

## Smoke or Vapor? Regulation of Tobacco and Vaping

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Given the well-known health harms of smoking, tobacco is regulated and taxed nearly everywhere in the world. With the introduction of electronic nicotine delivery systems (ENDS), commonly known as e-cigarettes, new questions have arisen about the risks to health from their use and whether they should be regulated as strictly as tobacco. In some quarters, the possibility that e-cigarettes and vaping could deliver an attractive, smoking-like sensory experience while avoiding the health harms that accompany combusting and inhaling tobacco has been greeted with enthusiasm, since the new products could help some smokers transition to a less risky product. In other quarters, and in much of the American public health community, e-cigarettes were greeted with skepticism and hostility, since they could potentially normalize smoking, set back the great gains in tobacco control of the past several decades, and hook a new generation of young people on nicotine and smoking. This chapter covers the regulatory history of tobacco and e-cigarettes, summarizes upcoming regulatory actions and challenges, discusses the key issues involved in the regulation of these activities, and includes suggestions for better regulation.

Readers will benefit from an understanding of some vaping technology and terminology. All e-cigarettes work by means of a

battery-operated heater that vaporizes a solution containing nicotine and flavoring (known as an eliquid), which is then inhaled by the user. Sometimes grouped with e-cigarettes are heat-not-burn products that heat ground tobacco without combustion. There are many types of e-cigarettes and vaping systems, from cartridge-based “closed” systems, in which the consumer buys a disposable, unmodifiable eliquid cartridge, to tank-based “open” systems, in which the vaper buys vials of eliquid for refill and can customize what is vaped. All of these will be referred to as “e-cigarettes” in this chapter, and their consumption will be called “vaping,” unless a distinction among products is required. The exception is that discussions of the scientific literature on the health effects of e-cigarettes exclude heat-not-burn products, which are typically not included in the studies. Finally, note that using e-cigarettes is not “smoking”—nothing is combusted and there is no smoke.

## **History of Tobacco Regulation in the United States**

From 1900 to 1963, per capita consumption of cigarettes grew rapidly, from a low figure in 1900 until in the latter year the daily average was more than half a pack per adult.<sup>1</sup> The watershed moment in the history of smoking in the United States was the publication of the Surgeon General’s report in 1964, which stated that “cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.”<sup>2</sup> After that year, consumption began its long decline, falling to 0.13 packs sold a day per adult in 2018.<sup>3</sup>

Of course, the average smoker consumes more than that. In 2018, adult smokers reported smoking a bit more than half a pack a day, while retail sales of cigarettes averaged a bit less than one pack per day per adult smoker.<sup>4</sup> That same year, there were about 34 million adult cigarette smokers in the US and 49 million adult users of any tobacco product, including e-cigarettes.<sup>5</sup> These figures imply that the prevalence of cigarette smoking has fallen to 13.7 percent among US adults, while the prevalence of any form of tobacco consumption is 19.7 percent. Adult cigarette smoking prevalence has declined about two-thirds from its peak in the 1960s.

The sale and use of tobacco in the US has been regulated in various ways for decades, although much of the regulatory action has come relatively recently compared to the long history of smoking. The first federal action regarding the tobacco industry and the health effects of its products was the requirement that cigarette manufacturers add the notice that smoking “may be hazardous to your health” on packs. The health warning, which came into effect in 1966, was the first of its kind in the world.<sup>6</sup>

Despite the landmark surgeon general’s report in 1964, until the 1980s tobacco was specifically exempted from legislation (e.g., the Toxic Substances Control Act) and regulation (e.g., by the Consumer Product Safety Commission) that otherwise would have curtailed the industry or the freedom to smoke.<sup>7</sup> Starting in 1985, a set of four rotating health warnings with stronger wording were required on cigarette packaging.<sup>8</sup> The FDA sought to add graphical health warnings in 2011, but legal action by the tobacco industry has delayed the requirement for almost a decade.<sup>9</sup>

The first federally mandated restrictions on where one could smoke came in the late 1980s, with bans on smoking on certain domestic airline flights.<sup>10</sup> The so-called Synar Amendment of 1992 required all states to adopt and enforce restrictions on the sales and distribution of tobacco to minors; federal enforcement of the restrictions (through the withholding of certain federal payments to the states) went into effect in 1996.<sup>11</sup> While as recently as the 1980s some states had no restrictions on sales to minors, however defined, by 1995 all states and the District of Columbia prohibited the sale and distribution of tobacco products to those under 18 years of age.<sup>12</sup>

In 1998, the three major tobacco manufacturers signed the Master Settlement Agreement (MSA) with 46 states. In exchange for immunity from legal claims by these states for costs incurred for smoking-related illnesses and deaths, the three major tobacco manufacturers agreed to pay the states an estimated \$206 billion, finance a \$1.5 billion anti-smoking campaign, and cease various forms of advertising, product placement, and event sponsorship, as well as any form of marketing aimed at youth. While the settling states say that “the central purpose of the MSA is to reduce smoking, especially in American

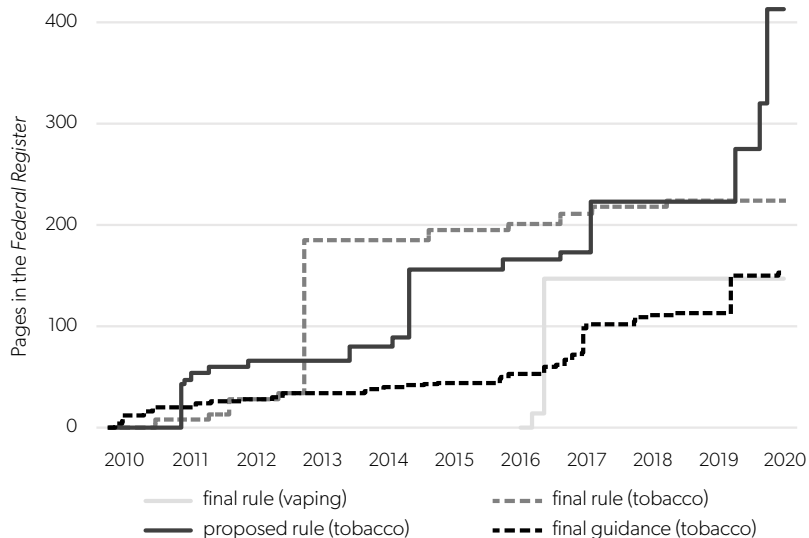
youth,”<sup>13</sup> it appears that the states spend little of the money collected from the MSA and tobacco taxes on tobacco prevention and cessation programs—well under 3 percent of it in 2020.<sup>14</sup>

The entering wedge for direct federal regulation of tobacco as a consumer product came in the form of Family Smoking Prevention and Tobacco Control Act of 2009, which granted the FDA authority to regulate tobacco products. The FDA’s first action under the act was to issue a rule in 2010 prohibiting the sale of cigarettes and smokeless tobacco to any person under age 18. (Such sales were already illegal in all states.)<sup>15</sup> Since that time, there has been a steady flow of proposed and final rules and “guidance” from the FDA regarding tobacco regulation. Figure 1 shows the growth of federal regulation regarding tobacco over time, as measured by the cumulative number of pages of rules in the *Federal Register*. By 2015, there were over 200 pages of binding regulations, and by the beginning of 2020 there were 224 pages of rules, more than 150 pages of guidance regarding those rules, and well over 400 accumulated pages of proposed rules. The pages of proposed rules nearly doubled in 2019 with recent actions by the FDA (about which more will be said below).

In the first of two recent federal regulatory actions, the age threshold for retail sales of tobacco products after December 2019 was raised from 18 to 21 years.<sup>16</sup> Before that time, well fewer than half the states had an age restriction that high. In its most recent action, the FDA issued rules requiring graphical warnings on cigarette packages.<sup>17</sup> These new color graphics depicting the negative health consequences of smoking will occupy the entire top half of the area of the front and rear faces of cigarette packages.<sup>18</sup> Some research indicates that such large graphical warnings are more likely to be noticed by smokers or more likely to lead them to consider cessation or smoking less.<sup>19</sup>

In addition to tobacco regulations, the federal government has levied excise taxes on cigarettes continuously since the time of the Civil War.<sup>20</sup> The tax remained at 8 cents a pack from 1951 until 1983, when it was doubled. In the early 1990s the tax was raised to 24 cents, and in the early 2000s it was raised by stages to 39 cents. In 2009, the largest increase yet resulted in a per-pack federal tax of \$1.01, where it remains in 2020.

