

# Chapter 5

## E-Cigarette Policy and Practice Implications

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## Introduction

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The previous chapters have set out what is currently known and not known about e-cigarettes. Despite the identified gaps in evidence and the dynamic, evolving patterns of the use of e-cigarettes, policy options are needed. These policy options are particularly important as they affect the use of e-cigarettes by youth and young adults. As this report has demonstrated, e-cigarettes are widely used by youth and young adults and are particularly risky for these age groups, and efforts to prevent their use by young people are needed. This chapter explores the policy landscape of e-cigarettes and sets forth recommendations that should protect the public's health, particularly as these policies relate to the short- and long-term health of youth and young adults.

The *Family Smoking Prevention and Tobacco Control Act of 2009* (or Tobacco Control Act) (2009) is meant to protect the health of the public, including young people. As previously discussed, on May 10, 2016, FDA published a final rule which deemed all other products, including e-cigarettes, meeting the definition of a tobacco product, except accessories of such products, to be subject to the *Federal Food, Drug, and Cosmetic Act*. This rule went into effect on August 8, 2016 (Federal Register 2016). Under the Tobacco Control Act, FDA likely will be required to consider the consequences of e-cigarette use for those who do not use tobacco products (as well as for those who do).

It can be stated that public health will be harmed *if* the availability of e-cigarettes:

- Increases exposure to nicotine among youth and young adults;
- Leads to the initiation of combustible tobacco smoking;
- Slows or prevents cessation of combustible products by nicotine-addicted smokers; or
- Increases the likelihood that former smokers will again become addicted to nicotine and/or use combustible products after being reintroduced to nicotine by e-cigarettes.

Potential harm also comes from secondhand exposure to the vapor or aerosol expelled from e-cigarette

users. Secondhand exposure comes from inhaling the aerosol or contacting vapor-contaminated surfaces. Each of the potential negative consequences of the availability of e-cigarettes could lead to additional disease and premature mortality (Chapter 3).

Relative to efforts in cigarette and smokeless tobacco use prevention and control, a polarized debate has been in progress for several years over the role of e-cigarettes. There is general agreement that exclusive use of e-cigarettes poses a lower health risk to the individual than the extremely high health risks of using conventional, combustible tobacco products (Farsalinos and Polosa 2014; Grana et al. 2014a,b), although more research is needed on this as more becomes known about the harmful constituents of e-cigarettes (Sleiman et al. 2016). The controversy reflects the relative degree of emphasis given to the potential harm to adolescents and young adults from using e-cigarettes at one pole compared with the potential for reduced risk for established adult users of conventional cigarettes at the other (if they transition completely to e-cigarettes). Although this characterization does not reflect the complexity of the situation, it is useful in defining the potential tradeoffs that are implicit: increased numbers of young people who are exposed to nicotine (and who may go on to conventional tobacco products) versus reduced health risks to individuals who completely switch from conventional, combustible tobacco products with their extremely high health risks. The discussion has become increasingly complicated as e-cigarette use has increased, and still-incomplete evidence potentially supports the views of those holding to both poles of the argument about reducing harm for the overall population. However, the majority of currently available scientific evidence does not support the recommendation to use e-cigarettes for the cessation of cigarette smoking (Hartmann-Boyce et al. 2016). Additionally, the use of e-cigarettes does not pose benefits to youth and young adults, and some data suggest that use of e-cigarettes could lead to the more harmful use of conventional cigarettes. In the context of young people, the precautionary principle should apply. The precautionary principle is defined by the United Nations Educational, Scientific and Cultural Organization (2005) as appropriate “when human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm” (p.14).

## Critical Issues Related to Policies on E-Cigarettes in 2016

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### The E-Cigarette Landscape Is Dynamic and Evolving

Considerations of policy approaches to e-cigarettes offered in this report are made in the context of a rapidly changing marketplace for nicotine-containing products that now includes primarily conventional cigarettes, cigars, smokeless products, hookahs, and e-cigarettes (see Chapter 2). The manufacture and sales of nicotine-containing products, once dominated by a few large companies selling conventional cigarettes, have been transformed and now include many smaller companies that manufacture and sell through stores and “vape shops.” E-cigarettes are also sold through websites and in places where conventional cigarettes have long been available—convenience stores, pharmacies, gas stations, and grocery stores. Currently, hundreds of different e-cigarette products are on the market: designs are evolving rapidly, and major tobacco companies have their own lines of e-cigarette products. However, unlike the situation in the past in which the marketing of conventional tobacco products changed relatively slowly and there were limited media outlets, information about e-cigarettes is now promoted quickly through new media, as well as television, in part to reach key target groups, including youth and young adults.

As documented in Chapter 2, patterns of use are rapidly changing among adolescents and young adults, and likely among other groups within the population. For some of the most critical issues related to e-cigarettes, longitudinal data are not yet available because the use of these products is recent and constantly changing, and whether and when the patterns of use will stabilize is uncertain. Additionally, surveillance data and research on the wide-ranging consequences of e-cigarette use, including such key issues as the likelihood of addiction and other health problems for users and those passively exposed, are lagging behind the highly dynamic changes in the nicotine-product marketplace and the impact of these changes on the use of tobacco products, including e-cigarettes.

With regard to the potential health consequences of using e-cigarettes, estimates can be made based on knowledge of the characteristics and components of the aerosols that are then inhaled. Unfortunately, evidence on short-term risks is limited, and long-term risks have not yet been identified because this would require monitoring users for years. For example, the impact of long-term inhalation of flavorings is not yet known. While some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are

generally unknown, and some flavorings have been shown to cause a serious lung disease, bronchiolitis obliterans, when inhaled (Kreiss et al. 2002; Barrington-Trimis et al. 2014). Whether the risk of lung disease or other disorders is truly substantial will require longer term epidemiologic and other research (Allen et al. 2016).

