studies were based on numerous interviews with subject matter experts in each community, as well as qualitative research. The case studies illustrate ways in which different communities can overcome obstacles and secure public support for e-cigarette policies, as well as tactics used in effective enforcement of these regulations.



E-Cigarette Policy Case Study: Anchorage



E-Cigarette Policy Case Study: San Francisco



E-Cigarette Policy Case Study: Boulder County



E-Cigarette Policy Case Study: Santa Barbara



COMMON POLICY ELEMENTS

Communities seeking to regulate e-cigarettes need to be clear about the policy's goal and scope, as well as the local government's regulatory authority to enact this policy. Regardless of the type of regulatory measure, an effective policy needs to be specific, well-crafted, and include realistic implementation steps and enforcement mechanisms. Here are some key elements found in such policies:

Findings and Statement of Purpose

Findings are brief statements of facts or statistics that outline the issue, support the need for the policy, and help clarify the policy goal. Regulations involving e-cigarettes typically include timely findings that detail the prevalence of e-cigarette use among youth and young adults (including, where available, community-specific data), and the known health risks of e-cigarette use or vaping (whether nicotine or other substances). Findings also typically explain how the policy is designed to address the problem. In the event of litigation, clear findings and statements of purpose provide the evidentiary basis for the policy and demonstrate the regulatory authority's rationale for adopting specific restrictions.

Statement of Authority

Whether included within the findings or in a separate provision of the law, it is useful to provide a clear, concise, and well-researched statement explaining the local government unit's authority to enact the law. The unit could be a school board, city council, board of health, or other local government entity. Such a statement may help avoid arguments that the local government lacks the authority to pass the law because of preemption, lack of home rule authority, or some other legal reasoning.

Clear Definitions and Concise Language

To avoid confusion about what constitutes an e-cigarette, definitions should explicitly state which tobacco products are covered, yet be broad enough to anticipate and capture future product innovations. This can eliminate ambiguities that may arise when new products that are functionally similar to existing products enter the market, but may not be included under a narrow definition. For example, e-cigarettes physically resembled cigarettes when they were introduced on the market, but are now manufactured in many different forms. Moreover, a definition that covers only products that contain tobacco-derived nicotine may be inadequate and would likely make enforcement difficult. Many cartridges are interchangeable, and e-cigarettes can be used to inhale not only tobacco-derived nicotine but also synthetic nicotine and other substances. A comprehensive definition should cover all of these variations. If a jurisdiction chooses to regulate and

include in its definition only products that contain nicotine derived from tobacco, it should consider adding language that presumes all e-cigarette products contain nicotine, absent proof to the contrary. This potentially eases enforcement by placing the burden on the tobacco manufacturer or retailer to prove the e-cigarette does not contain nicotine rather than on the jurisdiction enforcing the policy.

When drafting definitions, be sure to consider the range of products intended, the specific activity to be addressed, the existing laws within the particular jurisdiction, and the political environment. Definitions should be tailored to particular contexts and be easy for the average person to understand. For instance, when drafting a sales restriction law, it would be helpful to include language that exempts products approved by the FDA for sale as tobacco cessation aids that are being marketed and sold for that purpose. However, a similar exemption for a clean indoor air law could be problematic because it may create confusion, leading to enforcement difficulties.





Clear Enforcement/Compliance Check Procedures

Enforcing restrictions on the sale, marketing, pricing, and use of e-cigarettes can be challenging unless clear and practical procedures are established, including a reasonable and equitable compliance check and a penalty and appeals process. It is important to ensure that the proposed penalties are appropriate, equitable, and legal within the particular jurisdiction. Also, enforcement should be focused on retailers, rather than consumers, and penalties should not have a disparate impact on specific populations. Effective enforcement of these policies often includes coordination among different enforcement agencies and consistent procedures throughout a community. States could also use existing consumer protection laws to ensure that the public is protected from false claims made about these products.



Well-Planned Implementation Process

Establish a process for publicizing the policy and educating the community, as well as for receiving, tracking, and following up on complaints. Ideally, such education would include information about cessation resources. Set a realistic date that the policy will take effect and communicate that date clearly. For example, in the case of a sales restriction policy affecting e-cigarette retailers, it could help in implementation if retailers were educated ahead of time about the policy. Such educational materials could inform retailers of the policy's key provisions, explain how existing inventories may be treated (allowing time for existing inventories to be depleted), and provide them opportunities to ask questions.



Drafting Tips

In many cases, existing definitions for "tobacco products" in tobacco control laws need to be broadened to include e-cigarettes. It would also be helpful to include, as part of the definition of an e-cigarette, all component parts and accessories, regardless of whether they are sold together or separately. This may help prevent ambiguities as to what is covered under the e-cigarette definition. Finally, to ensure that inconsistencies or other problems do not occur, consult with a lawyer familiar with the laws of your jurisdiction, or contact the Public Health Law Center.

COMMON LOCAL AND STATE POLICY OPTIONS

States, tribes, and local governments play a critical role in regulating the sale and use of commercial tobacco products, including e-cigarettes. They have wide latitude, for instance, to license tobacco retailers, adopt clean indoor air laws and smoke-free laws, and establish pricing and taxing policies. ¹⁰³ The following sections will discuss each of those policy options in turn, with a focus on key elements and considerations.

As with most policies, there are no "one-size-fits-all" solutions when it comes to retail licensing, smoke-free laws, or pricing and taxing policies. The most effective solutions are those that have community buy-in, support, and are tailored to the unique needs of each community.

TOBACCO RETAIL LICENSING

One of the most common ways to regulate e-cigarettes is through tobacco retailer licensing. Jurisdictions often strengthen tobacco licensing policies by including retailer restrictions on e-cigarette marketing, sales, and promotions, as described below. Tobacco retailers such as vape shops and convenience stores are the primary brick-and-mortar outlets featuring e-cigarette marketing, which has been linked to greater youth initiation, driving their sales and use. ¹⁰⁴ Tobacco control policies that restrict the number of retailers, retailer location, and product pricing can have an impact on sales and significantly decrease youth initiation. ¹⁰⁵ This section describes the public health rationale behind placing restrictions on tobacco retailers; presents key elements of tobacco retail licensing laws, and provides a few examples of policies.



Public Health Rationale

In 1998, several large tobacco companies entered into what is known as the "Master Settlement Agreement" (MSA), which placed significant restrictions on cigarette advertising and most sponsorships, among other requirements. The MSA had few point-of-sale advertising restrictions, prompting tobacco companies to bolster spending at retail locations. Since the 1980s, point-of-sale advertising has been the largest spending category for tobacco industry marketing. The tobacco industry now spends approximately 98 percent of its marketing budget at retail outlets, with most spending dedicated to price discounts. Unsurprisingly, given the industry's investment in advertising, point-of-sale tobacco strategies work. They are associated with smoking initiation, particularly among youth, and they increase the likelihood that those who recently quit will purchase tobacco products. These strategies are also more common in neighborhoods that tend to be younger, more racially diverse, and lower-income, and at tobacco retailers that are located near schools where teenagers are more likely to shop. More than 40 percent of teenagers live or attend school near a tobacco retailer.