**Figure 1. Growth of Federal Regulation from the FDA Regarding Tobacco and E-cigarettes**



Source: Author’s calculations from FDA data, <https://www.fda.gov/media/88873/download>.

State taxes on tobacco vary widely, although most states have increased their cigarette taxes in the past two decades. From 1970 to 2018, the average state excise tax (not weighted for population or consumption) increased from 9.6 cents per pack to \$1.74—an annualized nominal growth rate of 7.5 percent and an inflation-adjusted growth rate of 3.6 percent (see figure 2). State taxes grew exceptionally quickly after 2000, with an inflation-adjusted growth rate of the average tax of 5.5 percent per year. Adding the federal tax on top of the state taxes shows that the combined nominal rates rose by an average of 5.7 percent per year between 1970 and 2018 and have risen by 6.9 percent per year since 2000. These large increases in the taxes over time resulted in almost 40 percent of the retail sales prices of cigarettes going to excise taxes in 2018—or, to put it another way, an effective 65 percent tax rate on a pack.

Figure 2 also shows the population-weighted averages of the taxes; these reflect the excise taxes facing the average person in the nation. For the most part these are similar to the simple averages, with the

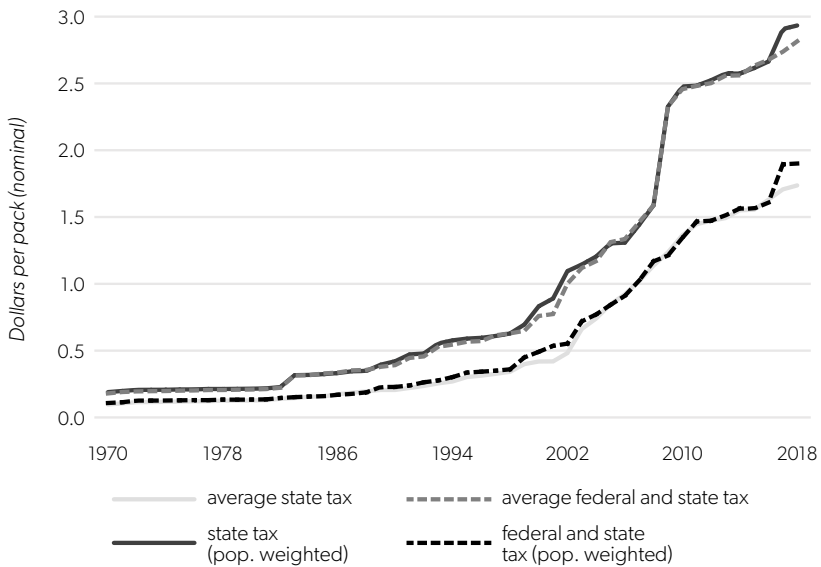
exception of a divergence in 2017 owing to California enacting a large tax increase. Overall, these levels of taxation make cigarettes one of the most highly taxed products in the nation. By comparison, state alcohol taxes averaged only three to five cents per drink in 2015.<sup>21</sup>

## History of E-cigarette Regulation in the United States

The market for e-cigarette products in the United States began to take off around 2006. In 2008, the e-cigarette market had only \$28 million in revenue from an estimated 190,000 vapers, but by 2017 it was a \$4.6 billion market with an estimated 8.4 million vapers.<sup>22</sup> Those figures represent a revenue growth rate of over 50 percent per year. Given the recent emergence of e-cigarettes as a significant product, it is unsurprising that the regulatory history of vaping is short. In 2016, the FDA “deemed” e-cigarettes (or, more properly speaking, ENDS) to be tobacco products.<sup>23</sup>

While the FDA has the legal authority to deem new or existing products to be tobacco products, and thus subject to its regulatory authority, it is worth noting that ENDS do not contain tobacco. While nicotine is

**Figure 2. Growth of State and Federal Excise Taxation on Cigarettes**



Source: Data from the Centers for Disease Control and Prevention, “Tax Burden on Tobacco, 1970-2018,” August 13, 2020, <https://chronicdata.cdc.gov/Policy/The-Tax-Burden-on-Tobacco-1970-2018/7nwe-3aj9>.

the addictive substance found in tobacco, it is the other constituents in tobacco that, when combusted and inhaled, cause the main health problems associated with smoking. In particular, to quote a report from the National Academies of Sciences, Engineering, and Medicine, “There is no evidence to indicate that nicotine is a carcinogen.”<sup>24</sup> Thinking of e-cigarettes as tobacco products thus greatly confuses the issue, a point to which I will return below.

After deeming e-cigarettes to be tobacco products, the FDA aimed its entire set of tobacco-related regulations at vaping products as well. Manufacturers of existing products had to register with the FDA and submit lists of products, their ingredients, and evidence about their health effects.<sup>25</sup> Manufacturers are now required to place on product packaging a warning that they contain nicotine and that nicotine is an addictive chemical. Products introduced between 2007 and August 2016 could continue to be sold while their applications for regulatory approval were considered by the FDA.<sup>26</sup> New e-cigarette products are not allowed to be introduced after August 2016 without premarket approval. Since the FDA has not ruled on any e-cigarette application yet, in part because continuing legal action made uncertain the deadline for submission of applications, anti-vaping advocates can still truthfully claim that there are no FDA-approved e-cigarettes on the market.<sup>27</sup> In January 2020, the FDA also effectively prohibited sales of flavored cartridge-based e-cigarettes (other than tobacco-, mint-, and menthol-flavored e-cigarettes).<sup>28</sup> However, flavored e-liquids for open-system tank vaping (typically available at vape shops) remain allowed.<sup>29</sup>

With e-cigarettes added to the regulatory purview of the FDA, age restrictions on sales to youth under age 18 and the prohibition of sales from vending machines came into force in 2016.<sup>30</sup> Most states had already banned sales to youth before the federal action (see figure 3), and over time many states raised their age restrictions on sales to 19 or 21 years. Near the end of 2019, as mentioned above, the federal age limit was raised to 21 for all tobacco products, including e-cigarettes.

States have also been free to impose other regulation on the sales and usage of e-cigarettes. The increasing number of other regulations among the states is depicted in figure 4. Some states require retailers

to obtain special licenses to sell e-cigarettes, typically with the goal of limiting youth access to vaping products; some place the same restrictions on vapers regarding using the devices in public as on smokers (thus applying “smoke-free” rules to a smoke-free product). Finally, a minority of states levy excise taxes on e-cigarettes (in contrast to ubiquitous state taxes on cigarettes).

## **Upcoming Potential Regulatory Changes**

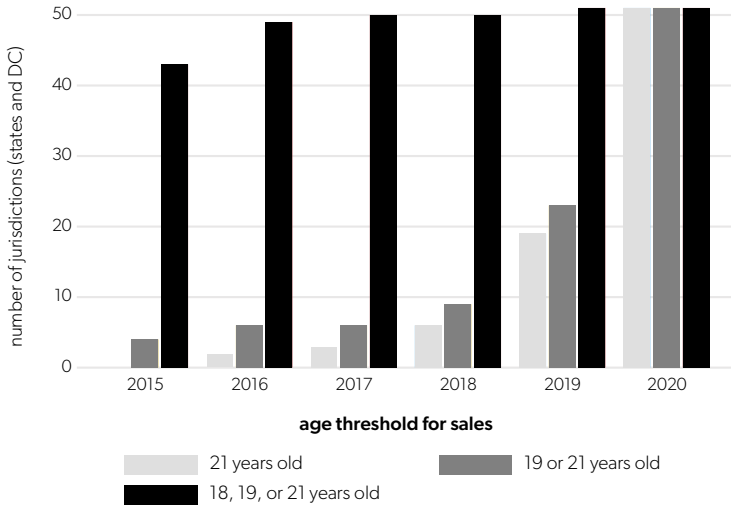
The FDA is currently undertaking several rulemaking processes on tobacco regulation. One regulatory proceeding is considering whether menthol flavoring in cigarettes will be banned (other flavors are already illegal).<sup>31</sup> Perhaps the most ambitious regulatory action contemplated by the FDA is to lower the nicotine content in cigarettes to minimally addictive or nonaddictive levels.<sup>32</sup> While the FDA does not have the authority to ban cigarettes outright, such action would effectively kill the legal market for the product as it exists today. Public comments on the latter two proceedings were due in the summer of 2018, but the FDA has not issued final rules for either (or announced that it is abandoning the effort) as of the start of 2020.