Thus, policy approaches must support control measures that (a) are as dynamic as the rapidly changing marketplace for e-cigarettes; (b) are supported by surveillance data; and (c) document in timely fashion the current status of the use of multiple types of tobacco products (including e-cigarettes); the emergence of state, local, tribal, and territorial policies; and the strategies being used to market these products.

### Risk Tradeoffs Are Inherent for E-Cigarettes

Policy discussions about e-cigarettes have highlighted the potential tradeoffs in risk that could occur, particularly if e-cigarettes are positioned as a harm-reducing alternative to combustible tobacco products. Some have characterized these products as new technologies that might lead to a dramatic decline in the use of more dangerous forms of nicotine delivery, particularly conventional cigarettes and other combustible tobacco products (Abrams 2014; Cobb and Abrams 2014; Fagerström and Bridgman 2014; Grana et al. 2014a; Hajek et al. 2014; Henningfield 2014; Schraufnagel et al. 2014; West and Brown 2014; Lindblom 2015). Correspondingly, e-cigarettes have been proposed by some as a harm-reduction strategy and as a tool for smoking cessation, but the data to date do not support e-cigarettes for harm reduction or cessation (Siegel et al. 2011; Abrams 2014). By contrast, others are concerned that the availability of these new products will expand the number of youth and young adults who are exposed to nicotine and will eventually lead to exclusive use of other conventional tobacco products or dual use of both (e-cigarettes and conventional cigarettes) (Leventhal et al. 2015; Primack et al. 2015). Early longitudinal evidence provides some support for these concerns, although further research on this issue is still warranted.

As reviewed in Chapter 3, uncertainty remains about the health effects of e-cigarettes, particularly in the long term. Such effects will remain unknown until sufficient observations can be made over time. However, current knowledge of the characteristics of the inhaled aerosol from e-cigarettes suggests that if a current adult smoker of

conventional cigarettes or other combustible tobacco products would use e-cigarettes exclusively instead of combustibles as a substitute nicotine delivery system, either en route to quitting tobacco completely or even as a long-term alternative, the risks of tobacco-related diseases would be reduced substantially compared with the risk imparted by continued smoking of conventional cigarettes (Fiore et al. 2014; USDHHS 2014; McNeill et al. 2015).

Still, as documented in Chapter 3, immediate and future health risks for youth and young adults who use e-cigarettes can be anticipated from exposure to nicotine, including addiction and harmful effects on brain development. Research must continue to characterize and quantify the full spectrum of potential health risks. Thus, in formulating policies related to the role of e-cigarettes in tobacco control and reducing the burden of tobacco-related disease, particularly among youth and young adults, e-cigarette products that deliver nicotine cannot be considered a risk-free alternative to conventional cigarettes or other combustible tobacco products.

Any analysis of the potential increased risks and reduced harms of e-cigarette use also needs to consider data on the actual patterns of use because more of the risks affect youth and young adults and most of the potential benefits from reduced risk to health largely accrue to older cigarette smokers (Chapter 2). However, the reports of the tobacco industry to investors indicate the industry's interest in maintaining a broad pattern of use of nicotine-containing products, including conventional cigarettes, for decades to come (Calantzopoulos 2015). When considered in the context of the tobacco industry's past changes to product design (e.g., the creation of so-called "low-tar" cigarettes), the broader array of tobacco products now being discussed within the tobacco industry's plans (e.g., "Heat-Not-Burn" products) could slow cessation (because smokers have historically been drawn to reduced-harm products) and thus the overall decline of tobacco-related diseases (USDHHS 2014).

The dynamic balancing between risks and potential benefits of e-cigarette use will be swayed by the impact of such use on the use of other tobacco products by youth and young adults over time. The availability of e-cigarettes could adversely affect the use of tobacco products in this group by slowing the decline of smoking because this population will be exposed to nicotine and possibly become addicted to that substance. Indeed, data reviewed in Chapter 2 show evidence of such trends. Although the decline in rates of smoking conventional cigarettes and other combustible tobacco products is viewed universally as positive, the increasing number of youth and young adults who use e-cigarettes is a serious concern for all the reasons cited above. West and Brown (2014) and McNeill and colleagues (2015) suggest that the limited

evidence from the United Kingdom does not support the concern that using e-cigarettes leads to the use of other tobacco products, and they maintain that the new adolescent users of these e-cigarette products include very few never smokers. However, the marketing of e-cigarettes is quite different between the United Kingdom and the United States, and the patterns of use, particularly among youth, are also quite different (European Parliament and Council 2014; England et al. 2015; Klein 2015; Leventhal et al. 2015; Primack et al. 2015; Barrington-Trimis et al. 2016; Wills et al. 2016; Institute for Global Tobacco Control n.d.). This pattern is also evident in some U.S. survey data from early in the era of e-cigarette use (as reviewed in Chapter 2), but not in more recent data, which indicate that e-cigarette products may contribute to nicotine addiction in a new generation of young people and thereby lead to increased use of a variety of nicotine delivery products, including combustible tobacco (Bauld et al. 2016; CDC 2016).

Fundamentally, the public health challenge and the charge to policy development can be framed as balancing the potential use of e-cigarettes as a new technology to reduce the use of combustible tobacco products against the possibility of expanding tobacco use among non-using youth and young adults, long-term former smokers, and other vulnerable populations (e.g., women of reproductive age and individuals with significant comorbidities, including those with mental health problems). Already, the e-cigarette companies are increasing the appeal of their offerings by enhancing the efficiency of nicotine delivery and using flavorings while they continue to advertise and promote their products aggressively.