Licensed tobacco retailers represent an important segment of the e-cigarette market, with 80 to 90 percent selling e-cigarettes at the state and national level.¹¹³ The number of dedicated vape shops operating in the U.S. has grown from 3,500 in 2013 to 10,000 in 2015.¹¹⁴ These outlets generally serve as social lounges in addition to sales outlets.¹¹⁵ Like conventional tobacco retailers, vape shops tend to be located near schools and universities, and in neighborhoods with high tobacco retailer density.¹¹⁶ Vape shops have learned from the tobacco industry to use price discounts, sampling, and loyalty programs to promote their products.¹¹⁷ This strategy has proved effective; advertising exposure has been shown to predict e-cigarette use among youth and has been a key factor in reducing concerns among teenagers about the harms and addictiveness of e-cigarettes and in influencing use patterns.¹¹⁸

Disproportionately high retailer density is particularly problematic for public health: neighborhoods with high tobacco retailer density also tend to be at higher risk for adverse health outcomes. ¹¹⁹ The tobacco industry has a long history of targeting African American, LGBTQIA+, Latinx, and other marginalized communities, ¹²⁰ and the e-cigarette industry has followed suit. ¹²¹ This high retailer density and resulting tobacco use exacerbate existing health disparities and burdens experienced by targeted populations. ¹²² Communities interested in regulating tobacco retailer locations to improve public health have several options, including regulating the type of retailers that can sell e-cigarettes and where they can be located.





Case Study

For an example of how one city passed a comprehensive tobacco retailer density policy that includes e-cigarette retailers, see our e-cigarette policy case study: San Francisco's Tobacco Retail Density Regulation.



Types of Licensing Laws and Policies

Local communities often use licensing and zoning laws to regulate how and where tobacco and e-cigarette retailers do business by requiring that retailers implement certain strategies before a license or permit will be granted or renewed. A tobacco retailer licensing (TRL) law requires all stores that sell tobacco products to obtain a license for the privilege of selling these products. An effective TRL law should reflect the best public health policy practices, strike a balance between state and federal minimum standards, and impose clear and practical measures for implementation and enforcement by local governments.

As of 2021, 32 states, the District of Columbia, the Northern Mariana Islands, Palau, and the U.S. Virgin Islands require retailers to have a license to sell e-cigarettes. These licensing laws can address a wide range of potential public health strategies. The most common and effective licensing strategies include restricting the types of businesses that sell e-cigarettes, regulating where retailers can be located, capping the number of retailers in defined areas, restricting point-of-sale advertising, and regulating product placement.



Restricting Types of Businesses that Sell E-cigarettes. Licensing laws are commonly used to restrict tobacco and e-cigarette retail locations. For example, some jurisdictions opt to replicate alcoholic beverage sales restrictions and limit e-cigarette sales to specialty shops, which prohibit underage people from entering. 125 Jurisdictions can also prohibit businesses like pharmacies, healthcare institutions, or even educational institutions from selling tobacco products. 126 Jurisdictions with such restrictions have experienced reduced tobacco retail density after enacting those laws, 127 suggesting that even relatively simple policy solutions can have a measurable impact. Moreover, the promotion and sale of tobacco products online, particularly electronic cigarettes, has also increased in recent years due to app-based "digital convenience retailers" like GoPuff and Postmates, despite regulation and voluntary efforts by credit card companies, PayPal, and private shipping companies. 128 TRL ordinances can require a "tobacco retailer" to be located in a fixed location and restrict licensed retailers to those that sell to walk-in customers. Ordinances can also prohibit direct-to-consumer deliveries or shipments of any tobacco product. 129



Regulating Where Retailers Can be Located. Communities can use licensing laws to restrict how close e-cigarette retailers can be to each other, schools, or other areas frequented by children or young people. These strategies have proven effective in limiting youth access to tobacco retailers. A 2015 study, for example, found that a statewide or county-level 500-foot minimum distance requirement between retailers in North Carolina would remove 1,640 outlets and reduce retailer density by 22 percent. The study also found that a 1,000-foot distance requirement from schools would remove 1,323 tobacco retailers and reduce density by 18 percent. Multiple studies have found even greater reductions when a density policy is combined with a ban on tobacco sales in pharmacies, showing that a combination of policies can have an outsized impact on tobacco retailer density. Further, sales restrictions based on proximity to schools have shown particularly strong potential for reducing socioeconomic and racial disparities by reducing retailer density in low-income neighborhoods. Importantly, jurisdictions should be wary of the potential that simply imposing a location restriction might cause retailers to congregate more densely in other areas.



Restricting Point-of-Sale Advertising. A more challenging policy option communities might consider – in consultation with legal counsel – is to set limits on point-of-sale advertising to combat its effectiveness, particularly on youth. For example, a TRL ordinance could prohibit retailers from honoring or redeeming coupons, multi-pack discounts, or any other type of price adjustment that would allow a customer to purchase a product at less than full retail price. A jurisdiction could also restrict window sign space to no more than 30 percent, limit the type of displays the stores can use (such as outdoor sandwich board-style ads), or prohibit advertisements within a certain distance of schools or playgrounds. ¹³⁵ Carefully review any restrictions or limitations on advertisements and consult with legal counsel to avoid potential constitutional challenges (discussed on page 23).





Capping Number of Retailers in Defined Areas. Retailer density is not uniform in most jurisdictions due to the intentional targeting of low-income communities and communities of color. This has inspired communities to combat disproportionate density by limiting the number of licenses issued to tobacco retailers. One possible approach is to set a cap on the number of vape shops or similar licenses issued in a specific jurisdiction, and once that number is reached, require prospective retailers to join a waiting list until an existing license becomes available.

To effectively reduce the number of retailers over time, communities could consider setting an absolute cap on issuing new licenses when a retailer closes, does not renew a license, retires the license, or enforcement action revokes a license. Policies can also lower that cap over time. For instance, a policy could allow only two new retailers for every three retailers that did not renew or that had their licenses revoked. Over a large geographic area, however, a cap alone may not be effective in reducing disproportionate density in targeted neighborhoods. San Francisco, for example, addressed this problem by breaking the city into 11 districts and limiting the number of retailers to 45 within each district. Cities such as Philadelphia have elected to limit the number of retailers in each of 18 districts to no more than one tobacco retailer per 1,000 residents, meaning the cap will change depending on the population by district. Designing density restrictions requires some groundwork, including population assessments, studies of existing retailers, and retailer education.



Regulating Product Placement. Tobacco products, including e-cigarettes, are always located in a very visible place in a convenience store because product placement sells products. So-called retail "power walls" are large visually appealing displays of products from companies that intentionally compete for prominent product placement in stores. 139 Product displays influence youth purchase attempts, encourage impulse purchases, and undermine cessation efforts. 140 While other countries have been able to prohibit these displays, federal law and the First Amendment limit the restrictions state and local governments can place on displays in the U.S. 141

However, localities can still restrict product placement. For example, although the Tobacco Control Act prohibits self-service displays in most retail locations, many jurisdictions prohibit self-service access to tobacco products, requiring the products to be behind a counter and a clerk to assist in all retail locations. ¹⁴² Other avenues are possible but should involve careful consideration and consultation with legal counsel.

