Chapter 9
The E-Cigarette Regulatory Landscape: Policy and Advocacy Approaches

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Introduction

Electronic cigarettes (e-cigarettes) entered the US marketplace around 2006 [1, 2]. At the time, traditional cigarettes were subject to regulations established decades prior. E-cigarette producers strategically circumvented those tobacco ordinances and have been able to market, sell, and dramatically expand the use of e-cigarettes in a largely unregulated market [3].

Regulatory delays have been fueled by legal controversies regarding how to classify electronic cigarettes; well-funded industry challenges to campaigns to regulate the manufacture, import, and sale of said products; legislative loopholes; aggressive advocacy efforts of lobbyists and pro-vaping groups; deceptive marketing; and controversial claims that e-cigarettes are harm-reducing products [3]. All of these missteps have worked in tandem, continuing to play a crucial role in the rapidly evolving youth vaping crisis.

As Big Tobacco companies own a substantial portion of the e-cigarette market, it is perhaps not surprising that the e-cigarette industry's current product growth strategies mirror those tobacco companies used years ago [2, 4, 5]. These tactics are designed to encourage youth smoking initiation and foster a lifetime of nicotine addiction, without regard for potential health consequences. Recent data underscores the industry's marketing success and disregard for the public's health. In less than a decade, rates of e-cigarette usage and associated disease have rapidly skyrocketed, particularly among adolescents. In 2011, 1.5% of high school students reported e-cigarette use in the past 30 days [6]; in 2016, high school student use had

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risen to 11.3%. By 2020, rates of high school student e-cigarette usage rose to 19.6%; 4.7% of middle school students also reported e-cigarette use in the last 30 days. Based upon these statistics, it is estimated that in 2020 over 3.5 million high school and middle school students used electronic cigarettes [7, 8].

In 2018, after delaying to impose e-cigarette regulations that had been written into federal law, Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration (FDA) at the time, declared e-cigarette use among adolescents an "epidemic," noting that "E-cigs have become an almost ubiquitous–and dangerous–trend among teens" [9]. In fact, large numbers of e-cigarette users have become addicted to nicotine; many will eventually turn to traditional cigarettes, vape other substances, and suffer acute or chronic adverse health consequences [10, 11]. Thousands of e-cigarette users have been hospitalized with the acute lung disease electronic cigarette or vaping-associated lung injury (EVALI), and numerous individuals are known to have died of e-cigarette-related illnesses [12–15].

Federal Regulations

The Federal Government's efforts to regulate e-cigarettes have been marked by legal battles, recurrent federal delays, loopholes, and only limited success. The first federal attempt to assert authority over these products occurred in 2008, when the FDA issued an import alert guiding districts to seize shipments of electronic cigarettes from China and ban the goods from entering the United States [16, 17]. Classifying e-cigarettes as "unapproved drug-device combination products," the FDA claimed that without FDA approval the products, like all FDA unapproved drug-devices, are prohibited under the Federal Food, Drug, and Cosmetic Act (FD&C Act) [17, 18].

FDA efforts to ban e-cigarette entry into US markets resulted in multiple drawn-out court battles [18]. Electronic cigarette manufacturers Smoking Everywhere and Sottera (now NJOY) challenged the FDA in court, arguing that in fact their products did not meet the criteria of "unapproved drug-device combination products" (*Sottera v FDA)* as they did not provide therapeutic effects [19, 20]. While the legal battles played out in court, e-cigarettes were aggressively marketed, distributed, and sold throughout the United States and their use continued to increase.

Advocacy groups such as Action on Smoking and Health and a coalition that included the American Medical Association, the Campaign for Tobacco Free Kids, the American Cancer Society, and the American Heart Association campaigned to grant the FDA authority over e-cigarettes based on law written into the *Federal Food, Drug, and Cosmetic Act (FD&C Act)* [21]. Some state and government officials, including the National Association of Attorney Generals, also advocated in favor of granting the FDA power to regulate e-cigarettes as well as to ban e-cigarette sales and use [22]. In September 2009, California passed a bill banning the sale of e-cigarettes in the state, yet Governor Schwarzenegger overruled the bill [23]. In 2010, legislators in New York and Illinois also submitted bills to ban e-cigarettes;

those bills failed to pass [3, 24, 25]. Supporting anti-smoking groups and electronic cigarette legislation, internet giant Amazon banned the sale of e-cigarettes on their website in 2009 and PayPal froze all e-cigarette vendor accounts that same year [21].

Nevertheless, in December 2010, the courts ruled in favor of the e-cigarette manufacturers, determining that electronic cigarettes cannot be classified as "drug-device combination products" or regulated as such. The courts further ruled that e-cigarettes must be classified and regulated as "new tobacco products" [18], while recognizing that they contain tobacco-derived substances, such as nicotine, rather than actual tobacco [19, 26].