## **Additional Evidence Suggested for Future Research**

To characterize the critical balance for public health between the harms and potential benefits of e-cigarettes, more evidence on each of the elements that determine that balance would be useful (Table 5.1). The needed data would come from surveillance of patterns of adoption of e-cigarettes and their use among the population generally, and particularly among the most critical populations for uptake: youth and young adults, former smokers, smokers, and other populations that are particularly at risk for adverse outcomes. Few studies have been done on the health risks posed by e-cigarettes and their potential effectiveness for smoking cessation (Hartmann-Boyce et al. 2016). However, as discussed in Chapter 2, there are still no standardized questions for research on

**Table 5.1 Comparative risk assessment: Potential harms and benefits of e-cigarettes**

Harms	Benefits
Increased youth exposure to nicotine and potentially greater initiation of conventional cigarettes	Reduced disease risk for current smokers who completely switch to e-cigarettes
Slowing cessation by smokers due to nicotine addiction	Reduced disease morbidity for smokers with existing heart or lung disease who switch to e-cigarettes
Nicotine addiction in former smokers who begin to use e-cigarettes and possibly transition back to smoking	Potential for cessation of combustible products
Renormalization of nicotine use and smoking as acceptable	Fewer users of combustible products in the entire population
Future disease risks for youth who are exposed to nicotine	
Increasing the dual use of e-cigarettes with combustible products	
Serving as a “gateway” to the initiation of tobacco smoking	
Increased disease risk vs. complete cessation among those who use both e-cigarettes and combustible products	
Exposure to secondhand aerosol and lack of clean air	

e-cigarettes, and there is a need for further testing and development of e-cigarette questions and measurements.

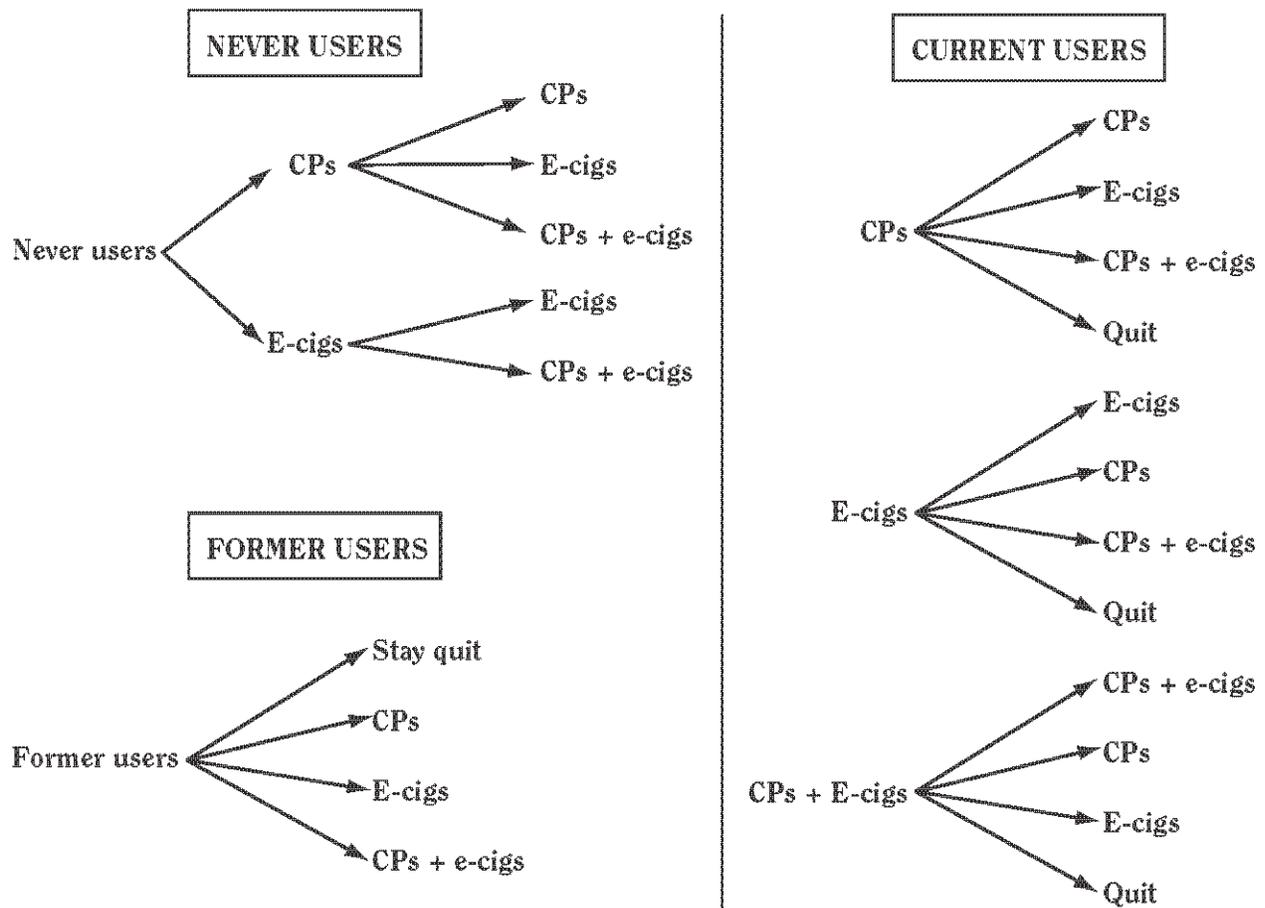
To characterize the harms and benefits of e-cigarettes to public health, models are used to project their overall impact on public health (Levy et al. 2016). The use of modeling was described in detail in the 2014 Surgeon General’s report (USDHHS 2014). Conceptual models are needed to define the potential scenarios of changes in patterns of use among youth, young adults, adult smokers, former smokers, and other significant vulnerable populations. Figure 5.1 displays the range of patterns that are emerging with the wider adoption of e-cigarettes (Cobb et al. 2015; Vugrin et al. 2015). Researchers and public health officials can use dynamic population models (Mejia et al. 2010; Kalkhoran and Glantz 2015; Vugrin et al. 2015; Levy et al. 2016) to analyze the potential impact on population health of the relative probabilities of these various paths. Initial modeling has shown that the potential population health benefits are very sensitive to several factors: the levels of product risk, particularly those of e-cigarettes; patterns of initiation and switching; and the extent of dual use (Mejia et al. 2010; Cobb et al. 2015; Kalkhoran and Glantz 2015; Vugrin et al. 2015). The benefits of smoking cessation, particularly as early in life as possible, are well documented, but the epidemiologic evidence that reducing (but not quitting) cigarette consumption can lower the risk of all-cause mortality, or mortality from cardiovascular diseases, remains inconclusive (USDHHS 2014). Thus, more research is needed to better characterize the health consequences of dual use, in particular, in comparison to the recognized health benefits of complete smoking cessation (or potentially only e-cigarette use). Similarly, the health risks to former smokers who become exposed again

to nicotine through e-cigarettes are uncertain. Data are still limited on the risk of starting (or not starting) to smoke conventional cigarettes again (after successful cessation) following exposure to nicotine via e-cigarettes.