The Public Health Law Center has worked with several jurisdictions, including <u>California</u> and <u>Minnesota</u>, to develop "model" policies that contain sample language, enforcement provisions, and additional explanatory text.





USE RESTRICTIONS

Policies that restrict the use of tobacco products in public areas and workplaces are an important policy step for communities looking to limit tobacco use and reduce exposure to secondhand smoke. Use restriction policies are common in the United States, but they can be strengthened to include e-cigarette use and expanded to cover other areas.

Comprehensive smoke-free laws are supported by strong, well-established scientific evidence on the toxicity and significant negative health impacts of secondhand tobacco smoke. Law Exposure to secondhand smoke significantly increases the risk of stroke, coronary heart disease, cancer, and respiratory conditions for adults as well as children, and kills more than 400 infants every year. Law In the United States, secondhand smoke exposure causes more than 41,000 deaths among nonsmoking adults and an estimated \$5.6 million in lost productivity each year. Law As a result, over 60 percent of the U.S. population is covered by local and state smoke-free laws that prohibit smoking in workplaces, including restaurants and bars. Law Including restaurants and bars. Law Including Includi



PUBLIC HEALTH RATIONALE

Current evidence suggests that the e-cigarette aerosol that users breathe from the device and exhale can contain harmful substances that may pose significant negative health risks.¹⁴⁷ Research has found at least twelve chemicals – including formaldehyde, acetaldehyde, lead, nickel, chromium, arsenic, and toluene – in e-cigarette aerosol known to cause cancer, birth defects, or other reproductive harm.¹⁴⁸ Moreover, e-cigarette aerosol contains varying concentrations of particles and chemicals, with some studies finding particle sizes and nicotine concentrations similar to, or even exceeding, conventional cigarette smoke.¹⁴⁹

In addition to the potential negative health impact of e-cigarette aerosol, failure to include e-cigarettes in smoke-free laws or policies can undermine the intent of smoke-free laws and promote an environment that discourages smoking cessation. Permitting e-cigarette use or vaping where smoking is prohibited can weaken smoke-free policies and tobacco-related social norms, and complicate enforcement efforts. This section describes a variety of settings where e-cigarette use is often prohibited or restricted to protect public health: public places, workplaces, schools, and multi-unit housing. It also discusses other venues where e-cigarettes are sometimes banned, such as outdoor areas.





Sample Language

"Smoking" Definition: "Smoking" means inhaling, exhaling, burning, or carrying any lighted, heated, or ignited cigar, cigarette, or pipe, or any other lighted, heated, or activated tobacco, nicotine, cannabis, or plant product intended for inhalation, including hookah and marijuana, whether natural or synthetic. "Smoking" also means using an electronic smoking device.



Public Places and Workplaces



At least 23 states have smoke-free laws that prohibit e-cigarette use where smoking is prohibited, which typically includes public places and workplaces, such as restaurants and bars. ¹⁵⁰ Many local jurisdictions also prohibit e-cigarette use in these areas.

Smoke-free/vape-free policies for public places and workplaces should contain all the elements of a good policy described in "Getting Started" above, including relevant definitions for the venues or settings where e-cigarette use is to be prohibited. States and localities with smoke-free policies that do not include e-cigarette use might want to consider modifying their policies by revising the definitions of "smoking" or "tobacco product" to encompass e-cigarette use and products. Enforcement and penalties vary by jurisdiction but typically include sanctions similar to those for smoke-free policy violations. These use restrictions, as indeed all tobacco control policies, should be equitably enforced by local communities or similar agents.¹⁵¹

Schools



Another important venue for regulating e-cigarette use is the school setting. Given the high prevalence of e-cigarette use among youth and growing awareness of the health risks associated with vaping, many schools are developing policies addressing e-cigarette use. More teenagers use e-cigarettes than other forms of tobacco products, ¹⁵² and youth spend a substantial portion of their waking hours at school. Therefore, educational institutions are in a unique position to reduce the problem of e-cigarette use among young people. Research suggests that school policies prohibiting tobacco product use, when consistently enforced, significantly lower teen tobacco use rates. ¹⁵³

When enforcing these policies, schools may want to consider <u>alternative enforcement measures</u> other than suspension and expulsion, which disproportionately affect students of color. ¹⁵⁴ Effective solutions to school policy violations focus on helping youth succeed. In light of evidence establishing the targeted marketing of e-cigarettes to youth, ¹⁵⁵ the science of addiction, and the long-term consequences associated with punitive tactics such as expulsion and suspension, these measures may be ineffective and counterproductive. Schools could consider alternative therapeutic interventions, such as offering tobacco education programs, community service, and cessation resources to help treat the underlying problem. The Public Health Law Center has developed a <u>commercial tobacco-free K-12 school model policy</u>, which contains sample language, enforcement provisions, and explanatory text.

Outdoor Places



States and local jurisdictions increasingly include e-cigarette use in their outdoor smoke-free policies that cover areas such as parks, playgrounds, beaches, sidewalks, and other recreational areas and community spaces. Schools, hospitals, and other employers are also adopting smoke-free campus policies, which extend to all outside grounds, such as parking lots, and property – whether owned, leased, or rented. Many campus-wide smoke-free policies include business vehicles. Also, many of these smoke-free policies are being expanded to prohibit e-cigarette use.

Smoke-free Outdoor Public Places. Including e-cigarette use in any smoke-free policy furthers the overall goal of smoke-free policies, whether indoors or outdoors. Outdoor smoke-free laws are typically enacted by city councils, county boards of commissioners, and local boards of health, which exercise their common authority to regulate smoking on public property. Often these laws are extensions of, or amendments to, indoor smoke-free policies.

<u>Smoke-free Campuses</u> and Related Settings. A growing number of colleges, universities, hospitals, and other employers have adopted smoke- or tobacco-free policies, and the <u>majority of these campus smoke-free policies</u> encompass e-cigarette use. Smoke- and vape-free policies in these settings can help reduce the prevalence of tobacco and e-cigarette use among young people and protect those who learn, live, work, and gather in these settings from the health risks of secondhand smoke and e-cigarette aerosol exposure.



Possible Challenges

One challenge that arises with smoke-free policies – particularly those covering outdoor areas – is how to enforce the policies. Effective education about the policy can result in compliance and measurable behavior changes. For example, an <u>Indiana University study</u> found that a campus-wide smoke-free policy that was lightly enforced significantly reduced students' smoking during a two-year period and changed students' attitudes toward smoking regulations. According to one of the study's authors, the positive changes observed in Indiana University despite the lax enforcement "may be attributable to increased awareness of the policy due to signage, media coverage, and a campus-bus completely wrapped with anti-tobacco messaging." This study suggests that the most important element of any smoke-free policy is education that increases a community's awareness of the policy.