As discussed earlier, apart from a single heat-not-burn product, the FDA has not issued rulings on any of the submissions for regulatory product approval for e-cigarette products. Thus, the industry faces a large degree of uncertainty going forward regarding the amount of effort required for successful submissions. The fact that the one approved product, IQOS by Philip Morris International, purportedly required billions of dollars for regulatory compliance on the part of the manufacturer and experienced two years of regulatory delay until approval does not bode well for any maker of e-cigarettes, apart from the largest tobacco manufacturers.<sup>33</sup>

The main upcoming regulatory action by the FDA—eagerly awaited by industry and the public health community—is not new regulation per se, but rather a definitive ruling on any of the regulatory approvals sought for e-cigarette products (discussed above). It remains to be seen whether any such products will be allowed to claim that they are safer than cigarettes or that they aid in cessation of smoking. It is also

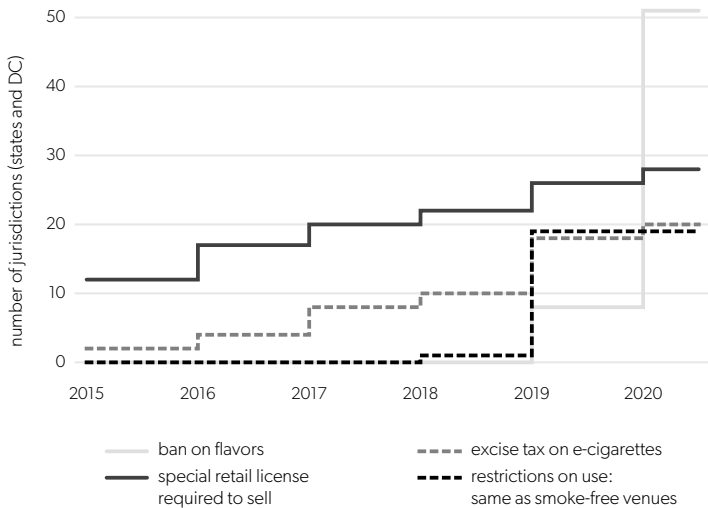


**Figure 3. Growth of State Regulation regarding E-cigarette Sales to Youth**



Sources: Tobacco Control Legal Consortium, *U.S. E-cigarette regulation: a 50-state review*, 2020. Available from <https://publichealthlawcenter.org/resources/us-e-cigarette-regulations-50-state-review>.

**Figure 4. Growth of State Regulations Regarding E-cigarette Sales and Usage**



Sources: Public Health Law Center, “E-Cigarette Tax : States with Laws Taxing E-Cigarettes,” 2020; Public Health Law Center, Retail Licensure on E-Cigarettes: States with Laws Requiring Licenses for Retail Sales of E-Cigarettes, 2020; Public Health Law Center, “U.S. E-Cigarette Regulation: A 50-State Review.”

unclear whether any cartridge-based ENDS flavored with something other than mint or menthol will be approved; despite the current sales ban, the FDA has not ruled out granting regulatory approval for such products. As mentioned above, the only ruling to date has been on a heat-not-burn product, which differs in many ways from traditional vaping products.

## **Issues Involved with Taxing and Regulating Tobacco**

This section covers the various rationales offered for regulating tobacco and some of the unintended consequences of doing so. The three main rationales for excise taxes and regulations on tobacco fall into two categories. The main *economic* rationale has traditionally been to tax tobacco to align the private and social costs of smoking. The main *actual* rationale appears to be paternalism. In recent years, a hybrid rationale has emerged in which theories from behavioral economics are used to justify paternalistic taxation and regulation. These rationales are all discussed here.

### **The economic rationale for regulation: externalities.**

The traditional economic rationale for tobacco taxation is that it serves to correct consumers' faulty incentives (i.e., it is taxation to correct for externalities, à la economist Arthur C. Pigou). In other words, the main economic rationale for tobacco taxation depends on the presence of negative externalities.

An externality in this context is an effect of consumption that creates adverse consequences for persons other than the decision maker. So-called Pigovian taxes are set to correct for the externalities, so that consumers consider the costs and benefits of their actions from the social rather than merely the personal perspective. The two externalities discussed for consumption of tobacco are the burdens imposed on taxpayers (fiscal externalities) and the burdens imposed on nonsmokers (health externalities).<sup>34</sup> When smokers degrade their likely future health by their consumption of tobacco, they create future expected costs for publicly funded health programs such as Medicare. However, whether it is proper to treat such "fiscal externalities" identically

to other externalities in the social calculus is debated.<sup>35</sup> Externalities require attention and possibly correction because they create inefficiencies, not because they transfer benefits from one party to another in the economy. The inefficiencies associated with fiscal externalities, however, are due to the inefficiencies inherent in subsidized healthcare, not to smoking per se. That is, the inefficiency (if any) arises because of the policy (Medicare), not the individual's action (smoking).

The remaining difficulties with an argument based on fiscal externalities, for those wishing to justify high tax rates on cigarettes, are twofold. First, the cost of a pack is borne today (by the buyer), but any external costs for society to fund healthcare are far in the future. The present expected discounted value of those future healthcare costs is small, and thus so would be the corrective taxes. (Note, however, that if healthcare cost increases continue to outpace general inflation, this first rebuttal loses some force.) Second, since smokers on average die younger than nonsmokers, they *reduce* the drain on the public purse for social security payments and have fewer years of eligibility for (costly) Medicare.<sup>36</sup>

Thus it is unsurprising that studies taking these considerations into account while computing the optimal tax to account for fiscal externalities alone generally find that current excise tax levels are too high compared to the net externalities.<sup>37</sup> Even using an astronomically high figure for the health cost to society of smoking a single pack (\$35), the optimal tax to correct for negative externalities would be only 40 cents per pack (compared to the actual excise tax, which averaged around \$2.80 in 2018).<sup>38</sup> The weight of the literature instead finds similarly small externalities, but some notable exceptions actually find social savings from smoking (although these tend to be in countries with higher public expenditures on health than the United States).<sup>39</sup>

However, fiscal externalities are not the only costs imposed on society by smokers. The other negative externality created by smoking is the burden imposed on nonsmokers, primarily through second-hand smoke. Such burdens include the annoyance of being exposed to others' smoke and any adverse health effects. Health-related externalities based on second-hand smoke gained prominence in arguments

for taxation and tobacco control in the US in the 1990s, after the earlier studies concluding that tobacco taxes were too high. Given that “everyone knows” how harmful secondhand smoke is, many people would be surprised to learn how weak the scientific evidence used to justify the indoor smoke-free laws of the 1990s actually was.<sup>40</sup> A landmark study in 1993 from the Environmental Protection Agency purported to show the adverse health effects of secondhand smoke and was influential in the passage of many local and state smoke-free ordinances. However, the report was savaged by a federal court.<sup>41</sup> The study, which stated that it reviewed the best available scientific evidence at the time, was thrown out by the court in part because it “did not demonstrate a statistically significant association between [secondhand tobacco smoke] and lung cancer,” which was its main claim. The point of rehearsing the story behind the first smoke-free ordinances is not to suggest that secondhand smoke does not have adverse health effects; that link is better established today. Rather, it is to note that, as is likely the case with the debate about e-cigarettes today (as will be covered below), the call to regulate smoking was sustained by political and social factors beyond those supported directly by the scientific knowledge at the time.<sup>42</sup>

Today, it is estimated that there are about 41,000 deaths per year in the United States attributable to secondhand smoke.<sup>43</sup> That figure represents about 1.5 percent of all deaths.<sup>44</sup> The negative effects of maternal and passive smoking on infant and child health are considered some of the most important negative externalities.<sup>45</sup> Various studies have associated smoking during pregnancy with reduced fetal growth, low birth weight, and, later in life, obesity, cardiovascular disease, and respiratory ailments. However, it remains the case that some of the links are weaker than people often assume. For example, one meta-analysis covering 76 studies on environmental tobacco smoke exposure found that there was no statistically significant association between environmental tobacco smoke in the home and premature births, low birthweight, spontaneous abortions, or lower Apgar scores at birth.<sup>46</sup> On the other hand, the same meta-analysis found a positive association of secondhand smoke with congenital malformations.<sup>47</sup> Furthermore,

many studies find that anti-smoking regulations are associated with better infant and child health.<sup>48</sup>

Before leaving the subject of negative externalities, it is important to note that a tax is a blunt instrument for reducing environmental tobacco smoke exposure. The price elasticity of market demand for cigarettes is estimated to be around 0.4, implying that a 10 percent increase in the price of cigarettes reduces total consumption in the market by only 4 percent. Other, more direct interventions can have much larger impacts. For example, consider concerns about the health of unborn children in a smoking household. One behavioral intervention that involved advising about health risks, introducing strategies within the home to eliminate exposure to smoke, and cognitive behavioral therapy for depression or intimate partner violence when necessary reduced the odds of secondhand smoke exposure by one-half.<sup>49</sup> From the viewpoint of political economy, it is important to recognize that policymakers may prefer tobacco taxes to behavioral intervention programs because the former raise revenue for the state while the latter require public expenditure.