As reviewed in Chapter 3, the long-term health risks of e-cigarettes will not be known for decades, although evidence to date suggests that they are generally less harmful than combustible products. However, less harmful is not the same as harmless. A substantial amount of evidence is available on some components of the aerosols inhaled by e-cigarette users. For many people, exposure to aerosol could occur across much of the life span, beginning in adolescence and even in childhood, when the lungs and brain are still developing. Flavorings are of particular concern with regard to pulmonary toxicity, as are the various effects of nicotine on the brain. Although the National Institutes of Health is now supporting a growing program of research on e-cigarettes, critical questions have not yet been answered. Given experiences with conventional cigarettes, long-term studies will be needed to identify the full health consequences of using e-cigarettes.

Thus, policies related to e-cigarettes will necessarily be made in the context of accumulating but incomplete evidence. The landscape is changing rapidly and, inevitably, research cannot keep pace. Quoting Sir Austin Bradford Hill’s landmark paper on environment and disease: “All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer on us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time” (Hill 1965, p. 300).

Figure 5.1 Potential patterns of use of combustible products (CPs) and e-cigarettes (e-cigs)



Source: USDHHS (2014). Adapted for this report.

## Potential Public Policy Approaches

In formulating public policies related to e-cigarettes, the context and possibilities vary across the national, state, local, tribal, and territorial governments and public entities. At the national level, progressive steps are being taken by FDA under the Tobacco Control Act. In 2010, the U.S. Court of Appeals for the D.C. Circuit determined that e-cigarettes and other products made or derived from tobacco may be regulated by FDA as tobacco products under the Tobacco Control Act and are not drugs or devices unless marketed for therapeutic purposes, such as being an aid to smoking cessation (*Sottera, Inc. v. Food and Drug Administration* 2010). In May 2016, FDA released its deeming rule to regulate the sale and distribution of e-cigarettes as a tobacco product (see Chapter 1) (*Federal Register* 2016). The rule is currently under litigation. The rule restricts the age of sale to those 18 years of age and

older and requires retailers to check the age identification of young people under age 27, restricts vending machines to adult-only facilities, prohibits free samples, requires a health-warning statement about nicotine on packaging and in advertisements, requires domestic manufacturers to register their products and disclose the ingredients of their products, requires the reporting of the levels of harmful and potentially harmful constituents to FDA, allows FDA to review any new or changed products before being sold, and requires manufacturers to show scientific evidence that demonstrates the overall public health benefit of any product before it can be marketed as a modified risk tobacco product (*Federal Register* 2016). The Tobacco Control Act does not provide FDA with authority to impose taxes on tobacco products (Bhatnagar et al. 2014; Huang et al. 2014; Tobacco Control Legal Consortium 2015) or

regulate indoor air quality (Schripp et al. 2013; Bam et al. 2014; Bhatnagar et al. 2014; Brandon et al. 2015a), occupational health and safety (USDHHS 2015; Whitsel et al. 2015), or hazardous waste disposal (Chang 2014; Krause and Townsend 2015).

FDA is not the only federal agency with potential jurisdiction over some aspect of e-cigarettes (Table 5.2). For example, the U.S. Department of Defense and U.S. Department of Veterans Affairs relate to specific populations, and other agencies relate to regulatory activities, such as the U.S. Federal Trade Commission, U.S. Department of Transportation, and the U.S. Environmental Protection Agency. Some agencies have coverage over specific areas, such as the General Services Administration and the National Park Service.

State, local, tribal, and territorial governments, as well as private entities, may also address these and other matters that are covered by the Tobacco Control Act (Freiberg 2012), and since 2010 many actions have been taken at the nonfederal level. State and local governments may utilize effective interventions that would also be expected to apply to e-cigarettes: increasing the price of tobacco products through taxation (Community Preventive Services Task Force 2012); creating and enforcing clean air policies (Hopkins et al. 2010); and passing comprehensive laws prohibiting sales to minors, combined with active enforcement (Community Preventive Services Task Force 2001). In addition, based on evidence that new e-cigarette products may addict a generation of young people to nicotine (Bunnell et al. 2015; CDC 2015b) and on mounting indications about potential harm from the use of these products in this population (Flouris et al. 2013; Barrington-Trimis et al. 2014; Goniewicz et al. 2014; Grana et al. 2014a; Pisinger and Dossing 2014; Goniewicz and Lee 2015), numerous health organizations have called for the extension of smoking-related policies to e-cigarettes (Association of State and Territorial Health Officials 2014; Bam et al. 2014; Bhatnagar et al. 2014; Offermann 2014; Schraufnagel et al. 2014; World Health Organization 2014a; Brandon et al. 2015a; USDHHS 2015). In the absence of causal findings that have guided evidence-based tobacco control for decades, the “precautionary principle” is relevant to decision makers as a guide to action to address e-cigarettes among youth and young adults. This principle supports intervention to avoid possible health risks when the potential risks remain uncertain and have been as yet partially undefined (Bialous and Sarma 2014; Saitta et al. 2014; Hagopian et al. 2015). However, the interventions should be appropriate to the currently perceived risk for future health consequences, in this case from e-cigarette use by youth, young adults, and pregnant

women, as well as from the secondhand exposure of non-users to e-cigarette vapor.