Very few outdoor smoke- and vape-free policies have been legally challenged. In most cases, courts have upheld local laws prohibiting smoking in outdoor areas on the grounds that such laws (1) are within the authority of local governments to protect public health, safety, and welfare; and (2) are not preempted (or superseded) by existing statewide smoke-free laws.¹⁵⁸ If statewide smoke-free laws do exist, they typically regulate smoking in enclosed or indoor areas only and rarely address outdoor smoking.



Example of Outdoor No-Vaping Policy

<u>Davis, California</u> expanded its smoke-free outdoor ordinance to encompass the city's outdoor spaces, including parks and recreational areas. Importantly, the updated ordinance employs a comprehensive definition of "smoking" that encompasses not only tobacco, but also "plant, weed or other combustible substance" in any manner or form, and the use of an e-cigarette. The Davis ordinance prohibits smoking (defined to encompass e-cigarette use) in various indoor and outdoor spaces, including enclosed public spaces, public parks and greenbelts, restaurants and bars, including outdoor dining, public events, and within 20 feet of any area in which smoking is prohibited.

Multi-Unit Housing

Indoor air experts and health authorities, including the U.S. Surgeon General and the American Society of Heating Refrigerating and Air Conditioning Engineers, all support inclusion of e-cigarettes in smoking restrictions. ¹⁵⁹ For tenants and owners of multi-unit housing, such as apartments and condominiums, tobacco and e-cigarette smoke infiltration from neighboring units can pose a risk to the health of others in the building. As a result, many local governments, housing authorities, and property owners have taken steps to prevent or eliminate secondhand smoke and provide housing that is 100 percent smoke-free. This section briefly describes policy options local governments, property owners, and landlords can take, provides links to sample language, discusses enforcement provisions and challenges, and describes a sample smoke-free housing policy.



Local Ordinance or Multi-Unit Housing Policy. A smoke-free policy for multi-unit housing developments benefits tenants and residents, as well as property owners and landlords. Studies have shown that tobacco smoke in any form exposes users and bystanders to serious health risks, including lung cancer and cardiac disease in nonsmokers, and is related to severe asthma attacks, respiratory infections, sinus infections, sudden infant death syndrome, and other cardiovascular and pulmonary diseases. ¹⁶⁰ As noted previously, exposure to e-cigarette smoke also poses health risks. ¹⁶¹ More than half of multi-unit housing residents in the U.S. support smoke-free building policies, and smoke-free housing policies ¹⁶² can also save landlords and property owners money by significantly reducing the costs of cleaning and repair. ¹⁶³

The use of cigarettes and other combustible tobacco products is a leading cause of residential building fires, and the use of e-cigarettes does not eliminate the risk of fire. In fact, the lithium-ion batteries in many e-cigarettes are prone to explosion, which can cause both bodily injury and fire damage. E-cigarette liquid also presents the hazard of possible ingestion by children or pets. Yet another benefit for property



owners considering adopting a smoke-free multi-unit housing policy is the likelihood of reduced building maintenance costs because cleaning and replacement expenses are significantly higher in units with tenants who smoke or vape.

Drafting a Smoke-free Multi-Unit Housing Policy.

Local governments and individual property owners and landlords can all adopt smoke-free housing policies that include e-cigarettes. An effective smoke-free housing policy should include an introduction that explains the policy's purpose; clearly defined terms; descriptions of all who must comply (such as residents, guests, and business visitors); and detailed implementation and enforcement information. ¹⁶⁶

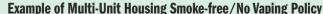
The Public Health Law Center has worked with many jurisdictions, including <u>California</u> and <u>Tribal</u> communities, to develop "model" smoke-free multi-unit housing policies that contain sample language, enforcement provisions, and additional information describing the rationale for certain provisions, as well as options for customizing the language.

Enforcement provisions can vary depending on whether policies are in an ordinance or adopted by landlords or building owners. An ordinance, for example, could contain a provision requiring all multi-unit residential leases to incorporate new lease terms restricting smoking. A jurisdiction could then take enforcement action against the property owner or landlord for violating the ordinance. ¹⁶⁷ On the other hand, a voluntary measure adopted by a landlord or building association could impose smoking restrictions on tenants and residents through lease addenda or similar building policies. Finally, existing legal mechanisms can provide individual tenants some private remedies when they are exposed to secondhand smoke or aerosol in their rental units. ¹⁶⁸



Challenges

Enforcing restrictions on smoking or vaping in multi-unit housing policies should be approached carefully and with health equity in mind. Housing is an important basic need and determinant of health, making the typical remedies in the context of smoke-free policies (e.g., asking a non-compliant person to leave a particular area) potentially unfair and unfeasible. Further, criminal and monetary penalties can carry significant risks of discriminatory enforcement, financial hardship, and housing instability for residents. Thus, entities drafting enforcement provisions in their smoke-free policies should consider community education, engagement, and buy-in, as well as providing information about and access to free cessation support trin before turning to eviction as a remedy.



Contra Costa, California, for example, adopted a <u>Secondhand Smoke Protections Ordinance</u> that prohibits the use of e-cigarettes in multi-unit housing in the county. Contra Costa's ordinance bans the smoking of tobacco products, including electronic smoking devices (e.g., electronic cigarettes, vape pens, Juuls), as well as marijuana, in all multi-unit housing with two or more units, including balconies, decks, and carports. The requirement applies to new and renewed leases as of July 1, 2018. The ordinance also covers areas within 20 feet of doors, windows, ducts, and air ventilation systems of multi-unit housing.



States and local communities may also want to consider implementing policies that raise the price of tobacco products, including e-cigarettes. This can include levying taxes on e-cigarettes or adopting policies that limit or prohibit the price-discounting of e-cigarettes.

Policies that raise the price of commercial tobacco products, including e-cigarettes, are highly effective in reducing tobacco initiation and use and in encouraging cessation, especially among price-sensitive consumers such as youth.¹⁷² Indeed, youth and young adults identify cost as one of the main reasons for their desire to quit e-cigarette use.¹⁷³ High commercial tobacco prices provide a financial incentive for smokers to quit, discourage young people from starting to smoke, and generate revenue that can help fund tobacco control efforts. These policies can be implemented at the local, state, or federal levels.

PRICE DISCOUNTING

Although tobacco taxation, discussed below, is the most common way to increase the cost of tobacco products, the tobacco industry's price discounting strategies can undermine its effect. Tobacco companies spend billions of dollars annually to lower the cost of their products through various price discounting strategies, including coupons, cents- or dollars-off promotions, buy-one-get-one-free deals, and multipack offers (e.g., two-for-one pricing). These promotions are often marketed and the products are redeemed at the point-of-sale. Tobacco companies reportedly spend over 70 percent of their cigarette marketing expenditure on price-discounts.¹⁷⁴

Local governments have several non-tax options available to counter industry price discounting practices, including:



Establishing minimum prices for commercial tobacco products, including e-cigarettes: A growing number of jurisdictions have established minimum prices for commercial tobacco products, including e-cigarettes. For example, San Diego County's tobacco retail licensing ordinance includes a provision setting a minimum price for e-cigarettes. Given the price-sensitivity of young people, setting minimum price policies for e-cigarettes could yield significant public health gains in reducing youth initiation and use. A retailer would thus be unable to sell products below the established minimum price. This type of policy could be crafted so the product price increases over time, either by a fixed amount annually or by tying the increase to inflation. A minimum price law for e-cigarettes could also include a prohibition on price discounts.