In June 2009, prior to the court's ruling, President Barack Obama signed the *Family Smoking Prevention and Tobacco Control Act* (*Tobacco Control Act*). This legislation amended the *FD&C Act* and granted the FDA authority to regulate "the manufacturing, distribution, and marketing of tobacco products," including cigarettes, cigarette tobacco, and smokeless tobacco products [27, 28]. In 2010, when the courts classified e-cigarettes as "new tobacco products," the courts also determined that the FDA's authority to regulate those products required formal revision of the *FD&C Act*, through the addition of the Deeming Rule [29]. During the period of time from 2010 (when the courts granted the FDA jurisdiction over e-cigarettes as new tobacco products) until 2016 (when the FDA finally published the Deeming Rule), e-cigarettes were intensely marketed and sold in a federally unregulated market; their use soared.

A draft of the Deeming Rule was first proposed in 2014, some 4 years after the court's ruling [29]. It was not until August 2016 that the FDA released the final Rule, extending the authority granted to the FDA to regulate "all tobacco products," including electronic cigarettes and other electronic nicotine delivery systems (ENDS), pipe tobacco, cigars, and hookah and waterpipe tobacco. The Rule grants the FDA oversight of e-cigarette ingredients, warnings regarding potential product health risks, and the registration of manufacturers [29, 30]. The Rule also sets a federal minimum age of sale of 18, requires retailers to obtain photo identification (ID) verification of the age of those under 27, prohibits distribution of free e-cigarette samples, and limits vending machine e-cigarette sales to adult only facilities [27, 29]. Importantly, the rule establishes an FDA premarket tobacco product application (PMTA) review process that requires the FDA's approval of all e-cigarettes prior to a product's sale in the marketplace [14, 29]. When submitting an application to market an e-cigarette product, manufacturers must "provide scientific data that demonstrates a product is appropriate for the protection of public health" [29, 31].

Two years after the passing of the Deeming Rule, the PMTA review process had still not been implemented. In fact, in August 2017 the FDA extended the deadline for the industry to submit a PMTA to August 2022 while continuing to allow e-cigarettes to be marketed and sold. In response to this extension, in 2018 a coalition of the American Academy of Pediatrics, the American Medical Association, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco Free Kids, and the Truth Initiative sued the FDA and the Department of Health and Human Services [32]. After

many court battles, the application deadline was changed to September 9, 2020 [33]. The FDA has nearly 1 year to review submitted applications and determine whether products are proven to be safe and can be legally marketed and sold [31]. During this review period, products can remain on sale in the marketplace. As such, the e-cigarettes on the market at the time of this writing have not been evaluated or approved by any government regulatory agency, nor have they been determined to be safe.

State and Local Tobacco Regulations

The 2009 *Tobacco Control Act* grants states and localities the explicit authority to enact tobacco control policies in addition to those established under federal law, specifically in areas in which the FDA has not been granted authority to set regulations [27, 28]. By law, states and municipalities can legislate smoke- and aerosol-free zones, increase tobacco taxes, establish product prices, raise the minimum legal sales age above 18, and even prohibit the sale or use of certain categories of tobacco and vaping products [18, 26].

While state governments play a crucial role in protecting the public's health through legislation, earlier tobacco control efforts illustrate that policy-based campaigns that begin at the local level are often more effective and efficient than those initially promoted at the state level [3, 34]. State-level tobacco control campaigns can be hindered by well-funded tobacco industry lobbying and targeted campaign contributions to key legislators [3, 35]. By contrast, local governments tend to be more responsive to their constituents, health professionals and community organizations than they are to lobbyists. In many instances, local government has been shown to offer a viable avenue for successful tobacco control legislation, as grassroots efforts launched at the local level can mobilize constituents and lead to statewide or even national legislation (Table 9.1) [3, 34]. As described below, many states and localities have passed tobacco control legislation, though e-cigarette regulations continue to lag behind those of traditional tobacco products.

Tobacco-Free Policies

Combustible Tobacco Smoke-Free Policies

Long before the arrival of e-cigarettes in the United States, for much of the mid-twentieth century, smoking was a centerpiece of American culture; smokers were free to light-up almost anywhere. Individuals were commonly found smoking combustible cigarettes in public spaces such as workplaces, hospitals, doctors' offices, restaurants, and on buses, trains, and airplanes. Images of cigarettes and smokers were prevalent, seen on billboards and magazine covers and in newspapers, television shows, and movies [37, 38].