## **Clean Indoor Air Policies**

Clean indoor air or smokefree policies prohibit the use of conventional tobacco products in indoor public places, such as worksites, restaurants, bars, and casinos. Because most of these policies predate the rise of e-cigarettes, their language does not necessarily cover emissions from these products. To protect the public from both secondhand smoke and secondhand aerosol, smokefree air policies should be modernized to include e-cigarettes. Such policies will maintain current standards for clean indoor air, reduce the potential for renormalization of tobacco product use, and prevent involuntary exposure to nicotine and other aerosolized emissions from e-cigarettes (Ingebrethsen et al. 2012; Schripp et al. 2013; Goniewicz et al. 2014; Offermann 2014; Schober et al. 2014). Updating existing policies to cover e-cigarettes (and all electronic nicotine delivery systems) will eliminate the introduction of airborne toxins into enclosed spaces and establish a uniform standard for preventing the use of both combustible and electronic tobacco products in public and private spaces, including schools, offices, restaurants, bars, casinos, and airplanes.

Prohibiting the use of e-cigarettes in enclosed spaces eliminates potential health risks to nonusers and ensures their right to clean air; may discourage the dual use of electronic and combustible tobacco products; simplifies public compliance with and enforcement of existing clean indoor air laws; facilitates reduced consumption of these products; and maintains clear, comprehensive non-smoking norms (Richardson et al. 2014; World Health Organization 2014a). As of January 1, 2016, six states (Delaware, Hawaii, New Jersey, North Dakota, Oregon, and Utah) had passed comprehensive smokefree indoor air laws that include e-cigarettes (CDC 2015a). These laws prohibit smoking and the use of e-cigarettes in indoor areas of private worksites, restaurants, and bars. Sixteen additional states had prohibited the use of e-cigarettes on some or all state property, and 475 local laws restricted e-cigarette use in 100% smokefree venues (Americans for Nonsmokers’ Rights Foundation 2015). Nationwide, more than 400 local jurisdictions prohibit e-cigarette use in 100%-smokefree workplaces (Americans for Nonsmokers’ Rights Foundation 2015). Major cities that have addressed e-cigarettes include Austin, Boston, El Paso, Chicago, Los Angeles, Minneapolis, San Francisco, and New York City.

**Table 5.2 Principle federal policies and regulations of tobacco that emphasize e-cigarettes**

Agency	Authority and description	Current	Potential
Executive Office of the President (EOP) and Office of Management and Budget (OMB)	—	Executive Order 13058, issued on August 9, 1997 (EOP 1997), generally prohibits the smoking of tobacco products in all interior space owned, rented, or leased by the executive branch of the federal government, and in any outdoor areas under executive branch control in front of air intake ducts. The Executive Order carves out an exception to its smoking prohibition for any residential accommodation for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased, or rented by the federal government.	—
Executive Office of the President (EOP) and Office of the U.S. Trade Representative (USTR)	—	Executive Order 13193, issued January 18, 2001 (EOP 2001), prohibits all U.S. executive branch agencies from promoting the sale or export of tobacco. It also prohibits using U.S. trade initiatives to restrict tobacco marketing and advertising regulations in other countries, unless those regulations discriminate against U.S. tobacco products in favor of that country's domestic tobacco products.	—
Federal Communications Commission (FCC)	Has broad regulatory power over commercial communication, including television, radio, and the Internet.	15 U.S.C. § 1335 (the “Broadcast Ban”), 15 U.S.C. § 4402(f): Prohibits advertising for cigarettes, little cigars, smokeless tobacco, and chewing tobacco on radio, TV, or any other medium of electronic communication under FCC’s jurisdiction.	Prohibit the advertising of smoking accessories, cigars, pipes, pipe tobacco, or cigarette-making machines on television; prohibit the advertising of e-cigarettes on television; and regulate the advertising of tobacco products on the Internet.
Federal Trade Commission (FTC)	<p>Publishes annual report on tobacco products.</p> <p>Reviews tobacco manufacturer-proposed schedules to rotate mandatory package warnings.</p> <p>Protects consumers. Enforces antitrust laws.</p>	<p>15 U.S.C. § 46 authorizes FTC to require entities to file special reports. On an annual basis, FTC collects and publishes information on the practices of the largest manufacturers of cigarettes and smokeless tobacco in the United States. Among other things, the information collected includes sales and, in several categories, expenditures for marketing.</p> <p>15 U.S.C. § 45: FTC has broad authority to prevent “unfair or deceptive” business practices. It is an unfair and deceptive act or practice for a firm to make unsubstantiated claims, express or implied, about such matters as a product’s efficacy, safety, or health benefits (FTC 1983).</p> <p>FTC is broadly authorized to prevent companies from using “unfair methods of competition” that affect commerce. FTC uses its antitrust authority to review and impose conditions on those proposed mergers of tobacco companies that raise anticompetitive concerns.</p>	<p>Collect sales, advertising, and information on promotion expenditures from e-cigarette companies and issue reports on same.</p> <p>Take enforcement action against unfair or deceptive advertising of tobacco products or e-cigarettes.</p>

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
General Services Administration (GSA)	In its role as an independent agency, GSA manages and maintains more than 1,550 federally owned buildings and leases space in an additional 7,100 buildings in the United States. GSA manages the federal government's automobile fleet and is the acquisition arm of the federal government.	GSA Order ADM, 5800. 1C: Smoking in GSA-occupied space and government-owned or -leased vehicles assigned to GSA is prohibited “to protect GSA employees, GSA contractors, and the visiting public from exposure to tobacco smoke in the Federal workplace.” The Order prohibits smoking in or on all “interior GSA-occupied space, exterior GSA-occupied space, including courtyards, garages, loading docks, stairwells, rooftops and balconies, and other outdoor areas under GSA control within 25 feet of doorways and building air intake ducts; and government-owned or leased vehicles assigned to GSA” (U.S. General Services Administration 2009).	Clarify that existing policies include e-cigarettes.  Implement a tobacco-free campus policy in GSA-occupied space.
Office of Personnel Management (OPM)	—	While not regulatory in nature, OPM and GSA coordinate standard responses to frequently asked questions about the use of e-cigarettes in government facilities.	—
U.S. Department of Agriculture (USDA)	Commodity and inspection standards for agricultural products. Administers SNAP and WIC programs.	7 U.S.C. § 30: USDA provides commodity standards for tobacco. 7 U.S.C. § 2012: Under the <i>Food and Nutrition Act of 2008</i> , tobacco products cannot be purchased with SNAP benefits. ENDS are included in the policy because the USDA interprets ENDS to be tobacco products. 7 CFR 246.10: USDA identifies requirements for WIC-eligible foods.	—