Prohibiting price discounts for commercial tobacco products: To keep the price of commercial tobacco products, including e-cigarettes, high and reduce consumption, state and local governments could explicitly prohibit price discounting. Such policies could prohibit all or some forms of price discounting, including the redemption of coupons, cents-or dollars-off promotions, buy-one-get-one-free deals, and multi-pack offers. For more information on these strategies, see <u>Death on a Discount: Regulating Tobacco Product Pricing</u>.

Example of E-Cigarette Pricing Policy

A growing number of local jurisdictions are implementing pricing policies that encompass e-cigarettes or extending existing policies to e-cigarettes. ¹⁷⁵ In 2019, Benton County, Minnesota, for example, updated their <u>tobacco policy</u> to, among other things, prohibit price promotion and coupon redemption. This policy extends to all commercial tobacco products, including e-cigarettes.

POLICY PLAYBOOK FOR E-CIGARETTES 2.0



TAXATION

The most common pricing strategy to combat tobacco use is to raise state cigarette excise taxes. In fact, increasing the price of e-cigarettes by 10 percent has been shown to lead to a 10 to 18 percent reduction in demand or consumption of e-cigarettes – a higher price elasticity compared to combustible cigarettes. Increasing the price of tobacco products has the greatest impact on youth, who are particularly price-sensitive. 176

As a result, states and the federal government often use taxation to decrease tobacco use and generate revenue.¹⁷⁷ As e-cigarette use has increased, particularly among youth, states and localities have begun to adopt e-cigarette-specific taxes. This section will describe the regulatory landscape for e-cigarette taxes, provide links to sample language, discuss key policy considerations, and provide brief examples of state e-cigarette tax policies.

State Action. Taxation is an area of commercial tobacco regulation in which the FDA has no regulatory authority, and Congress has not acted to tax e-cigarettes at the federal level. Therefore, e-cigarette taxation to date has occurred at the state and local level. Because every state's tax code is different, communities and policymakers seeking to tax e-cigarettes should work with an attorney familiar with their jurisdiction's tax code.

Local jurisdictions may have the authority to impose their own taxes, although their ability to do this will likely depend on the availability of resources to administer and enforce a taxation program. When developing tax policies applicable to e-cigarettes, local jurisdictions should consider which parts of the device and its components should be taxed, where a tax should be levied, how the tax should be structured, as well as possible enforcement obstacles.

Taxing Specific Parts of E-cigarette Products. E-cigarettes and their component parts may be subject to taxes differently, depending on how they are sold or their functionality. Some jurisdictions may tax e-liquid that is sold in nicotine cartridges that cannot be removed but may not tax a device that is sold separately from the cartridge. For example, Minnesota adopted an e-cigarette tax in 2013, which includes nicotine solution products but excludes reusable or refillable devices sold separately from starter kits, as well as non-nicotine cartridges or e-juice. 179 North Carolina, meanwhile, taxes "vapor products" at a rate of \$0.05 per fluid milliliter of consumable product. 180







Case Study

For an example of how one city imposed a tax rate on e-cigarettes, see our e-cigarette policy case study: Anchorage's Taxation of E-cigarettes.



In taxing e-cigarette products and their component parts, policymakers should consider including all e-liquid and parts of the device necessary for its operation in the tax base. Such an approach could exempt accessories, such as lanyards or carrying cases, as well as products that have a universal application, such as batteries.¹⁸¹

Where to Levy the Tax. Another important policy consideration is where a tax should be levied. With cigarettes, the product is sold to the consumer in a form identical to that passed on by the distributor or wholesaler. Vape shops, however, often mix e-liquid at the retail level, creating a different, more valuable product. One possible approach is to require retail vape shops that mix product on-site to obtain a special retail license, or perhaps even define the shops as "manufacturers." The feasibility of this approach will be jurisdiction-specific and likely depend on factors such as whether there is a statewide licensing system and whether an e-cigarette tax can be integrated into the existing system or whether the tax code needs to be updated to incorporate new products.

How to Structure the Tax. Most jurisdictions that have enacted e-cigarette taxes have either opted to impose a specific tax on the volume of e-liquid or the amount of nicotine in a product, or they have opted to adopt an "ad valorem tax," which taxes the final product at a percentage of the assessed value of the item. Item. Item leading, an e-cigarette tax would be on parity with other tobacco products to avoid unintentionally influencing marketing and use patterns. Item leads to support the same patterns of the item. Item leads to support the same patterns of the same patterns. Item leads to support the same patterns of the same patterns of the same patterns. Item leads to support the same patterns of the same patterns of the same patterns of the same patterns. Item leads to support the same patterns of the same patterns. Item leads of the same patterns o

In the context of e-cigarettes, an ad valorem tax could minimize the potential negative effects of a volume-based tax, which might incentivize the sale of products separately, or result in higher nicotine concentrations, although a nicotine concentration-based specific tax might also eliminate those concerns.¹⁸⁴ An ad valorem tax also has the additional benefit of inherently including an inflation adjustment, as well as potentially being easier to integrate into an existing tax scheme.¹⁸⁵

Possible Enforcement Obstacles. Due to the unique, jurisdiction-specific nature of tax collection and enforcement, it is important to seek input from those who are charged with implementing and enforcing any proposed tax policy. If an e-cigarette tax is incorporated into existing tobacco-product tax laws, the implementation and enforcement are likely to be much easier than it would be if a completely new tax scheme is created.

Example of E-Cigarette Pricing Strategies

Minnesota taxes e-cigarettes at a rate of 95 percent of the wholesale price of the taxed products. ¹⁸⁶ This percentage also applies to chewing tobacco, snuff, and non-premium cigars. ¹⁸⁷ In Massachusetts, electronic nicotine delivery systems are taxed at a rate of 75 percent of the wholesale price, though this is not the same across different products. ¹⁸⁸ While concentration based nicotine taxes are rare, the Governor of the State of California recently proposed a new e-cigarette tax that would tax e-cigarettes at a rate of \$1 for every 20 milligrams of nicotine – this would be in addition to the existing ad valorem tax already placed on tobacco products in the state. ¹⁸⁹





In addition to the policies described earlier, states and local jurisdictions may want to consider other strategies to regulate e-cigarettes depending on their community's goals, resources, tobacco control history, stakeholders, political will and support, state preemption, and other considerations.¹⁹⁰

SALES RESTRICTIONS

Restricting the sales of commercial tobacco products, including e-cigarettes, is an effective way to limit youth access, use, and initiation to these products. Sales restrictions may be included as part of a broader licensing structure or, where a licensing scheme is not feasible, as stand-alone policies. Common ways to restrict tobacco sales are (1) to restrict the sales of e-cigarettes (regardless of flavor); (2) to restrict the sale of flavored tobacco products, including e-cigarettes, which are known to be very popular among youth; and (3) to establish a minimum legal sales age for tobacco products.