Table 9.1 Strategies and operationalization for public health advocacy [34]

Strategy type	Operationalization
Local advocate/change agent	Recruit respected members of local community, who can coordinate with local and national advocacy groups and use vignettes to illustrate the importance of proposed legislation. Include nurses, pediatricians, counselors, school administrators, teachers, etc.
Geographic proximity	Enlist leaders from locations that have already passed the proposed legislation to approach bordering jurisdictions yet to pass. Work with more progressive border towns of major cities to pass the legislation first, in order to "surround" locations where passage might be more challenging.
Simple messaging	Develop a one-page document with the key arguments for the proposed legislation concisely summarized. Poll jurisdictions and ask if they would like more information regarding the proposed legislation. Start advocacy with those jurisdictions expressing greatest levels of interest.
Youth advocacy	Work with youth advocates, such as high school and college students, to advocate for passage.
Inoculation against counterarguments	Understand the most common counterarguments and preempt those arguments with opposing research and data.
Press and media [36]	Develop op-eds and contact the press/media about meetings to provide local coverage.

It was not until the 1970s and 1980s that evidence of the harmful health effects of inhaling secondhand smoke emerged. While the tobacco industry and multiple smoker-advocacy groups pushed back on the scientific findings, national groups such as the American Nonsmokers' Rights Foundation and Action on Smoking and Health, and grassroots organizations such as the Group Against Smoking and Pollution actively petitioned for designated non-smoking areas in public places [39]. These early advocacy efforts launched the non-smokers' rights movement. This powerful coalition of individuals and organizations successfully campaigned at the state and local levels for smoke-free policies designed to protect non-smokers from the health consequences of secondhand smoke, effectively discouraging smoking initiation and a culture that embraces cigarette use [40].

The first smoke-free state legislation was passed in the 1970s, when states such as Minnesota began to limit smoking through the creation of smoking and non-smoking zones in public spaces [37, 39]. Over time, other states and localities enacted smoke-free ordinances, which varied in scope and in the nature of their restrictions. In 1990, San Luis Obispo, California, became the first municipality to pass major smoke-free legislation, banning smoking in buildings open to the public, including restaurants and bars. In 1995, Utah banned smoking in restaurants, becoming the first state to pass a statewide smoke-free law. California followed, banning smoking in restaurants in 1995 and in bars in 1998. In 2002, Delaware passed the first comprehensive smoke-free laws, laws that the CDC defines as prohibiting smoking in all indoor worksites, restaurants, and bars [41]. New York soon followed, passing comprehensive smoke-free restrictions in 2003 [42, 43].

As of April 2021, 27 states and the District of Columbia have passed comprehensive smoke-free laws. Nine additional states have passed more stringent legislation, limiting the restrictions to workplaces, restaurants, and/or bars, but not all three locations. Further, over 1000 cities and counties have enacted comprehensive smoke-free mandates, and an additional 450 localities have passed less inclusive smoke-free legislation [43]. Private organizations and industries, such as hotels and gyms, have also established rules that ban combustible cigarette use on private property or limit the usage of tobacco products to designated smoking areas. Some of these private locations that prohibit or limit smoking are found in states in which there are otherwise few smoke-free regulations [44, 45].

Although most efforts to enact smoke-free laws banning traditional tobacco product use have been left to states and municipalities, the Federal Government and its agencies have passed smoke-free policies that specifically focus on three types of locations: Federal Government buildings, airlines, and public housing. In 1997, President Clinton issued Executive Order 13058, banning smoking in all Federal Government buildings [46]. Tobacco control advocates had campaigned for such a policy as early as 1971, while previous presidents had drafted similar executive orders and multiple legislatures had proposed such a policy in the senate. However, responding to tobacco lobbyist pressures, the attempts of earlier administrations to sign such restrictions into law were defeated [47]; only at the end of the century was this Executive Order finally issued.

In the airline industry, federal restrictions were imposed only years after individual consumers and organized groups, such as flight attendants, voiced complaints to the industry and its leaders regarding dangerous exposures to secondhand smoke. Those who opposed the harms of secondhand smoke also advanced their agenda by joining the advocacy efforts of groups such as "the Group Against Smoking and Pollution and the American Nonsmokers' Rights Foundation, organizations that had battled for years with tobacco lobbyists and secured the support of the American Medical Association, the American Lung Association, and the American Heart Association [37].

In 1971, United Airlines became the first airline company to identify smoking and non-smoking zones on their aircraft. Soon, other airlines followed. By 1973, the Civil Aeronautics Board declared the establishment of non-smoking sections on all airplanes to be a federal requirement [37]. While the tobacco and airline industries joined forces to defeat all efforts to ban smoking on airlines, the first such ban went into effect in 1988, eliminating smoking on all flights of 2 hours or less. By early 1990, legislation had passed banning smoking on all domestic flights [37, 44]. In 1995, after Delta Air Lines banned smoking on all domestic and international flights, other airlines also adopted this smoke-free policy. By 2000, a comprehensive federal law was finally passed banning traditional cigarette smoking on all flights entering and leaving the United States, an important victory for individuals and groups that had championed non-smokers' rights since the early 1970s [48].