### **The behavioral rationale for regulation: “internalities.”**

Since taxes on tobacco may already be adequate or too high from the usual point of view of taxing to correct for externalities, tobacco control advocates in recent years have turned to justifications based on behavioral economics. The nontechnical version of these arguments proceeds along the following lines: “Youth are not rationally forward-thinking consumers, and most smokers begin smoking in their youth.” The former assertion, coupled with the latter empirical observation, and supplemented with survey evidence showing that most smokers say that they wish they had not started smoking,<sup>50</sup> have led many advocates to call for higher tobacco taxes despite the absence of the usual economic rationales.

Arguments against this rationale include the observation that (as discussed earlier) taxes are blunt instruments to prevent smoking, especially since many youth do not pay for their cigarettes and, in particular, for their *first* cigarettes.<sup>51</sup> The greatest weight of a cigarette tax falls on adults, not youth. Furthermore, sales of tobacco to youth are already illegal; if

the “infinite tax” tacitly imposed by a ban does not prevent youth from starting to smoke, then why would a finite tax do so—especially since both forms of tax can be evaded, as discussed below? The evidence is inconclusive regarding the impact of cigarette prices on youth smoking. At least some studies find that higher prices lower the propensity of youth to smoke,<sup>52</sup> although other research indicates that the actual primary driver affecting youth’s smoking behavior is anti-smoking sentiment or regulations in the state rather than prices per se.<sup>53</sup>

Extending the behavioral economic rationale for tobacco taxes to adults requires a theory involving so-called internalities—irrational behavior due to limited self-control or foresight. Such theories, when applied to tobacco consumption, assume that there is a “behavioral wedge” between the price of the good and the value to the consumer of the last unit consumed.<sup>54</sup> Whereas a rational consumer (roughly speaking) spends money on a commodity to the point where it is just worth it, in terms of satisfaction gained for the price paid, the behavioral wedge implies that the individual “overconsumes” the good, even as evaluated by the person’s own (eventual) preferences. Such individuals will look back on past decisions and wish that they had not consumed so much of the good. This may happen, for example, if youth, when they first try smoking, underestimate the likelihood that they will get addicted and become lifelong smokers (with all the resulting pecuniary and health costs). The implication is that, theoretically, increasing the price of a good by increasing an excise tax may actually increase some people’s welfare. Thus, a tax may help “nudge” a consumer toward an outcome that is better for that person, in the estimation of that person. One study adopting this approach arrived at the conclusion that an “optimal” tax to correct for internalities might be as high as \$15 per pack—far higher than any tax in the nation.<sup>55</sup> Such conclusions regarding optimal taxes make the behavioral approach a convenient rationale for parties advocating for higher tobacco taxes.

### **The paternalistic rationale for regulation.**

As is clear from the discussion of the behavioral rationale for tobacco regulation, many policy analysts and policymakers approach the subject

of tobacco regulation with a heavy dose of paternalism. They view smokers as faulty decision makers who need to be saved from their own poor choices. Some authors are quite explicit about this. For example, in one behavioral economic study performed for a lung cancer group, the authors explain, “we will focus on failures of individual self-control which lead to excessive smoking relative to desired levels. In such a case, tobacco taxation can provide a corrective force to combat failures of self-control.”<sup>56</sup> In this approach, the power of the state to tax provides a corrective force to nudge (or shove) irrational, tricked, or self-deluded smokers toward cessation.

Paternalism is a comfortable position for many policymakers to adopt, since—given smoking’s negative correlation with income and education—relatively few of them smoke today. As Kip Viscusi, a University Distinguished Professor at Vanderbilt University, has pointed out, since policymakers have chosen not to smoke, it is therefore easy for them to assume that smokers are mistaken, irrational, or in need of policy nudges toward cessation.<sup>57</sup> Of course, the fact that a behavior is hard to quit does not necessarily prove that the choice to begin was irrational (as most coffee drinkers would attest).<sup>58</sup> Furthermore, assumed faulty choices based on mistaken perceptions of the health effects of smoking appear to be unlikely, since, if anything, the American public *overestimates* the risks of smoking today.<sup>59</sup> (The evidence about whether youth in particular hold correct perceptions of the risks involved in smoking is inconclusive, however.)<sup>60</sup>

Evidence for intertemporal irrationality and time inconsistency in decision-making (by which economists mean that the future self will regret decisions made by the present self) comes mainly from lab experiments. These are typically performed on college students at elite universities—hardly a representative demographic. There is also a small empirical literature that claims to find time inconsistency in real-world economic decisions (other than decisions about smoking).<sup>61</sup> Such apparent irrationality follows from individuals in the data not making the choices that the economic theorists think that they should after estimating impressively technical yet still restrictive models of consumers’ choices. It remains to be seen whether these findings will

hold up when more realistic models of economic behavior based on less restrictive assumptions are investigated.

While the arguments for paternalistic action by the state thus assume that smokers “need help helping themselves,” arguments for less paternalism can be based on normative and positive grounds.<sup>62</sup> Normative ideas include the idea that the proper role of government is to protect the liberty of the citizens regarding—among other concerns—economic decisions, and the idea that (absent compelling reasons to the contrary) individuals should be free to make choices without government interference. Conversely, even granting the premise of limited cognition and the desire to optimize the behavior of individuals who cannot do so themselves, bounded rationality can raise the costs of government decision-making relative to private decision-making.<sup>63</sup> Positive arguments against paternalistic tobacco taxes are based on the unintended consequences that such taxes can have. For example, evidence from the 1990s indicates that higher prices caused smokers to switch to cigarettes that were higher in tar and nicotine, and therefore more harmful and addictive.<sup>64</sup> Other unintended consequences are covered in the next subsection.<sup>65</sup>

### **Unintended consequences of taxes and regulations.**

An effective approach to policy must focus less on what policymakers hope will happen and more on what is likely to happen. This takes us into the realm of unintended consequences.

A standard desideratum for taxation is equity, based on the ability-to-pay principle. This principle leads to the system of progressive income taxation in the United States, for example. Excise taxes on cigarettes are regressive, however: poorer individuals spend a greater share of their income on consumption, and therefore an excise tax takes a greater share of a poor person’s income than it does of a wealthy person’s income. Furthermore, cigarette smoking is more prevalent among lower-income groups in the United States. These facts compound to make tobacco taxes doubly regressive.<sup>66</sup> While tobacco taxes may constitute only a small part of the total financial burden facing most smokers, in some cases the tax burden could be onerous. Consider, as an extreme



example, a full-time minimum-wage worker in Chicago, where combined federal, state, county, and local tobacco taxes during the second half of 2019 were \$8.17 per pack.<sup>67</sup> During that period, the taxes alone on a pack-a-day smoking habit would have taken up 12 percent of the individual's gross wages.<sup>68</sup>

If higher taxes encouraged many low-income individuals to quit smoking, then one could argue that the regressive impact of tobacco taxes would be blunted or removed entirely. The evidence for the predicate is weak, however. There is evidence that higher prices are associated with a lower number of smokers, even among the low-income population, but evidence for a link between prices and cessation is less clear (in part because cessation is harder to study than smoking prevalence). One study found that there is no correlation between successful cessation among smokers below the poverty line and cigarette prices in their state of residence, either in bivariate analysis or after controlling for other factors.<sup>69</sup> Low-income individuals who still smoke tend to be hard-core smokers whose behavior is difficult to change; taxing them simply raises their financial burdens if they do not quit.<sup>70</sup>

The indirect evidence for higher taxes leading to cessation is stronger: several studies show that tax increases lead to a lower smoking prevalence among older adults.<sup>71</sup> Given that few people begin smoking once out of their twenties, a lower prevalence of smoking among older smokers than younger smokers is indicative of cessation.<sup>72</sup> Regardless, another study found that, cigarette tax increases remain regressive even accounting for the different sensitivity among income groups of smoking to prices.<sup>73</sup>

Proponents of higher tobacco taxes often respond to the regressivity argument by contending that revenue from the taxes should be directed toward cessation programs intended to help low-income smokers quit or toward relieving these smokers' financial burdens.<sup>74</sup> Funding cessation programs may be an admirable intention, but—as mentioned earlier—less than 3 percent of current tobacco tax and MSA payments are spent on cessation.<sup>75</sup> Taxing to relieve a household's financial burden is an odd argument, since no scheme taxing a subset of the poor could result in net financial gains for those taxed. A final open question

regarding the equity of taxes is whether the health benefits of reduced smoking accrue disproportionately to lower-income individuals and families. If so, the direct regressivity of the taxes would be attenuated (or even reversed) by the offsetting health benefits.