FLAVORED TOBACCO

Numerous studies indicate that flavors in e-cigarettes make them more appealing to young people. 191 Most youth and young adults who use e-cigarettes report using a flavored product, and many claim they were drawn to e-cigarettes because "they come in flavors I like." 192 The thousands of appealing flavors in e-cigarettes undoubtedly have contributed to the epidemic use of these products among youth. Thus, restricting the sales of flavored e-cigarettes would likely offer substantial public health benefits in reducing e-cigarette initiation and use.

The federal government's limited regulation of e-cigarettes offers state and local governments an opportunity to close existing loopholes. As mentioned above, while the Family Smoking Prevention and Tobacco Control Act prohibited the sale of flavored cigarettes, this flavor ban **did not extend to menthol-flavored cigarettes or other non-cigarette tobacco products, such as cigars and e-cigarettes.** ¹⁹³

In early 2020, in the wake of alarming reports of vaping-related lung injury, the U.S. Food and Drug Administration (FDA) enacted a minimal and temporary measure to restrict the sales of e-cigarettes: the agency issued guidance prohibiting the sales of pod- or cartridge-based e-cigarettes that are not flavored with menthol or tobacco. This measure is minimal because it does not include all e-cigarettes, other tobacco products, or all flavors. It is also temporary because the prohibited products may be readmitted into the market following the FDA's premarket review process.

<u>State and local governments</u> are increasingly acting to close existing loopholes related to the regulation of sales of flavored tobacco products, including e-cigarettes. In September 2020, for example, California became the second state following <u>Massachusetts</u> to pass a <u>fairly comprehensive prohibition</u> (including e-cigarettes and menthol-flavored cigarettes) on the sales of flavored tobacco products. Many local jurisdictions have also enacted similar measures.







Case Study

For an example of how one county amended its tobacco retail license to prohibit retail sales of all flavored e-cigarettes, see our e-cigarette policy case study: <u>Santa Barbara County's</u> Sales Restriction of Flavored Tobacco Products.

RAISING THE MINIMUM LEGAL SALES AGE

Policies that raise the minimum legal sales age ("MLSA") of tobacco products are also effective in reducing youth tobacco initiation. National data indicates that 95 percent of adults who smoke begin smoking before they turn 21. 195 Moreover, the time between ages 18 and 20 is a critical period when many adults who smoke move from experimental smoking to regular, daily use. 196 In 2015, the Institute of Medicine (now the National Academy of Medicine) concluded that raising the MLSA for tobacco products nationwide would reduce tobacco initiation, particularly among adolescents aged 15 to 17, improve health across the lifespan, save lives, and over time, lead to a 12 percent decrease in smoking prevalence. 197 According to a recent study, exposure to local tobacco 21 policies is associated with decreased likelihood of tobacco use among youth. 198

In December 2019, Congress passed amendments to the Tobacco Control Act, which raised the minimum legal sales age for tobacco products from 18 to 21. **Despite this law, states and local jurisdictions with minimum legal sales ages under 21 should still consider amending their laws.** Since all retailers are subject to the federal law, alignment with the federal law would provide clarity for retailers trying to comply with the law and ease enforcement for state and local authorities.

Moreover, funding for states and U.S. territories from the Substance Abuse and Mental Health Services Administration (SAMHSA) under the Synar Amendments will be tied to the new federal legal sales age of 21. Finally, it is important to note that the federal law merely sets a floor, not a ceiling; states and local jurisdictions remain free to raise their minimum legal sale age beyond 21.

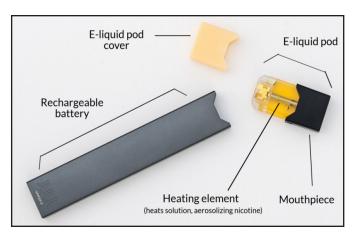




E-WASTE/HAZARDOUS WASTE

The nicotine in e-cigarettes is considered a particularly harmful – "acute" – <u>form of hazardous waste</u> by the U.S. Environmental Protection Agency (EPA). That designation, along with the fact that e-cigarette batteries can <u>catch fire and explode</u>, means that most e-cigarettes carry a unique health and safety hazard and should be handled and diposed of in accordance with EPA, state, and local requirements for hazardous waste management.²⁰⁰ Most young people, however, <u>do not know how to properly dispose</u> of e-cigarettes, as e-cigarette manufacturers have been less than transparent about the hazardous waste status of their products.²⁰¹

Some states and localities have already begun grappling with how to provide guidance to schools, government entities, retailers, and others on how to properly handle and dispose of e-cigarettes that are confiscated or <u>disposed of on school grounds</u>. For example, Colorado's Department of Public Health and the Environment has issued <u>guidance</u>²⁰² to businesses, government agencies, and schools on proper handling and disposal of e-cigarettes, and Utah's Department of Environmental Quality has issued its own <u>guidance</u>²⁰³ to retailers. The FDA Center for Tobacco Products has a "best practices" <u>guide</u>, ²⁰⁴ and the Public Health Law Center has a <u>publication</u>²⁰⁵ on e-cigarette disposal for schools and other organizations. EPA representatives have also <u>indicated</u> that the agency plans to issue guidance to schools on the proper handling and disposal of e-cigarettes.



Jurisdictions or other entities seeking to implement policies or provide guidance to help curb the accumulation of e-cigarette hazardous waste at schools and elsewhere should contact their local hazardous

waste departments to determine how to best handle and dispose of these devices. Ultimately, any policy or practice that has an impact on consumption, including but not limited to policies that restrict the sale of e-cigarettes, can have a beneficial impact on their environmental footprint.





Case Study

For an example of how one county collected and disposed of vaping products in all its schools, see our e-cigarette policy case study: <a href="Mounty-state-collection-example-collectio

POLICY CONSIDERATIONS

State and local governments – where not preempted by the state – generally have the authority to pass, implement, and enforce laws that regulate the sale of tobacco products, including e-cigarettes, and they can do so in ways that address local concerns. Still, due to the tobacco industry's interest in protecting its profits, even the most carefully drafted e-cigarette regulation cannot avoid all risk of legal challenges.

POSSIBLE LEGAL CHALLENGES TO E-CIGARETTE POLICIES

Communities considering measures to regulate e-cigarettes should ensure that policies are drafted carefully and that they are aware of potential legal issues. This section describes several common claims brought by the industry: a jurisdiction's alleged lack of local authority to pass the policy, its alleged violation of the "takings" clause of the Fifth Amendment of the U.S. Constitution, and its alleged infringement of the First Amendment's free speech protections.