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Defense (DoD)	<p>May issue general instructions and restrictions in regulating the sale and/or use of tobacco products. Individual service branches may expand these regulations. Individual bases may also draft regulations. These typically are based on DoD instructions, directives, or service policies. DoD has authority over TRICARE.</p>	<p>DoD follows the smoking policy in federal facilities covered in 41 CFR 102-74.315, which states, “pursuant to Executive Order 13058, ‘Protecting Federal Employees and the Public From Exposure to Tobacco Smoke in the Federal Workplace’ it is the policy of the Executive Branch to establish a smokefree environment for federal employees and members of the public visiting or using federal facilities. The smoking of tobacco products is prohibited in all interior space owned, rented or leased by the Executive Branch of the federal government” (<i>Federal Register</i> 2008, p. 77518).</p> <p>Each of the armed services has issued statements clarifying that the prohibition on smoking tobacco products extends to the use of e-cigarettes.</p> <p>The 2015 NDAA directs the sale of cigarettes, cigars, and chewing tobacco at military commissaries. These items cannot be sold on military bases at prices lower than the most competitive prices in the local community. The NDAA replaced Directive 1330.09 (U.S. Department of Defense 2005), which established that tobacco prices on U.S. military bases should be no lower than 5% below the most competitive commercial price in the local community.</p> <p>Branches of the armed services have tobacco policies:</p> <ul style="list-style-type: none"> <li>• U.S. Navy and Marines, Instruction 5100.13E (U.S. Navy 2002)</li> <li>• U.S. Army, Army Health Promotion Policy Regulation 600–63 (U.S. Army 1996)</li> <li>• U.S. Air Force, Instruction 40-102, Air Force Tobacco Policy (U.S. Air Force 2013)</li> </ul> <p>TRICARE covers limited tobacco cessation counseling from any TRICARE-authorized provider in the United States. This coverage includes up to 18 counseling sessions per quit attempt, with up to 4 individual counseling sessions per quit attempt. Two quit attempts per fiscal year are automatically covered, with coverage extending to a third with a doctor’s justification and pre-authorization. TRICARE also covers tobacco cessation products, including prescriptions and over-the-counter products, with 120 days’ use of a tobacco cessation product per quit attempt.</p>	<p>DoD-unified regulations on tobacco use in common housing.</p> <p>Increased restrictions on commissary sales.</p>

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
U.S. Department of Education (ED)	Funding for tobacco control programs	In FY 2014, pursuant to 20 U.S.C. § 7131, <i>Safe and Drug-Free Schools and Communities Act</i> , ED awarded the first round of 5-year grant awards under the School Climate Transformation Grant—Local Educational Agency Grants program. These FY 2014, Year 1 grant awards provided more than \$35.8 million to 71 school districts in 23 states; Washington, DC; and the U.S. Virgin Islands. The funds should be used to develop, enhance, or expand systems of support for implementing evidence-based, multitiered behavioral frameworks for improving behavioral outcomes and learning conditions among students. The goals of the program are to connect children, youth, and families to appropriate services and supports; improve conditions for learning and behavioral outcomes for school-aged youth; and increase awareness of mental health issues and the ability to respond to such issues among school-aged youth. School districts can also use the funds to implement models for reform and evidence-based practices. Drug prevention, including preventing tobacco use by youth, is an allowable activity. Grantees are encouraged, as part of their local needs assessment, to measure drug use among students along with other relevant issues and problems. This assessment of local needs will also be used by grantees to help identify and select the most appropriate evidence-based programs and practices. If the needs assessment indicates that drug abuse is an issue for students, prevention of drug abuse should be addressed by a multitiered behavioral framework.	—
U.S. Department of Education (ED)	Restrictions on tobacco use	20 U.S.C. § 7181: <i>The Pro-Children Act of 2001</i> prohibits smoking in any indoor facility that provides routine or regular kindergarten, elementary, or secondary education and library, health, or day care services to children, if such services and/or facilities are funded by the federal government, whether directly or through state or local governments, by federal grant, loan, loan guarantee, or contract programs.	—

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (continues on next page)	Sets policies regarding Medicaid coverage for tobacco cessation products and counseling.	<p>42 U.S.C. § 1396r–8(d)(7): Tobacco cessation medications cannot be excluded from coverage under Medicaid prescription drug benefits. Section 2502 of the <i>Affordable Care Act</i> amends section 1927(d)(2) of the <i>Social Security Act</i> by removing barbiturates, benzodiazepines, and agents used to promote smoking cessation from the list of drugs that a state Medicaid program may exclude from coverage or otherwise restrict.</p> <p>42 U.S.C. §§ 18021(a)(1)(B), 18022(b)(1): Tobacco use screening and cessation must be provided at no cost as an essential health benefit and a preventive benefit. This includes Medicaid expansion plans, plans sold on insurance exchanges, and private plans.</p> <p>For youth: Tobacco cessation services are coverable as part of EPSDT, the Medicaid benefit for children and adolescents. EPSDT provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children, and adolescents under age 21, as specified in Section 1905I of the <i>Social Security Act</i>.</p> <p>For pregnant women: Section 4107 of the <i>Affordable Care Act</i> amends section 1905 of the <i>Social Security Act</i> to require coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women. Section 1905(bb)(2) of the <i>Social Security Act</i> defines the new tobacco cessation coverage services for pregnant women as services recommended in the 2008 PHS Guideline, or any subsequent modification of this Guideline, and such other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women.</p> <p><i>Affordable Care Act</i>, Section 4108, Medicaid Incentives for Chronic Disease Prevention Program: This is a grant program in which states apply for funds to incentivize Medicaid recipients to prevent chronic disease, including through tobacco cessation.</p>	—