Illicit trade in response to tobacco taxes is also a concern. As stated in a leading economics textbook on public finance, “markets do not take taxes lying down.”<sup>76</sup> Furthermore, to borrow a statement attributed to John Maynard Keynes, “the avoidance of taxes is the only pursuit that still carries any reward.” A large body of research indicates that increasing tobacco taxes can have the unintended consequence of stimulating illicit trade in tobacco products (ITTP).<sup>77</sup> In the United States, most ITTP takes the form of legitimately manufactured cigarettes that are transported between states to be sold illicitly, avoiding state and local excise taxes at the point of retail sale. ITTP also involves counterfeit cigarettes, untaxed sales from Native American reservations, illicit whites (cigarettes legal in the country of manufacture but intended for illegal sales in other markets), and gray market reimported goods.<sup>78</sup> ITTP is big business. The National Academy of Sciences found in 2017 that illicit sales compose between 8.5 percent and 21 percent of the total market for cigarettes in the United States. This range represents between 1.24 and 2.91 “billion packs of cigarettes annually and between \$2.95 billion and \$6.92 billion in lost gross state and local tax revenues.”<sup>79</sup> Worldwide, the avoided taxes from ITTP are estimated to be in the tens of billions of dollars per year, putting ITTP in the same financial class as the global traffic in illicit drugs.<sup>80</sup>

The economic explanation for ITTP is simple: licit and illicit cigarettes are substitutes, and when the tax-inclusive price of the licit good rises, some users will switch to the illicit substitute. The degree to which tax increases and tax differentials among states and localities cause substitution toward ITTP depends on many factors, including the rule of law, enforcement at customs borders and at points of sale, the ease of access to illicit sources, the price differential between licit and illicit cigarettes, and the moral sentiments of the smoker.<sup>81</sup>

While the basic fact that an increase in taxes leads to more ITTP, holding other factors constant, is generally accepted by most economists,

there is much disagreement over the policy implications. If tax rates across states were unified, then presumably raising a unified rate would not stimulate as much ITTP as raising an already high local tax (such as in Chicago or New York City), given the large role that interstate tax arbitrage currently plays in ITTP.<sup>82</sup> Some in the public health community downplay any suggestion that taxes are linked to ITTP, dismissing the argument through guilt by association, since the tobacco industry makes this claim.<sup>83</sup> Others argue either that the effects are small or that other measures can be taken to combat illicit trade.<sup>84</sup> Careful empirical investigation has shown, however, that raising taxes can lead to sizeable increases in ITTP.<sup>85</sup> Notwithstanding, the evidence is clear that in most cases ITTP may erode but does not reverse revenue gains from increased taxes. Similarly, taxes do decrease consumption of tobacco products, even though ITTP may attenuate the amount by which they do so.<sup>86</sup>

Before leaving the subject of ITTP, it is important to note that it creates harms to health additional to those of smoking genuine, fully taxed cigarettes. Counterfeit cigarettes have been shown to contain pesticides, human and animal waste, heavy metals, and other harmful substances.<sup>87</sup> Furthermore, law enforcement directed at ITTP can create other harms, including those from incarceration and violence, given the well-known link between enforcement action against illicit drug markets and violence.<sup>88</sup>

## **Issues Involved with Taxing and Regulating E-cigarettes**

This section reviews the most prominent issues regarding the regulation of ENDS and potential unintended consequences.

The main issues surrounding vaping concern its safety, its relationship to smoking (including whether it is a promising avenue for harm reduction), and unintended consequences of regulation and taxation. Harm reduction refers to policies and approaches aimed at reducing the harms from an addictive substance, but not the use of the substance per se.<sup>89</sup> The viewpoint of harm reduction is widely accepted in the public health community for alcohol and illicit drugs, but it is controversial in the tobacco control community, mainly because of guilt by association with Big Tobacco, which “has been seen by some to lead

the harm reduction push (through the development of new nicotine delivery devices).<sup>90</sup> Thus, in traditional tobacco control abstinence is taken as the goal, rather than finding safer ways to consume nicotine. The rejection of harm reduction as a guiding philosophy is sometimes justified with reference to the precautionary principle, which posits that lack of scientific certainty should not delay action to regulate or ban new products such as e-cigarettes.<sup>91</sup> Notwithstanding, the discussion to follow examines the issue through the lens of harm reduction and whether e-cigarettes could be part of such an approach.

### **Is vaping safer than smoking?**

What many consider to be the most important question is the easiest to answer: Is vaping safer than smoking? Because e-cigarettes do not involve combustion, and because the combustion of the organic material in a cigarette creates nearly all the health hazards, it would be surprising indeed if e-cigarettes were found to be as risky for health as smoking. This simple expectation has been greatly muddled in the public mind by certain public health advocates who hold a priori goals of abstinence for both smoking and vaping. Thus, a review of the state of current knowledge on this topic may be useful.

To begin with, from the standpoint of harm reduction, the question is not whether e-cigarettes pose *no* health risks at all (except perhaps for the subject of initiation by youth, a subject to which I will return below). In the context of the public health disaster caused by smoking, the proper first question must be whether e-cigarettes are *safer* than cigarettes, and to what degree. After considering the state of the evidence, the official health ministry of England declared that vaping is at least 95 percent less harmful to health than smoking.<sup>92</sup> The purpose of Public Health England's statement in 2015 was not to present a precise risk multiple, but instead to effectively encourage smokers who have been unable to quit by other methods to switch to vaping instead of smoking.<sup>93</sup>

Eliquids and vapor contain substances known to be harmful to human health when inhaled, including irritants, carcinogens, and particulates.<sup>94</sup> Then again, much of modern life exposes individuals to harmful substances. Thus the question is what the short- and long-term

health effects from such exposure are, and how they compare with those from smoking.

One difficulty in discussing the health effects of vaping is the great multiplicity of products: there is no “standard” vapor, concentration of chemicals in e-liquids, or intensity of inhalation. Notwithstanding, one study found that along the spectrum of products tested, the preponderance of products produced vapor with cancer potencies of less than 1 percent of those of tobacco smoke.<sup>95</sup> Fewer harmful substances in the vapor means that fewer end up in the body. Another study concluded that switching completely from cigarettes to e-cigarettes “substantially reduced levels of measured carcinogens and toxins” in the body.<sup>96</sup> Overall, the National Academy of Sciences report on e-cigarettes found that “there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.”<sup>97</sup>

Perhaps the strongest case against vaping on the grounds of deleterious health effects would be based on respiratory disease, since exposure to particulates and flavorings in e-cigarette vapor could potentially impair the function of the lungs. Several studies find that vaping can cause acute respiratory symptoms such as coughing and wheezing, particularly among adolescents. Some of these studies do not control for concurrent or past smoking; controlling for these confounding factors removes the positive associations between vaping and respiratory symptoms in some studies.<sup>98</sup> Even here, however, the recent National Academy of Sciences report concluded that “there is no available evidence whether or not e-cigarettes cause respiratory diseases in humans.”<sup>99</sup> Conversely, the same report found “limited evidence” for improvement in symptoms from asthma and chronic obstructive pulmonary disease when smokers who suffered from those ailments switched completely to vaping. Summarizing evidence concerning a variety of potential ill health effects, the report found that there is “substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems,” including the respiratory system.

To conclude, while there is great uncertainty about the long-term effects of vaping, the answer to whether using e-cigarettes is better for health than smoking is almost surely yes. Viewed as part of a continuum of nicotine delivery methods arranged in terms of health risk, e-cigarettes appear to be much closer to nicotine replacement therapies than to smoking. However, the strongest arguments for the potential for e-cigarettes to reduce health harms to users can be made for users who switch completely away from smoking. There is no available evidence about whether long-term e-cigarette use among users who continue to smoke, called dual users, changes morbidity or mortality compared to smokers who do not vape.<sup>100</sup>

### **Do e-cigarettes aid in cessation?**

Is vaping a useful aid to help smokers quit smoking, or does it just prolong the habit by allowing smokers another way to consume nicotine when they are temporarily unable to smoke? It appears likely that e-cigarettes would be a more appealing cessation aid than nicotine replacement therapies (NRTs) such as patches, gum, or lozenges, given the sensory and behavioral similarity of vaping to smoking. The scientific literature on e-cigarettes and cessation is still in its early stages; given the novelty of vaping, no long-term studies on e-cigarettes and cessation have been performed. However, the initial literature is mainly encouraging.