Authority & Preemption

Any governmental unit seeking to regulate e-cigarettes should first ensure that it has the authority to enact the regulation. While states have the authority to pass regulations restricting or prohibiting commercial tobacco sales or use, a local government's authority depends largely upon the authority a state has reserved for itself and what it has delegated to local governments through special legislation, home rule charters or similar laws. Even where local legislative authority generally exists, preemption may bar local legislation on a particular issue. Preemption occurs when a higher level of government (e.g., federal or state) eliminates or limits the authority of a lower level of government (e.g., state or local) to regulate a certain issue. A local government wishing to implement any e-cigarette regulation should investigate its state's tobacco regulatory scheme to ensure that the local government is not preempted from enacting tobacco or e-cigarette regulations. For more on the doctrine of preemption and local authority, please see the Public Health Law Center's resources.

"Takings" Under the Fifth Amendment of the U.S. Constitution

The Fifth Amendment of the U.S. Constitution states, in part: "[N] or shall private property be taken for public use, without just compensation." This is commonly referred to as the "Takings Clause." There are two ways the government can take property under the Fifth Amendment: (1) a possessory taking (which involves physical occupation, as in eminent domain) and (2) a "regulatory" taking. A regulatory taking occurs when a law impedes a property owner's investment so significantly that it amounts to a "taking" of the property.

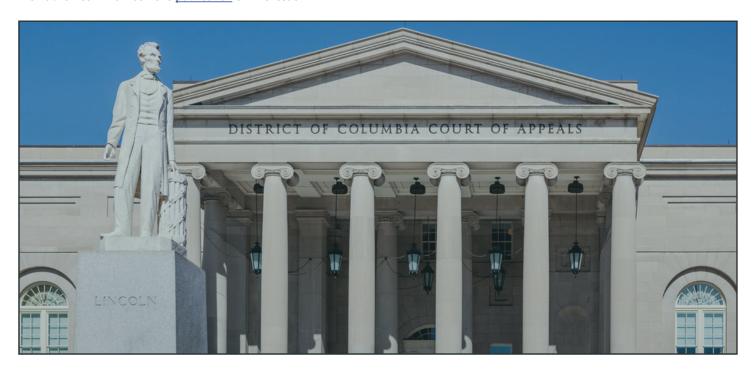
E-cigarette manufacturers and vendors may argue that because these products make up a substantial portion of their sales, any state or local regulation that prohibits their sale constitutes a "taking." To determine whether or not the law constitutes a taking requires a fact-specific analysis of the nature of the action balanced against the interests involved. ²¹⁴ While a local or state law restricting the sale of e-cigarettes might have some economic impact on vendors, it would

Example of Legal Challenges Based on Preemption

As flavored products and e-cigarette sales restrictions become more common, the tobacco industry has raised federal preemption-based arguments in its legal challenges. Recently, the city of Los Angeles's flavored product ordinance faced two legal challenges from the tobacco industry. The industry plaintiffs argued that because Los Angeles's ordinance prohibited the sale of flavored products, which necessarily involves placing restrictions on the products' ingredients and additives, the ordinance was preempted by the Tobacco Control Act. The federal district court judge dismissed both cases, finding that the ordinance imposed a sales restriction, not a tobacco product standard. Because the ability of state and local governments to impose sales restrictions on certain products is expressly preserved in the Tobacco Control Act, the court ruled that the ordinance is not preempted. P.J. Reynolds appealed the ruling to the Ninth Circuit Court of Appeals. The case was argued before a three-judge panel on October 19, 2021, and the parties are awaiting a ruling.

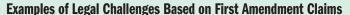


still allow for a substantial volume of other economic activity, such as the freeing up of space to sell other products.²¹⁵ Further, the analytical balancing test would require weighing the economic burden on the industry in light of the public health nature of the action and the social benefit of reducing youth use rates of e-cigarettes. Given existing legal precedent, it is likely that the government's interest in the common good would outweigh the economic impact on the industry. For more on the Takings Clause in the context of tobacco regulation, please see the Public Health Law Center's publication on this issue.²¹⁶



First Amendment Challenges

Although the Tobacco Control Act allows states and localities to place some restrictions on tobacco marketing, the First Amendment still protects speech by tobacco companies, thus acting as a limitation on the FDA's authority over marketing and advertising restrictions. The First Amendment has been interpreted to protect a broad range of spoken and written communication, as well as expressive conduct. Because of speech includes advertising, banners, logos, etc., and can include expressive conduct, such as how products are displayed in a store window. The level of protection certain speech is afforded depends on the type of speech at issue, and the limitations the government places on that speech. First Amendment protections are also implicated when the government compels speech – e.g. when it requires a warning label on a package.



First Amendment claims brought by the tobacco industry are common. In fact, the tobacco industry has been fighting the Tobacco Control Act's graphic warning labels requirement (applicable to cigarette packages and advertisements) since shortly after it was passed. In 2009, six manufacturers and retailers challenged the graphic warning label requirement under the Tobacco Control Act in *Discount Tobacco City & Lottery, Inc. v. United States*, ²²³ and two years later, the industry challenged the first iteration of the graphic warning rule issued by the FDA. ²²⁴ The graphic warning requirement in the Act was upheld by the Sixth Circuit in Discount Tobacco, but the rule itself was overturned by the D.C. Circuit Court of Appeals in 2012. ²²⁵ Eight years later, after being successfully <u>sued by public health groups</u> for its long delay, ²²⁶ the FDA issued a second iteration of the graphic warning rule. ²²⁷ This rule was also challenged in two separate industry-led lawsuits, which are being litigated in district courts as this publication goes to press: *R.J. Reynolds Tobacco Company et al. v. U.S. Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. Apr 03, 2020) and *Philip Morris USA Inc. and Sherman Group Holdings, LLC v. U.S. Food and Drug Administration et al.*, No. 1:20-cv-01181 (D.D.C. May 06, 2020).



OTHER E-CIGARETTE LAWSUITS

While there are many legal challenges that center on claims brought by the tobacco industry against governmental entities, there are also examples of individuals, localities, school districts, and states bringing lawsuits against e-cigarette companies – most notably Juul Labs, Inc., – for their role in fueling the e-cigarette epidemic. For example, there is currently a large, multidistrict lawsuit underway that consolidates lawsuits filed across the U.S., all alleging that Juul marketed its e-cigarettes intentionally to attract youth; that its marketing misrepresented that its products were more addictive than combustible cigarettes, that the products are defective and unreasonably dangerous, and that they created a public nuisance that the company should be required to help abate, among other claims. ²²⁸ As with the lawsuits brought against tobacco companies in the 1990s, many of these lawsuits also allege violations of the Racketeer Influenced and Corrupt Organizations (RICO) Act, which is a federal law designed to combat organized crime.