In 2016, a third federal smoke-free zone was established by the US Department of Housing and Urban Development (HUD) [49]. This action followed intense local, city, and state advocacy efforts that were accelerated by legal and ethical

arguments to ban smoking in all public housing authorities [50]. HUD passed a rule requiring all public housing agencies to implement a smoke-free policy banning the use of tobacco products—excluding e-cigarettes—in low-income public housing units by July 2018 [49]. This ordinance was encouraged by a study that found that children in multi-unit housing complexes had significantly higher rates of cotinine biomarkers in their blood, even when no one in their personal housing unit smoked [51]. The successes of tobacco control activists, who battled with the tobacco industry and lobbyists regarding regulating smoke-free zones, illustrate an effective model in which public health action at the grassroots level spurs important legislative and even industry-wide change [34].

E-Cigarette Clean Air Policies

Notably, while states, municipalities, federal agencies, and industries have gradually endorsed smoke-free rules regulating traditional tobacco products, e-cigarettes are not automatically subject to these same prohibitions. In fact, because smoke-free laws were written to prohibit "smoke" and e-cigarettes emit an aerosol that contains a suspension of fine particles and harmful chemicals rather than smoke, policy makers initially failed to prohibit smokers from using e-cigarettes in most locations [1]. The tobacco industry has taken full advantage of this legislative loophole, originally marketing e-cigarettes as devices that circumvent smoke-free zones and provide individuals with the "freedom to smoke anywhere" [52, 53].

As of 2021, some states and municipalities have amended their existing smoke-free policies to include e-cigarettes, supporting the health of those who choose not to inhale the toxic aerosol e-cigarettes produce. In 2009, Suffolk County, New York became the first community to update its smoke-free tobacco ordinance to include electronic cigarettes [54]. In 2010, New Jersey followed by North Dakota and Utah were the first states to impose these same restrictions. Additional states including Hawaii and Delaware passed comprehensive e-cigarette clean air legislation in 2015. California, Vermont, and New York followed in 2016–2017 [54]. As of April 2021, 15 states and the District of Columbia have passed comprehensive smoke-free laws that include electronic vaping devices. These states prohibit the use of both traditional cigarettes and e-cigarettes in worksites, bars, and restaurants [55, 56].

While more than a quarter of US states impose comprehensive e-cigarette restrictions, many other states impose regulations that are narrower in scope. For example, Maine bans e-cigarette use in restaurants and bars, while Nevada places restrictions on e-cigarette use in workplaces and restaurants [26]. Some states, such as Georgia and Illinois, only prohibit e-cigarette use in the buildings and on the grounds of state universities. Other states specifically prohibit electronic cigarette use in public schools, ambulances, correctional facilities, museums, hospitals, railways, and/or childcare facilities. As of April 2021, only Idaho, Indiana, and Mississippi have failed to pass any statewide restrictions on the use of e-cigarettes in particular locations [26, 56]. Although this data suggests an overall positive trend, it also indicates that nearly half

of the states that have comprehensive smoke-free ordinances that prohibit the smoking of traditional cigarettes in public spaces do not include e-cigarette use in those policies. This data highlights a significant regulatory gap and the urgent need for targeted advocacy efforts in many states.

In addition to state laws regulating aerosol-free zones, municipalities throughout the United States have passed ordinances that establish local e-cigarette clean air zones in public spaces [56]. These local regulations are particularly important in states that have not passed statewide policies regulating e-cigarette use. While some of these municipalities have comprehensive laws that include workplaces, restaurants, and bars, other municipalities have passed more stringent laws restricting the use of e-cigarettes in select locations. The number of localities that impose aerosol-free laws has increased dramatically in the last decade. In 2013, 181 municipalities had implemented such a law; 5 years later, e-cigarette clean air regulations had been implemented in 745 municipalities [54]. As of April 2021, nearly 1000 municipalities have passed restrictions on the use of e-cigarettes in certain public spaces [56]. Local e-cigarette clean air laws have been passed in municipalities in all states that do not otherwise have statewide smoke-free laws [56].

On the federal level, smoke-free ordinances that ban traditional cigarette use have recently been applied to the use of e-cigarettes on airlines. In 2016, the US Department of Transportation issued a rule banning e-cigarette use on all flights on which the use of traditional cigarettes is prohibited, including charter flights [57]. Although HUD has not announced a policy regulating e-cigarette use in public housing facilities, at the time of this writing the agency has granted individual public housing authorities jurisdiction to restrict the use of e-cigarettes in housing units and on surrounding property [58].

Smoke-free cigarette and e-cigarette zones are critical to safeguarding the public's health. History verifies that they are also crucial because of their potential to transform the culture of acceptance that now surrounds e-cigarette use, particularly among youth [37]. As they did for traditional cigarettes, clean air regulations for e-cigarettes can redefine the fundamental values and social assumptions that surround electronic cigarette use and assist in the establishment of healthier cultural norms.