A review of existing studies conducted in 2015 found that, overall, use of e-cigarettes was positively associated with both cessation of smoking and reduction in the intensity of smoking (for those who did not quit).<sup>101</sup> A more recent review of studies on cessation came to a similar conclusion, but only after excluding numerous published studies that did not meet standard levels of quality for scientific research in medicine or public health.<sup>102</sup> The latter meta-analysis found that rates of smoking cessation with e-cigarettes were generally similar to rates of cessation with NRT, while the former found e-cigarettes to be twice as effective as NRT.<sup>103</sup> Some research conducted after these reviews also suggests that e-cigarettes can play a role in cessation.<sup>104</sup>

### **Are kids getting addicted to e-cigarettes?**

There have been many dire, headline-grabbing reports issued in recent years referring to the “vaping epidemic” among youth. For example, in 2019 many variations on the headline “Teen Vaping Surges to More Than One in Four Students” appeared.<sup>105</sup> However, the much-publicized “27 percent” statistic pertains to the proportion of high school students who have used an e-cigarette once or more during the past 30 days. There is clearly a lot of casual use among high schoolers, since the prevalence of *substantial* use of e-cigarettes among high school students (defined as use on 20 or more days out of the past 30) is less than 10 percent.<sup>106</sup>

Furthermore, substantial use of e-cigarettes is mostly confined to youth who already smoke. Among students who had never tried any actual tobacco product in 2018, the prevalence of substantial use of e-cigarettes was found to be only 1.0 percent.<sup>107</sup> For such never-smokers, only 3.8 percent reported craving nicotine and only 3.1 percent reported wanting to use an e-cigarette within 30 minutes of waking. Combined with evidence that most dual-using high schoolers began with smoking, not vaping (see the next subsection), the researchers computing these statistics conclude that the data “do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes.”<sup>108</sup> Nevertheless, the prevalence of vaping—however it is measured—continues to rise among youth, and consequently it will require continued monitoring.

Finally, it is worth noting that not all youth vaping represents net health harms to the individual and society, given that in a counterfactual “no e-cigarettes” world, some young vapers would be smokers instead (or, in the case of dual use, potentially heavier smokers). The relationship between vaping and smoking is discussed in the next subsection.

### **Does vaping lead to smoking among youth?**

The findings discussed in the previous subsection that most e-cigarette use by youth is by smokers, coupled with other evidence that the same is true for adults,<sup>109</sup> lead to the question of which came first. Does vaping lead to smoking (the “gateway hypothesis”), or do underage smokers just find vaping a more convenient (and likely cheaper)<sup>110</sup> way

to consume nicotine while at school or elsewhere? First, it should be noted that many of the claims that e-cigarette use “causes” smoking are based on nothing more than the observation in population studies that many youth are dual users. However, it is likely that part of the association between vaping and smoking among youth is due to smoking leading to vaping. Another large part of the association is likely due to underlying (confounding) factors (such as a desire for risk-taking or exposure to smoking family members or peers) that make a youth more likely to vape *and* smoke.<sup>111</sup>

Given that it is unethical to perform randomized controlled trials involving exposure to vaping on youth, evidence can only come from observational studies of the population. Such studies, however, are inescapably beset by potential confounding factors. Population studies can control for certain observable demographic and behavioral confounders. Studies doing so that follow youth over time who do not initially smoke find that there is, in the estimation of the National Academy of Sciences report, “substantial evidence” that e-cigarette use increases the risk of trying cigarettes among youth and young adults.<sup>112</sup> However, it is impossible to control for all of the many genetic, behavioral, psychological, and environmental factors that surely must influence the propensities to smoke and vape, and none of the studies use econometric techniques designed to give some assurance that causal effects were identified. Some researchers, therefore, conclude that the association between vaping and smoking is more likely to be spurious than to be evidence for the gateway hypothesis.<sup>113</sup> As better data and more sophisticated statistical techniques are brought to bear on this question, it may be hoped that researchers, policy-makers, and the public can place greater confidence on one conclusion or the other.

If the conclusion in the National Academy of Sciences report is statistically meaningful, one would expect that as vaping among youth has risen, so will have youth smoking rates. This is not the case, however. Simply put, youth smoking initiation has been falling while the prevalence of vaping has been rising. A recent trend analysis of the relationship between vaping and youth smoking found that “while trying electronic cigarettes may causally increase smoking among some youth,



the aggregate effect at the population level appears to be negligible.”<sup>114</sup> Furthermore, the criterion of temporal precedence for causality states that if vaping causes smoking, then vaping must come before smoking. However, for the great majority of high school smokers, cigarettes were tried before e-cigarettes.<sup>115</sup> In 2014, only 2 percent of current high school age e-cigarette users who had smoked at least 25 cigarettes in their lifetimes said that they began with e-cigarettes. In 2015, that proportion had risen, but was still only between 8 percent and 15 percent.<sup>116</sup>

Another way to pose the question is whether restrictions on youth access to e-cigarettes will decrease smoking. The scant evidence on this subject appears to point to the opposite conclusion. Imposing minimum age laws for sales of e-cigarettes is estimated to have increased youth smoking participation by about one percentage point, which suggests that some youth who otherwise would have purchased e-cigarettes either began smoking or failed to quit.<sup>117</sup> Evidence in a similar vein comes from another study of underage rural girls: laws restricting sales of e-cigarettes to youth increased the prevalence of smoking during pregnancy by 0.6 percentage points, and evidence indicates that the cause was reduced cessation of smoking.<sup>118</sup> Given that the goal of minimum age laws is not just to discourage vaping but ultimately to improve health, these iatrogenic effects partially dilute the benefits of such laws.

### **Will the new federal minimum age law reduce youth vaping?**

People between 18 and 21 years of age could legally purchase e-cigarettes in the majority of states at the beginning of 2019 (see figure 3), whereas none of them could a year later. How much the new age restrictions will reduce vaping among youth is as yet unknown. On the basis of previous experience with tobacco minimum age laws, we should expect that without enforcement the new law will have little to no effect on underage use.<sup>119</sup> With enforcement, it is natural to expect that youth vaping would decline at least to some extent, if experience with earlier tobacco laws and youth smoking is any guide.<sup>120</sup>

However, several factors suggest that the minimum age laws will not eliminate use by underage vapers. First, most youth do not buy their

own e-cigarettes at retail stores, since in most places those under 18 have already been disallowed from purchasing them since 2016; acquiring e-cigarettes from social sources (e.g., friends and family) is much more common.<sup>121</sup> However, the hope of those raising the legal purchasing age is that younger teens will have fewer members of their social sourcing networks who are over 21. Furthermore, many youth who vape have already demonstrated willingness to break the law. Over two-fifths of youth who use e-cigarettes report vaping THC (tetrahydrocannabinol), which is illegal for youth even in states that have legalized cannabis.<sup>122</sup> Finally, even in relatively high-enforcement states such as California, approximately 7 percent of stores in 2018 were willing to sell e-cigarettes illegally to underage vapers.<sup>123</sup> This latter finding is in accord with research showing that the majority (75%) of underage smokers who attempt to purchase tobacco in the US are not refused because of age.<sup>124</sup>

### **Does vaping create externalities?**

As discussed earlier, a classic argument for taxing tobacco rests on health harms created by secondhand smoke. What about secondhand exposure to vapor from e-cigarettes, or even thirdhand exposure to chemical residue that settles from vapor onto surfaces? If secondhand and thirdhand exposure create large health harms, then taxes on e-cigarettes and restrictions on where they can be used may be justified.