Several states have also filed suits against Juul alleging that the company engaged in unfair and deceptive trade practices, marketing and targeting highly addictive nicotine products to youth and misleading them on the risks associated with these products. Thus far, Juul has entered into settlement

agreements with two states – North Carolina²²⁹ and Arizona.²³⁰ Among other things, these agreements require the company to make monetary payments to the states and to cease marketing and advertising that appeal to persons under the age of twenty-one, including the use of social media and social media influencers, and outdoor advertising near schools.



FUTURE POSSIBLE CHALLENGES

E-cigarettes are relatively new products in comparison to combustible cigarettes. The e-cigarette industry and its spin-off products and accessories continue to evolve, while promotional innovations, including the phenomenal influence of social media, exert a huge impact on the market. Although the FDA's regulation of e-cigarettes is currently minimal, the federal regulatory landscape may change in the future.

Policymakers and regulators need to remain alert to all product, marketing, and regulatory actions, craft policies that can accommodate foreseeable changes, and update policies as necessary and appropriate for public health.

OTHER REGULATORY ISSUES AND CONCERNS

While any policy regulating e-cigarettes is a step in the right direction to protect the health of youth, unintended consequences can occur unless such policies are part of a comprehensive regulation of all commercial tobacco products. For instance, a policy banning flavored e-cigarettes that does not include menthol increases the risk that youth users will simply switch from banned e-cigarette flavors to menthol e-cigarettes if they are not already using a mint or menthol flavor. Even a ban on all flavored e-cigarettes including menthol could push nicotine-addicted youth to transition to menthol-flavored combustible cigarettes or flavored cigarillos or cigars, which are legally sold in most communities. Regulating e-cigarettes as part of a comprehensive commercial tobacco regulation also eases enforcement and supports the community's overall public health goal.

Regulating e-cigarettes as part of a comprehensive commercial tobacco regulation also eases enforcement and supports the community's overall public health goal.

E-CIGARETTES: BACKGROUND & OVERVIEW

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- Youth Tobacco Use: Results from the National Youth Tobacco Survey, U.S. Food & Drug Administration
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- <u>U.S. E-Cigarette Regulations-50 State Review</u> (50-state review of state e-cigarette regulations, updated quarterly), Public Health Law Center

FEDERAL E-CIGARETTE REGULATION

- Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS), U.S. Food & Drug Administration
- Extension & an E-Cigarette Epidemic: FDA's Gatekeeping Authority for E-Cigarettes, Public Health Law Center
- Other Public Health Law Center resources related to e-cigarettes and federal regulation

TOBACCO RETAIL LICENSING

- ASPiRE Center to Tobacco Retail Licensing website resources
- Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, U.S. Department of Health & Human Services
- STATE System Licensure Fact Sheet, Centers for Disease Control & Prevention
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- <u>Licensing, Zoning, and Retailer Density, Counter Tobacco</u>
- Location, Location, Location: Tobacco & E-Cig Point of Sale Regulating Retailers for Public Health, Public Health Law Center
- Comprehensive Tobacco Retailer Licensing Ordinance (sample model ordinance), Public Health Law Center
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SMOKE-FREE/VAPE-FREE/USE RESTRICTIONS

- The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General, U.S. Department of Health and Human Services
- <u>CDC Vital Signs—Secondhand Smoke: An Unequal Danger</u>, Centers for Disease Control and Prevention
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- <u>Taxation of Emerging Tobacco Products</u>, Tobacconomics
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- Death on a Discount: Regulating Tobacco Product Pricing, Tobacco Control Legal Consortium
- Regulating Tobacco Product Pricing: Guidelines for State and Local Governments, Tobacco Control Legal Consortium

FLAVORED TOBACCO PRODUCTS (INCLUDING E-CIGARETTES)

- Regulating Flavored Tobacco Products, Public Health Law Center
- U.S. Sales Restrictions on Flavored Tobacco Products, Public Health Law Center
- Tobacco Products and Health Harms: Flavored Tobacco Products, Campaign for Tobacco-Free Kids

TOBACCO 21

- Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products, Institute of Medicne
- <u>The Health Consequences of Smoking 50 Years of Progress: A Report of the Surgeon General</u>, U.S. Department of Health & Human Servixwa
- Tobacco 21: Model Policy, Public Health Law Center
- The Vape Epidemic, Tobacco Twenty-One

TOBACCO PRODUCT WASTE

- <u>Tobacco and Its Environmental Impact: An Overview, World Health Organization</u>
- Alert: Public Health Implications of Electronic Cigarette Waste, 108 Am. J. Pub. Health 1489, Yogi Hale Hendlin
- Disposing of E-Cigarette Waste: Frequently Asked Questions for Schools and Others, Public Health Law Center
- Tobacco Product Waste: Frequently Asked Questions, Public Health Law Center and American Lung Association of California
- Commercial Tobacco Pollution, Public Health Law Center
- Other Public Health Law Center resources related to tobacco product waste

ADVOCACY TOOLS & INTERVENTIONS

- Nine Questions: A Strategy Planning Tool for Advocacy Campaigns, County Health Rankings
- <u>Public Health Media Advocacy Action Guide: Elements of a Media Advocacy Campaign</u>, Advocacy Incubator
- Advocacy Action Guide: A Toolkit for Strategic Policy Advocacy Campaigns, Advocacy Incubator
- Youth Advocacy Toolkit, Tobacco Resistance Unit (TRU)
- Reducing Vaping Among Youth and Young Adults, Substance Abuse and Mental Health Services Administration (SAMHSA) Guide



POSSIBLE LEGAL CHALLENGES TO COMMERCIAL TOBACCO REGULATIONS

General

- Public Health Law Center resources on commercial tobacco litigation
- Public Health Law Center resources on federal tobacco regulation and related legal challenges

Local Authority & Preemption

- Public Health Law Center, Dillon's Rule, Home Rule, and Preemption
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- Tobacco Control Legal Consortium, <u>Preemption: The Biggest Challenge to Tobacco Control</u>

Takings

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- Tobacco Control Legal Consortium, Regulating Tobacco Marketing: "Commercial Speech" Guidelines for State and Local Governments
- Tobacco Control Legal Consortium, Restricting Tobacco Advertising Tips & Tools
- Public Health Law Center, <u>Commercial Speech Flowchart for Public Health Regulation</u>



ORGANIZATIONS

CHECK OUT PARTNERING ORGANIZATIONS WHO SUPPORT A WIDE ARRAY OF VAPING PREVENTION & CONTROL ACTIVITIES.



Public Health Law Center at the Mitchell Hamline School of Law



Vaping Prevention Resource



<u>UNC Lineberger</u> Comprehensive Cancer Center



Counter Tools



American Lung Association



American Heart Association



American Cancer Society



Center for Tobacco Products



Truth Initiative



ChangeLab Solutions



Campaign for Tobacco-Free Kids



Tobacconomics



Preventing Tobacco Addiction Foundation/Tobacco 21



Parents Against Vaping E-Cigarettes

Centers for Disease Control and Prevention (CDC)

American Nonsmokers' Rights Foundation

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- on the claimant;" "the extent to which the regulation has interfered with distinct investment-backed expectations;" and "the character of the governmental action." *Id.* at 124.
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