Federal, State, and Local Tobacco Taxes

A strong body of evidence has shown that tax increases on traditional tobacco products are among the most effective policies to reduce smoking rates. The 2014 *Report of the Surgeon General* notes that "significant increases in tobacco taxes and prices reduce tobacco use by leading some current users to quit, preventing potential users from initiating use, and reducing consumption among current users" [40]. The 2016 report of The National Cancer Institute and World Health Organization entitled *The Economics of Tobacco and Tobacco Control* echoed similar findings: "A substantial body of research, which has accumulated over many decades and from many

countries, shows that significantly increasing the excise tax and price of tobacco products is the single most consistently effective tool for reducing tobacco use" [59]. As with the tax on traditional cigarettes, early research suggests a tax on e-cigarettes to be an effective strategy to reduce e-cigarette use, particularly among adolescents. For example, a 2018 study notes that a 10% increase in e-cigarette prices is associated with a 9.7% reduction in the number of days middle and high school students use e-cigarettes [60].

The federal excise tax on traditional cigarettes was first levied in 1864 as a means of raising revenue during the American Civil War [61]. Currently, the federal cigarette tax is $1.01 per pack, which represents an over 12-fold increase from 8 cents per pack in 1970 [62]. All US states also levy a state excise tax on cigarette packs. As of January 2021, the lowest state cigarette tax is $.37 per pack in Georgia, followed by $.44 in North Dakota. By contrast, Connecticut, New York, and the District of Columbia have the highest tax rates, at $4.35, $4.35, and $4.50 per pack, respectively [62].

Over the last two decades, 48 states and the District of Columbia have increased cigarette tax rates 141 times [62]. In addition to excise taxes, most states also apply a state sales tax to the cost of cigarettes. While the majority of counties and cities do not impose an additional local cigarette tax, more than 630 local jurisdictions do. Chicago, Illinois, has the highest combined state and local tax rate at $7.16 per pack. Evanston, Illinois, has the second highest rate at $6.48 per pack [62].

Notably, while the Federal Government imposes an excise tax on all traditional cigarettes, the government does not impose a tax on electronic cigarettes or other vaping products. Similarly, although every US state imposes a tax on cigarettes and some non-cigarette tobacco products (such as cigars or chewing tobacco), at the time of this writing only roughly half of states and a select group of localities impose a tax on e-cigarettes. Some of these states impose a tax through laws newly created to tax e-cigarettes; others have amended their tobacco tax laws to include e-cigarettes and other vaping products [63].

Review of the history of taxes on electronic cigarettes indicates that in 2010 Minnesota was the first state to impose a tax on e-cigarettes [64]. It was 5 years before other states followed: North Carolina, Louisiana, and the District of Columbia imposed such a tax in 2015 [26]. By the start of 2019, nine states and the District of Columbia had imposed an e-cigarette excise tax. By the end of that year, that number had more than doubled. As of March 2021, 29 states and the District of Columbia have enacted an excise tax on e-cigarettes. While Alaska does not impose state taxes on electronic cigarettes, municipalities within the state impose local e-cigarette taxes [26, 55].

Data confirms that there have been some increases in state efforts to regulate e-cigarettes through evidence-based economic strategies that can result in a decline in e-cigarette use while also raising revenue. However, the number of states and localities that impose e-cigarette taxes continues to significantly lag behind that of jurisdictions that tax traditional cigarettes, suggesting an important strategy that many states and municipalities have yet to adopt to affect a decline in youth e-cigarette use and reverse the current vaping epidemic.

Whereas taxes on cigarettes are uniformly imposed on a per pack basis, states and municipalities that levy taxes on e-cigarettes do so utilizing three different models. Some tax e-cigarettes based on a percentage of the items' wholesale prices; others tax a flat rate per millimeter of e-liquid or per e-cigarette cartridge; yet other states use a system that is a combination of these two approaches [65]. Of those states that tax based on a percentage of product value, Minnesota has the highest rate (95%) followed by the District of Columbia (91%) and Massachusetts (75%) [63].

Numerous public health advocacy groups, individual stakeholders, and community groups have launched campaigns to advocate for their state legislatures to implement an excise tax on e-cigarettes and other vaping products. For example, the Foundation for a Healthy Kentucky coordinated with the state Chamber of Commerce, the Cancer Foundation, the Health Collaborative, the Medical Association, and the Kentucky Youth Advocates to campaign for an excise tax bill on e-cigarettes, which successfully passed in April 2020 [66]. In Utah, parents, students, school staff and administrators, and numerous health, public health, and religious groups campaigned for a tax on e-cigarettes as a means to reduce youth e-cigarette use. These groups included the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco Free Kids [67], Students Against Electronic Vaping, The Church of Jesus Christ of Latter-day Saints, and the St. George Interfaith Council [68]. Utah passed the tax bill in February 2020, though many legislators were displeased that the original proposed tax of 86% was reduced in the final passed legislation to a 56% tax on e-cigarettes [26, 69].