Given that the health harms of vaping are not yet known with precision, it is unsurprising that the secondary and tertiary health impacts are also largely unknown, at least in the sense that no “optimal tax” can be calculated yet to align private and social incentives. One systematic review of the scientific literature led to no stronger a statement than that second- and thirdhand exposure to vapor from e-cigarettes has “the *potential* to lead to adverse health effects.”<sup>125</sup> The influential National Academy of Sciences report concluded that using an e-cigarette indoors “may involuntarily expose non-users to nicotine and particulates” but also that the effects of such exposure remain unknown.<sup>126</sup> Even if exposure to others’ vapor proves eventually to be harmful, it is highly likely to be less harmful than exposure to secondhand smoke. The two studies just cited state that the “risk from being passively exposed to . . . vapor

is likely to be less than the risk from passive exposure to conventional cigarette smoke<sup>127</sup> and that there is “moderate evidence that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes.”<sup>128</sup>

### **Do restrictions on advertising tobacco apply to e-cigarettes? Should they?**

Many of the restrictions on advertising tobacco do not apply to e-cigarettes, since the most important restrictions—most notably, the ban on advertising cigarettes on television and radio—are not FDA regulations. When the FDA deemed e-cigarettes to be tobacco products, any regulations promulgated by that agency thenceforth applied to e-cigarettes. Thus, since 2018, by federal law all advertisements for e-cigarettes must display the warning that “This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.” The notice must occupy at least 20 percent of the area of the advertisement.<sup>129</sup> However, there is no federal law against advertising e-cigarettes on television, radio, websites, billboards, public transportation, and other outdoor venues, whereas these advertisements are prohibited in most of the US for cigarettes.<sup>130</sup> Some states, however, ban advertising e-cigarettes on billboards.

Whether advertising e-cigarettes helps or hinders public health depends on how youth and adults respond to advertising, the health effects of vaping, and whether smokers use e-cigarettes to aid cessation. One recent study found that viewing television (but not magazine) advertising of e-cigarettes encouraged smokers to quit, with most of the effect due to greater success per quit attempt rather than to an increase in attempts.<sup>131</sup> The authors estimate that 3 percent of the decrease in the prevalence of adult smoking is due to television advertising. This evidence, which the authors call “tentative” since it was gathered from a relatively short period (two years of data), should give policymakers pause if they are considering indiscriminate bans on advertising e-cigarettes. Whether and how ads targeting or particularly attractive to youth can be prevented without banning all advertising remains an open question, both for vaping and for other goods, such as alcohol.<sup>132</sup>

## **What about the recent health scares involving vaping and lung illness?**

In mid-2019, a spate of visits to emergency rooms around the country linked vaping to acute lung injuries, and the government responded promptly—by creating an acronym for the phenomenon: e-cigarette- or vaping-associated lung injury (EVALI). While by the end of the year the tide of cases of illness and death from EVALI appeared to be receding, the highly publicized events raised the issue of the health effects of e-cigarettes to prominence in the public's eye. As I write this chapter, officials are still investigating the causes of EVALI, and given that products of questionable legality appear to be involved in many cases, the true causes may never be nailed down. However, the following paragraphs summarize what seems to be known at the present.

As of February 18, 2020, there were 2,739 hospitalizations and 68 deaths connected with EVALI.<sup>133</sup> The emergency room visits rose sharply in August 2019 and peaked in September. Note that since e-cigarette usage had been growing smoothly and steadily since at least 2006, a suddenly appearing (and declining) epidemic such as EVALI cannot logically be caused by vaping in general. The most plausible current guess about the cause of EVALI centers on vitamin E acetate, a chemical added to e-cigarettes containing THC (loosely speaking, “marijuana vapes”) that the Centers for Disease Control and Prevention says is “strongly linked to the EVALI outbreak.” In government tests, 48 of 51 EVALI patients examined had vitamin E acetate in their lung fluid, compared to *none* found in a comparison group of 99 healthy people.<sup>134</sup> Of the roughly 2,000 EVALI patients for whom data were available, 82 percent reported using THC-containing products; given that such products are illegal in some places under state law and illegal everywhere under federal law, this percentage is undoubtedly lower than the actual proportion of THC vapers. Of those using THC-containing products, 84 percent reported acquiring products from informal sources other than physical commercial sources such as dispensaries and vape shops: friends, dealers, off the street, or online sellers.<sup>135</sup> Furthermore, the most commonly used brand in a sample of 86 EVALI patients was a generic THC cartridge made by multiple unregulated manufacturers

and sold on the black market.<sup>136</sup> On the basis of the evidence, the Centers for Disease Control and Prevention concludes that vitamin E acetate has been identified “as a primary cause of EVALI.”<sup>137</sup>

While some public health officials seized upon the epidemic as evidence that vaping in general is deleterious to health, the official recommendations from the Centers for Disease Control and Prevention (as I write this chapter) are to avoid vaping THC, to avoid the additive vitamin E acetate, to be aware of “the wide range of health effects” associated with THC use, and to seek help for abuse of cannabis from a healthcare professional. In particular, the CDC specifically warns against returning to smoking instead of vaping for those who quit smoking or are trying to quit.

### **If we heavily regulate, tax, or ban e-cigarettes, what might be the unintended consequences?**

Some of the potential unintended consequences of over-regulating e-cigarettes are similar to those discussed earlier for tobacco, while others differ. The tax equity issue because of the regressivity of excise taxation remains, although not to the same extent as for cigarette taxes, since it is not the case that lower-income individuals are more likely to vape than higher-income individuals.<sup>138</sup> The more important consideration concerns the health consequences of discouraging the use of a nicotine product at the lower end of the continuum of risk and the potential for black-market substitution.

The harm reduction (as opposed to the abstinence) approach to tobacco control views tobacco and nicotine-containing products as lying along a continuum of risk.<sup>139</sup> Combustible products, most notably cigarettes, pose the greatest hazards, while nicotine replacement therapies are the least hazardous products. Some public health authorities embracing the harm reduction approach, perhaps most notably Public Health England, place e-cigarettes close to the low-risk end of the continuum. The key question for harm reduction is what will happen if e-cigarettes are banned, heavily taxed, or saddled with overly burdensome regulation? If more people continue to smoke instead of switching to vaping or quitting, then the evidence reviewed above indicates that it

is highly likely that public health would suffer. Per-unit or ad valorem taxation of e-cigarettes may also encourage substitution toward products with higher concentrations of nicotine, which may increase health harms for youth.<sup>140</sup> On the other hand, if vaping renormalizes smoking and increases initiation among youth, public health could suffer in the future. (Discussion of these consequences continues in the next section.)

Given the relative novelty of vaping, illicit trade in e-cigarette products is much less studied than illicit trade in tobacco products.<sup>141</sup> Apparently a thriving black market in counterfeit e-cigarettes already exists, although the prevalence is unknown and claims by manufacturers may be overstated. A worrisome feature of counterfeit eliquids is the uncertainty about what they contain; one study found that many of them contain nicotine even when they are labeled as zero-nicotine products.<sup>142</sup> Black-market THC vaping products have been found to contain pesticides, heavy metals, and lead, and counterfeit nicotine eliquids have been traced to illicit, unsanitary facilities in China.<sup>143</sup> Packaging and supplies to assemble counterfeit vaping products are readily available online.<sup>144</sup> The barriers to entry into the market for counterfeit products therefore seem to be low. As in any other market, as taxes or sales restrictions on licit products rise, substitution of illicit sources by some users should be expected, although the sensitivity to taxation of illicit trade in e-cigarette products has not been explored yet.

There is another important factor linking regulation of e-cigarettes to illicit trade, however. When e-cigarettes are readily available to smokers at reasonable prices, they offer smokers an attractive alternative to buying illicit tobacco products to reduce the costs of consuming nicotine. E-cigarettes could thus attenuate the link between higher cigarette taxes and stricter regulation of traditional tobacco products and ITTP. An econometric study found empirical support for this hypothesis.<sup>145</sup> Using data from Europe, econometric analysis showed that in places lacking availability of e-cigarettes, there was a sizeable, statistically significant positive relationship between tax increases for cigarettes and ITTP. However, the availability of e-cigarettes attenuated the size of that link: “the more available e-cigarettes become, the less the ITTP market share rises in response to tax-driven price increases for conventional

cigarettes.”<sup>146</sup> In places where e-cigarette markets are large enough, cigarette prices no longer have any significant effect on illicit trade.

### **Steps toward Better Regulation**

If more were understood about the actual health effects of vaping and exactly what the relationships are among the prices of tobacco and e-cigarettes, vaping, and youth initiation of smoking, and furthermore if society agreed that vapers and smokers need to be “saved from themselves” because of irrational choices, then in principle one could compute optimal prices for tobacco and e-cigarettes and levy taxes to achieve them. Complicating the analysis are the additional factors discussed above regarding the relationships among the price of tobacco, the price and attractiveness of vaping, and illicit trade. Furthermore, policymakers would also have to decide whether and how to weigh the equity considerations raised by tobacco taxation. Given the great uncertainty about the precise degree to which vaping is safer than smoking, no such tax rates can be computed at present. However, although a “first best” regulatory policy toward tobacco and vapor cannot be determined, there are sensible steps that can be taken that are likely to be in the right direction.