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
(continued from previous page) U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS)	—	<p>42 U.S.C. § 1395x (ddd): Medicare covers tobacco cessation programs (Centers for Medicare &amp; Medicaid Services 2010): Effective for claims with dates of service on or after August 25, 2010, CMS will cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries:</p> <ul style="list-style-type: none"> <li>• Who use tobacco, regardless of whether they have signs or symptoms of tobacco-related disease;</li> <li>• Who are competent and alert at the time that counseling is provided; and</li> <li>• Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.</li> </ul> <p>Intermediate and intensive tobacco cessation counseling services are covered under Medicare Parts A and B when the above conditions of coverage are met, subject to frequency and other limitations. Medicare covers two individual tobacco cessation counseling attempts per 12-month period. Each attempt may include a maximum of four intermediate or intensive sessions, with a total benefit covering up to eight sessions per 12-month period per Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than 3 minutes, up to 10 minutes) and intensive (more than 10 minutes) cessation counseling sessions for each attempt. Medicare beneficiaries also have access to smoking cessation prescription medication through Medicare Part D.</p>	—
U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS)	Sets policies regarding private and marketplace health plan coverage of tobacco cessation products and counseling.	<p>42 U.S.C. §§ 18021(a)(1)(B), 18022(b)(1): Tobacco cessation must be provided at no cost as an essential health benefit. This includes Medicaid expansion plans, plans sold on insurance exchanges, and private plans.</p> <p>42 U.S.C. § 300gg-6 (Public Law 114-38): Tobacco cessation must be covered in employer plans. Plans should cover two cessation attempts per year, including (1) all FDA-approved cessation medications (both prescription and over-the-counter) and (2) four tobacco cessation counseling sessions, including telephone, group, and individual counseling.</p> <p>42 U.S.C. § 300gg(a)(1)(iv)): Tobacco users may be charged 50% more for insurance than nonusers of tobacco.</p> <p>42 U.S.C. § 300gg-4(j)-(k): Employers may reward or penalize employees by up to 50% of the cost of health care coverage based on their tobacco use, if the employer offers a health-contingent wellness program designed to prevent or reduce tobacco use.</p>	—

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Health and Human Services, National Institutes of Health (NIH)	NIH is a tobacco-free campus.	NIH's policy specifically includes e-cigarettes. In accordance with the tobacco-free initiative from HHS, the use of cigarettes, e-cigarettes, cigars, pipes, smokeless tobacco ("snuff"), and any other tobacco product is prohibited on the NIH campus in Bethesda, MD (NIH 2016).	—
U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse (NIDA), National Advisory Council on Drug Abuse (NACDA)	The mission of NIDA is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. NACDA serves crucial roles in advising NIDA on research priorities and policy and in providing a secondary level of review for applications under consideration for federal funding.	<p>NIDA (2016) urges grantees to recognize that:</p> <ul style="list-style-type: none"> <li>• Receiving funding from the tobacco industry may compromise the perceived objectivity of their research results, which in turn could impact the overall credibility of their research findings, including its interpretation, acceptance, and implementation;</li> <li>• Acceptance of tobacco industry funds is viewed by many as contributing directly or indirectly to the industry's interests, and thus harmful to the public health; and</li> <li>• Any connection between tobacco industry-supported research (or tobacco industry scientists) and NIDA could negatively impact NIDA's credibility and the public's trust in NIDA-funded research.</li> </ul>	—

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA)	Implements the Synar Amendment, which requires states, in order to receive their full Substance Abuse Prevention and Treatment Block Grant awards, to enact and enforce laws that prohibit the sale or distribution of tobacco products to individuals under the age of 18.	More information about the Synar Program is available online: <a href="http://www.samhsa.gov/synar/about">http://www.samhsa.gov/synar/about</a>	SAMHSA is exploring opportunities to align the Synar regulation with the federal statutory definition of tobacco products, which includes e-cigarettes.
U.S. Department of Homeland Security (DHS)	Sales and use restrictions for the U.S. Coast Guard. DHS Management Directorate-Directive No. 06603 Smoking Policy.	COMDTINST M6200.1B limits smoking to designated outdoor areas, prohibits use of tobacco by recruits, and prohibits tobacco use in any Coast Guard-controlled living quarters, including common areas. This policy includes extensive sales and advertising restrictions, but it does not consider NRT to be a tobacco product.	Implement a policy to enforce a ban on e-cigarette use on federal property.
U.S. Department of Homeland Security (DHS), Bureau of Immigration and Customs Enforcement (ICE)	Issues standards for facilities housing immigration detainees	Detainee smoking is prohibited in all buildings, including detainee-housing units. If smoking is permitted at a particular facility, the only designated smoking areas are outside of all buildings (Immigration and Naturalization Service 2000).	—