In the case of e-cigarette taxes, statewide legislative successes have often followed local advocacy efforts. This underscores the role that partnerships between local community leaders and state and national health and tobacco control organizations can play in campaigns designed to curb e-cigarette initiation and use. Because they have been shown to be an effective tobacco control measure, e-cigarette taxes should be a major target of advocacy efforts designed to combat the current youth vaping epidemic.

Regulation of E-Cigarettes and Characterizing Flavors

The 2009 *Family Smoking Prevention and Tobacco Control Act* bans the marketing and sale of all traditional cigarettes containing any characterizing flavor (e.g., fruit), with the exception of menthol [28]. Evidence shows that the 2009 Act contributed significantly to declines in youth smoking rates. A recent study found that the flavors ban led to a 43% reduction in underage smoking (ages 12–17) and a 27% decline in smoking among young adults (ages 18–25) [70]. An earlier study reports that after the signing of the 2009 Act the likelihood of youth initiating smoking declined significantly as did the number of cigarettes those who were smokers smoked [71]. These and similar findings demonstrate that the ban on flavored

traditional cigarettes is a necessary tobacco control policy to protect youth from smoking initiation, decrease the appeal of cigarettes, and ultimately reduce the societal harm of tobacco products.

Although banning the sale of flavored cigarettes was known to lower youth smoking rates, flavored e-cigarettes were left unregulated for years, largely due to tobacco industry pressure. The industry has taken full advantage of the regulatory gaps it helped create, steadily increasing the introduction of flavors into the e-cigarette marketplace [1, 72]. E-cigarette products have been distributed and sold in a panoply of enticing flavors, such as chocolate, cotton candy, gummy bear, peanut butter, whipped cream, banana split, fruit medley, and menthol, all of which target youth and encourage e-cigarette initiation and nicotine addiction [71]. By 2017, more than 15,500 e-cigarette flavors were available for purchase, up from slightly under 8000 flavors in 2014 [1, 71].

The menacing role of flavors in the current vaping crisis is confirmed by a 2019 study that reports that over 70% of high school students who use e-cigarettes use flavored products [73]. In 2016, fruit and candy were the most popular flavors among high school students; since then, fruit and mint/menthol have grown to be the first-choice e-cigarette flavors among youth [14, 74].

While the 2016 Deeming Rule grants the FDA the authority to regulate flavored vaping products, the agency has taken delayed and only limited action to do so [14]. In September 2019, the Federal Government announced a plan to ban all flavored e-cigarettes and nicotine pods [75]. After extensive tobacco industry and lobbyist pushback, the FDA rolled out the Government's final policy in January 2020 [76]. This ordinance prohibits the sale, distribution, and production of certain flavored cartridge-based e-cigarette products (such as JUUL), except for tobacco, mint, and menthol flavors. The weakened regulation also allows for the sale of flavors in non-cartridge-based vaping products, such as e-cigarettes that use refillable e-liquids. Additionally, it does not prohibit the sale of flavored disposable vaping products [76].

While the FDA restriction specifically bans the distribution and sale of flavored cartridge-based vaping products, none of the e-cigarettes on the market at the time of this writing have received the FDA's approval through the premarket tobacco application process. Given this current status, the FDA announced that the flavor restrictions are not a "ban," but rather an outline of the agency's enforcement priorities. The FDA notes, it "will make enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources" [76]. In July 2020, the FDA further announced restrictions on the sale of flavored disposable e-cigarettes such as Puff Bar® and ordered that they be removed from the marketplace. However, due to the FDA's limited enforcement capacity, those products remained widely available for sale throughout the United States through at least 2020 [77]. Numerous health and advocacy groups have protested the FDA's less-regulated version of the flavor ban, including the American Academy of Pediatrics, the American Heart Association, the American Lung Association, the American Cancer Society Cancer Action Network, the Campaign

for Tobacco Free Kids, and the National Association for the Advancement of Colored People [78].

Some advocates have turned their campaigns to the state level, where they have found that legislative efforts to enact a ban on flavored e-cigarettes have led to disappointing delays and legal battles. Michigan is one such state; notably, the courts blocked the Governor's 2019 efforts to ban the marketing and sale of all flavored vaping products [79]. As with other tobacco control efforts, a large percentage of the campaign to restrict flavors now focuses on the local level, where teens, parents, teachers, counselors, school administrators, religious groups, and community groups and leaders join with organized advocacy groups [3, 34].