For tobacco, difficult and honest discussion needs to take place about the role of high rates of excise taxation. Given the evidence discussed above that current tax rates are higher than those required to correct for externalities and that the burden falls heavily on low-income individuals, the remaining rationales for taxation rest on paternalism, whether it is dressed in the clothing of behavioral economics or not.<sup>147</sup> How much of states’ and localities’ desire to tax tobacco stems from the ease of raising revenue from a socially disfavored minority?

Regarding e-cigarettes, the following seven recommendations can guide policymakers toward better regulation. First, the overriding principle that shapes thinking about regulating tobacco and e-cigarettes should be risk-proportionate regulation.<sup>148</sup> Products that are not as harmful to health as cigarettes should be regulated less stringently, taxed at lower levels, or even encouraged if they aid in cessation of tobacco use. By deeming e-cigarettes to be “tobacco products,” the

FDA created a setting that prompted all the anti-tobacco crusading zeal to be indiscriminately directed at vaping as well. But since vaping is almost surely less harmful to health than smoking, the regulatory touch should also be lighter.

Second, the public health community in the United States needs to curb its tendency to understate the likely health benefits of switching from cigarettes to e-cigarettes. Sometimes this understatement happens because people confuse the absolute risk from vaping with the relative risk of vaping versus smoking, since the absolute risk is often characterized in more certain or inflated terms than the current body of scientific evidence warrants. Since e-cigarettes may cause some health harms (this argument runs), therefore vaping is no better than smoking. When anti-vaping advocates in the public health community take the uncertainty in the scientific literature as license to make statements implying that e-cigarettes could be comparably risky to cigarettes—or even more dangerous—their statements are technically true, since the long-term health effects of vaping are unknown. But they are also highly misleading.<sup>149</sup>

Such statements have helped convince many members of the public to hold potentially dangerous attitudes about the relative health harms of smoking and vaping. Surveys indicate that today the majority of Americans believe e-cigarettes are just as harmful as cigarettes, and about 10 percent think that vaping is more dangerous than smoking.<sup>150</sup> Fewer than 3 percent of adults think that e-cigarettes are much less harmful than cigarettes.<sup>151</sup> These negative perceptions of e-cigarettes have grown rapidly in recent years. This is concerning, given that the perceived risk of smoking relative to vaping is known to affect the decision to use e-cigarettes.<sup>152</sup>

Third, the uncertainty regarding the health effects of e-cigarettes should not be used to discourage smokers from switching to vaping. The personal negative health impacts from smoking are large and well studied. Switching completely away from such a harmful activity to an activity that is very likely to be less harmful—even if the degree of relative risk is uncertain—is likely to improve the health prospects of the individual switching. The potential costs to public health of



discouraging smokers from switching to e-cigarettes are high. One study found that, compared to the status quo, replacement of cigarette use by e-cigarette use over a 10-year period would result in 1.6–6.6 million fewer premature deaths and 20.8–86.7 million fewer years of life lost.<sup>153</sup>

Fourth, given the potential benefits to adult smokers from switching to e-cigarettes and the potential harms to youth from taking up vaping or, in consequence, smoking, targeting regulation narrowly at youth may be better than blunt, broadly applied rules. Thus the current age limits on purchases of e-cigarettes are mainly uncontroversial, as is the FDA's enforcement against eliquids designed to resemble child-friendly food products. So would be, presumably, future restrictions on advertising aimed at youth. Of course, youth-oriented restrictions may prevent some young people who already smoke from switching to a less harmful product, since most current smokers began their habit before age 18. (As noted earlier, the age restriction for e-cigarette sales is now 21.)

Expending tobacco control funds on campaigns and information to alert youth to the potential dangers of vaping, in principle, is also relatively uncontroversial, since nicotine may have adverse health effects for adolescents that it does not have for adults.<sup>154</sup> However, as with any abstinence campaign, it is likely that some youth will reject such messages, particularly if they sense that the claims are overblown or manipulative. Given the absence of solid knowledge about adverse health effects, some youth-oriented anti-vaping messages instead rely on false syllogisms along these lines: "Big Tobacco wants you to vape, and tobacco kills—therefore vaping will kill you." Others attempt to parlay the recent epidemic of EVALI into messages not to use licit products such as JUUL and other commercially available, non-THC e-cigarettes, which does not appear to be a supportable conclusion (given the current but evolving knowledge reviewed earlier in this chapter).<sup>155</sup> It is an open question why the same public health community that rejects fear-based anti-drug messages as ineffective or, worse, causing a boomerang effect<sup>156</sup> embraces them for the anti-vaping crusade.

Fifth, given the benefits of using regulation to target vaping by youth, heavily taxing e-cigarettes is not likely to be in the best interests of public health. As discussed previously, a tax (or any general regulation

affecting all ages of users) is a very blunt instrument. While higher prices may deter some youth from using e-cigarettes, given the apparently large current appetite for black-market vapes that the EVALI epidemic revealed, coupled with the evidence from tobacco taxes and ITTP, it seems very likely that high taxes on e-cigarettes will drive more youth demand toward less reputable and potentially much more dangerous sources. In any event, sales to those under 21 years of age are already banned, which is equivalent to an infinitely high tax that applies only to youth. Furthermore, burdening adult smokers with high taxes will discourage some of them from switching to vaping, to the likely detriment of their health.

Indeed, if e-cigarettes are viewed as a form of nicotine-replacement therapy, there might even be a case for subsidizing them for smokers attempting cessation (as NRTs are subsidized through private health insurance and various public programs) rather than taxing them. Thus, proposed legislation such as the E-cigarette Tax Parity Act, which seeks to tax nicotine equally regardless of the mode of delivery, not only almost certainly violate the principle of risk-proportionate regulation but also may be harmful to public health.<sup>157</sup>

Sixth, careful consideration is warranted about whether banning the use of e-cigarettes in public spaces is appropriate. As reviewed above, it is far more certain that switching from smoking to vaping is beneficial for the health of the user than it is that e-cigarettes create substantial health harms from secondary exposure. But the ability to use e-cigarettes to consume nicotine, even if only in designated areas, while at work or in public spaces could be a powerful incentive for a smoker to switch. On the flip side, the ability to consume nicotine more easily may also prevent or delay some smokers from cessation (the “dual use” case). More study will be required to resolve these uncertainties, but it is not at all clear that excessive caution is better than cautious optimism regarding the social costs and benefits of vaping bans in public and work spaces. Banning vaping where smoking is banned also sends the message that the two activities are equally harmful, when they most likely are not—see again the second and third points discussed above.

Seventh, efforts to resolve the regulatory uncertainty at the federal level should be regarded as highly important. The FDA currently states that “no ENDS products have been authorized by the FDA—meaning that all ENDS products currently on the market are considered illegally marketed and are subject to enforcement, at any time, in the FDA’s discretion.”<sup>158</sup> Yet the agency has so far allowed sales of commercial nicotine e-cigarette products, as long as there are no sales or marketing to youth. The current regulatory environment is thus one in which the industry and the specific manufacturers and retailers in the industry are subject to a higher degree of regulatory dependence and uncertainty than affects most other industries. The negative effects of regulatory uncertainty and regulatory delay on investment and product innovation are well studied in other industries.<sup>159</sup> If e-cigarettes aid cessation or otherwise reduce harms from smoking, then innovation in that product space should be encouraged rather than discouraged.

Finally, in regard to both tobacco and e-cigarettes, policymakers must pay serious attention to the interplay among taxation, regulation, and illicit markets. If e-cigarettes are inexpensive, attractive to users, easy to obtain, and able to be used in places where smoking is forbidden, then current smokers will be less likely turn to the black market when they are faced with higher taxes on cigarettes or increased restrictions on smoking.<sup>160</sup> Because the argument that higher taxes stimulate ITTP is convenient for tobacco manufacturers lobbying for lower tax rates, the public health community has a long history of discounting the possibility out of hand. This is despite the well-established links economists have found between cigarette taxation and smuggling.<sup>161</sup> The already-present black market in tobacco, e-cigarettes, and eliquids should not be viewed as a theoretical possibility of limited practical import. Instead, illicit trade in all these product markets—and the likelihood that stricter regulation and higher taxation will exacerbate it—must be part of the policy calculus from the beginning.

Policymakers should plan for enforcement against illicit markets, and this enforcement must include action stronger than the tool currently preferred by the FDA—warning letters sent to noncompliant retailers and manufacturers.<sup>162</sup> Policymakers must also recognize that harsher,

more effective enforcement can create its own harms—a notion familiar to the harm reduction community regarding illicit drugs, but curiously absent among anti-tobacco advocates.<sup>163</sup>