Such an advocacy model has proven to be an effective public health strategy in Massachusetts, the first state in the nation to pass a comprehensive ban on all flavors, including mint and menthol. Public health advocates launched successful local campaigns throughout the state. In July 2014, Yarmouth was the first Massachusetts town to pass the ban on flavored e-cigarettes; Newton and then Sherborn followed in September of that same year [80]. By late 2019, over 161 municipalities in Massachusetts had passed local policies banning the sale of all flavored vape and tobacco products. These local advocacy efforts ultimately led to Governor Charlie Baker's November 2019 signing of a statewide comprehensive flavor ban applying to the sale of all tobacco products: *An Act Modernizing Tobacco Control* [81, 82]. This legislation asserts a ban on all flavors in electronic and traditional cigarettes and cigars (except tobacco flavor) and includes mint and menthol.

The movement to ban flavored electronic cigarettes at the local level has increasingly gained momentum. In 2018, San Francisco was the first major city in the nation to successfully ban all flavored e-cigarettes, including mint and menthol [83]. Since that time, many other municipalities have passed similar ordinances. Groups such as the American Cancer Society, the American Heart Association, the American Lung Association, and the Campaign for Tobacco Free Kids, and individuals such as former New York City Mayor Michael Bloomberg supported the San Francisco ban with aggressive funding, advocacy efforts, and pushback against the well-funded tobacco industry [84]. By the end of 2019, 274 localities had placed restrictions on some flavored vaping products; importantly, 88 of those localities had comprehensive bans, meaning they included menthol products. As of December 2020, the number of jurisdictions with flavor restrictions has increased to 331, including 7 states and 143 cities; 14 states have at least 1 jurisdiction with restrictions against flavored vaping products [85].

States that have passed comprehensive statewide flavor bans on e-cigarettes include Massachusetts, New York and Rhode Island; Massachusetts is the only state as of this writing to include regular menthol cigarettes in its flavor ban. Other states have imposed less broad restrictions. Maryland prohibits all cartridge-based and disposable e-cigarette flavors except for menthol. Utah similarly allows the sale of menthol as well as mint products, while prohibiting other flavors. Yet other states impose more limited flavor restrictions [85].

A recent study conducted after San Francisco banned flavors concluded that the overall use of flavored tobacco products in the city declined significantly and that local flavor bans can effectively reduce e-cigarette use [86]. Studies such as this provide strong evidence that the elimination of flavored vaping products is pivotal to policies designed to reduce adolescent and young adult initiation and use of those products [87]. As the nation awaits the FDA's actions on the electronic cigarette premarket tobacco application process, cities and municipalities are well situated to undertake campaigns to ban flavored tobacco products and defend against the youth vaping crisis.

Tobacco 21 Enactment and Enforcement

Tobacco 21 (T21) refers to state and federal legislation that raises the minimum legal age of tobacco sales from 18 to 21. This policy first emerged in the United States in Needham, Massachusetts, in 2003 [34]. At the time, the Needham Board of Health announced the policy as a response to community concerns regarding youth cigarette smoking rates; the policy went into effect in 2005. Some 7 years later, after data was published documenting a dramatic decline in smoking rates in Needham youth from 2006 to 2012, two pediatricians launched a movement throughout Massachusetts to raise the minimum age of tobacco sales from 18 to 21. Through strong advocacy efforts, T21 policy spread from town to town in Massachusetts, as well as to towns, cities, and states throughout the nation before passing at the federal level in 2019 [34].

Soon after the 2012 passing of T21 legislation in a number of towns in Massachusetts, the "Big Island" of Hawaii adopted the policy in November 2013. This was quickly followed by the passing of T21 legislation in New York City [34]. In 2015, Hawaii became the first state to pass Tobacco 21 legislation, followed by California in 2016, and New Jersey in 2017. The following year Massachusetts, Oregon, and Maine passed statewide T21 legislation. At the time that Massachusetts passed the statewide legislation, over 230 towns in the state had raised the minimum tobacco sales age from 18 to 21 [88].

Notably, in December 2019, the Federal Government amended the FD&C Act and raised the federal minimum age of sale of all tobacco products, including e-cigarettes, from 18 to 21 years [89]. At the time, 19 states had passed Tobacco 21 legislation. Since the federal passing of this tobacco control legislation, additional states have passed their own versions of T21 ordinances with state-specific enforcement parameters. As of June 2021, 37 states, the District of Columbia, and over 550 counties nationwide have adopted Tobacco 21 policy [90, 91].

Since the adoption of Tobacco 21 at the federal level, it has been officially illegal to sell tobacco products—including traditional cigarettes, cigars, and e-cigarettes—to anyone under the age of 21. However, when the policy was signed into law, the FDA and retailers were granted a transition period during which to formally adopt

and implement the new minimum age of sale law. That transition period ended in September 15, 2020. The FDA continued to use those under 18 as trained decoys in its compliance check program during this transition period [92] and has since been using those under 21 [93].

The current federal law prohibiting the sale of all tobacco products, including e-cigarettes, to those under 21 supersedes all established state and local ordinances. Notably, some of these ordinances align with the Federal Government's ruling and are supported by that mandate, while others do not. All states and localities have established legislation that minimally prohibits the sale of both traditional tobacco products and e-cigarettes to minors under the age of 18, in line with previous federal law. While 37 states have implemented T21 policy, states such as Alaska impose a sales age of 19 [90, 91]. The Department of Health and Human Services has given states 3 years to demonstrate compliance with the age 21 ruling; those states that do not comply will be in danger of losing federally available Substance Abuse Prevention and Treatment Block Grant funds [94, 95].

Confusion may abound regarding the enforcement of the minimum age of sale of tobacco products in those states where state legislation designates the minimum age to be under the federal law of age 21. In locations where the state-legislated minimum age of sale remains 18, trained decoys under the age of 18 continue to be used in state compliance checks, even though selling e-cigarettes or other tobacco products to persons under 21 violates federal law [94]. Similarly, in such locations state and local officials are unlikely to enforce federal law, raising the possibility that retailers in some states may continue to sell tobacco products to those under 21.

The recognition that certain states and municipalities have not raised the minimum sales age to 21 highlights the critical need for locations to align with the federal law in order for enforcement and compliance checks to play an effective role in controlling youth access to tobacco products including e-cigarettes. Strong partnerships among community and youth leaders, tobacco-control groups, departments of public health, boards of health, and local politicians can further the spread of Tobacco 21 policy throughout localities and encourage consistent enforcement of T21 regulations [1].

Tobacco Retail Licensing

Many municipalities, cities, and states require retailers to obtain a tobacco or e-cigarette retail license (TRL) before engaging in the sale of tobacco or e-cigarette products. This requirement helps to control the density, number, and location of tobacco and/or e-cigarette retailers and assists with the collection of fees that support some of the costs of enforcement. Retail license requirements also encourage retailers to abide by local, state, and federal tobacco regulations, such as minimum age of sale laws—if only so that retailers avoid penalties, fines, and potential suspension or revocation of a granted license [96].

As of March 2021, 38 states and the District of Columbia set licensing requirements for traditional cigarette retailers. By comparison, 36 states and the District of Columbia have passed laws requiring retailers to obtain a license in order to sell electronic cigarette products, either in store or online [26, 97]. Retailers who conduct business in municipalities where they are not obliged to obtain a tobacco or e-cigarette license cannot be mandated to abide by tobacco or e-cigarette control laws. For example, such retailers are not subject to Tobacco 21 compliance checks or penalties for sales to minors; nor are they limited in where or how they market or sell their products. States and municipalities that do not require retailers to obtain tobacco and/or e-cigarette licenses set the stage for a lucrative unregulated market in cigarette and e-cigarette sales as well as for increased youth access to these products. Advocating for laws that require all retailers of traditional tobacco and e-cigarette products to obtain a license could result in reduced physical access to those products and more limited opportunities for the e-cigarette and tobacco industries to market, sell, and distribute those products, particularly to vulnerable youth [96].

Future Directions

Leaders and organizations can play a critical role in mobilizing constituents and advocating for policies that fully ban the sale of all e-cigarette and vaping products, as occurred in San Francisco in June 2019 [98]. As an alternative to banning the marketing and sale of such products, action can focus on advocating to local and state governments to implement evidence-based policies that discourage youth initiation and use of electronic cigarettes (Table 9.2). In addition to such policy-based measures, school staff and healthcare providers can play important roles in educating adolescents about e-cigarettes' harmful effects, counseling youth to avoid e-cigarettes, and encouraging youth to become engaged in tobacco control advocacy efforts in their schools and local communities [99]. When coupled with strong enforcement efforts, public health policies and local initiatives effectively discourage youth initiation and use of e-cigarettes and can reduce the associated potential for a lifetime of nicotine addiction and adverse health consequences. Such policies are critical to reversing the current youth vaping crisis that is affecting communities across the nation.

Table 9.2 Targets for evidence-based e-cigarette policy

Comprehensive aerosol-free clean air zones
State and/or local e-cigarette taxes
Comprehensive flavor bans that include mint and menthol
Tobacco 21 laws and enforcement
Mandatory licensing requirement

History verifies that when federal and state government actions do not align with public health needs, campaigns at the local level can and should move forward. As they build community support and gain momentum, these advocacy efforts can influence municipalities and successfully advance to the state and even federal level [34], counterbalancing the ill-intentioned tobacco industry and filling those gaps in legislation and enforcement that continue to undermine the public's health.

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