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Housing and Urban Development (HUD)	Resident health in assisted housing	<p>Public and Indian Housing (PIH) Notice 2009-21 strongly encourages HUD-funded public housing agencies to adopt smokefree policies in some or all of their public housing units.</p> <p>Housing Notice 2010-21 encourages owners and management agents of HUD-assisted multifamily housing to implement smokefree housing policies in one or all of the properties they own or manage.</p> <p>Both notices focus on cigarettes that “burn” as their mechanism for generating smoke, and so their applicability to e-cigarettes is uncertain.</p> <p>Regarding its Weaver Building headquarters (the only building for which GSA has designated HUD as the facility management authority), HUD follows GSA Order ADM 5800.1C, GSA’s smoking policy for federal offices (U.S. General Services Administration 2009). This GSA policy permits smoking in exterior space under GSA control that is beyond “25 feet of doorways and building air intake ducts,” except for “courtyards, garages, loading docks, stairwells, rooftops, and balconies.” The management of HUD’s other facilities, federally owned or leased, is not delegated to the Department, and so GSA makes the decision on smoking policy for those campuses.</p>	<p>HUD’s Office of PIH published its proposed rule on Instituting Smoke-Free Public Housing (80 FR 71762) on November 17, 2015, accepting comments through January 19, 2016 (<i>Federal Register</i> 2015). In addition to inviting comments on all aspects of the proposed rule, the notice specifically solicited public comments on nine questions (e.g., should the policy extend to electronic nicotine delivery systems, such as e-cigarettes, and/or to waterpipe tobacco smoking?).</p> <p>Based on responses to HUD’s Request for Information on Adopting Smoke-Free Policies in PHAs and Multifamily Housing (77 FR 60712) (<i>Federal Register</i> 2012), HUD may consider drafting a regulation or notice that could prohibit smoking in some or all HUD-assisted multifamily housing. Such a proposal could cover e-cigarettes.</p> <p>HUD is beginning to prepare for the adoption and implementation of a campus-wide tobacco-free policy, which would include e-cigarette use, at the Weaver Building headquarters by January 1, 2017.</p>

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
U.S. Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)	ATF is given primary jurisdiction to combat cigarette trafficking and administration (via the CCTA) and to stop tobacco diversion (via the PACT).	<p>18 U.S.C. § 2342: Under the CCTA, it is illegal to possess more than 10,000 unstamped cigarettes in a state that requires a tax stamp.</p> <p>18 U.S.C. § 2343: Any person who distributes more than 10,000 cigarettes must keep accurate records pertaining to the shipment, receipt, sale, and distribution of cigarettes.</p> <p>18 U.S.C § 2320: Trafficking in counterfeit cigarettes.</p> <p>15 U.S.C. § 375: It is illegal to ship cigarettes to a non-licensee in a state without notifying the state taxation authority.</p> <p>15 U.S.C. § 375–377: Requires online retailers to check the identification of customers at purchase and delivery: section 375 covers definitions; section 376 covers reports to state tobacco administrators; and section 377 covers penalties.</p> <p>The <i>Smuggled Tobacco Prevention (STOP) Act</i> amends the IRC to restrict the sale, lease, export or import, or delivery of tobacco production machines to persons lawfully engaged in (1) the sale, lease, export or import, or delivery of such machines; (2) the manufacture or packaging of tobacco products or processed tobacco; or (3) the application of unique identification markings onto tobacco products or processed tobacco packages.</p>	—
U.S. Department of Justice, Bureau of Prisons (BOP)	BOP has authority to govern the control and management of federal penal and correctional institutions.	<p>28 C.F.R. § 551.162: Smoking is generally prohibited in and on the grounds of BOP institutions and offices, with exceptions for smoking as part of an authorized inmate religious activity, and for smoking only in smoking areas designated by the warden, for BOP staff and official visitors.</p> <p>28 C.F.R. § 551.163: Possession of smoking apparatus and tobacco in any form is prohibited for inmates, unless as part of an authorized inmate religious activity.</p>	BOP Operations Memorandum 006-2015 (BOP 2015) sets out guidelines for e-cigarette use. Guidelines state that e-cigarette use is to be limited to designated outdoor areas that are reasonably accessible to employees and provide a measure of protection from the elements. These areas may only be used by employees, but must be separate from the areas presently designated as “smoking areas” for use of tobacco products. Indoor use of e-cigarettes shall not be permitted in BOP facilities, except in perimeter towers and perimeter patrol vehicles when occupied by one person.

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Labor, Occupational Safety and Health Administration (OSHA)	Sets standards for indoor air quality.	29 CFR 1910.1000, Air Contaminants: This policy restricts employee exposure to several of the main chemical components found in tobacco smoke. OSHA rules apply to tobacco smoke only in rare and extreme circumstances, such as when contaminants created by a manufacturing process combine with tobacco smoke to create a dangerous air supply that fails OSHA standards for the workplace. In normal situations, exposures would not exceed permissible exposure limits and, as a matter of prosecutorial discretion, OSHA will not apply the General Duty Clause to environmental tobacco smoke.	Have smokefree workplaces. In the 1990s, OSHA proposed a regulation setting indoor air quality standards for environmental tobacco smoke, but this rulemaking was terminated ( <i>Federal Register</i> 2001).
U.S. Department of Transportation (DOT)	Sets restrictions on tobacco use on commercial and personal aircraft.	49 U.S.C. § 41706: Prohibits smoking on passenger flights. 14 CFR Part 252: DOT rule implementing 49 U.S.C. § 41706, and prohibiting smoking on most passenger flights. DOT interprets current Part 252 to include e-cigarettes in smokefree policies.  Note: FAA regulations also prohibit smoking on most aircraft from an aircraft safety perspective, not from a health perspective (see notes to 14 CFR Part 252).	In early 2016, DOT issued a final rule (RIN 2105-AE06). In keeping with section 41706, the rule amends Part 252 to prohibit smoking on charter flights where a flight attendant is a required crew member. The rule also makes explicit the determination that the use of e-cigarettes falls within the definition of smoking.  DOT's Pipeline and Hazardous Materials Safety Administration has proposed a rule to prohibit the charging of e-cigarettes in an aircraft cabin, and to prohibit stowage of e-cigarettes in the cargo hold of an aircraft (this is a hazardous material/safety rule, not a health/tobacco rule).

**Table 5.2 Continued**

Agency	Authority and description	Current	Potential
U.S. Department of Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB)	<p>TTB administers the provisions of the Internal Revenue Code (IRC) of 1986, as amended, that impose federal excise taxes on tobacco products and cigarette papers and tubes, and it establishes a comprehensive civil and criminal framework to protect the revenue.</p> <p>Among other issues, TTB investigates illegal production, underreporting of production, smuggling or unlawful importation, and diversion of domestic tobacco products intended for export.</p>	<p>26 U.S.C. 26 § 5701–5763, Tobacco Products and Cigarette Papers and Tubes: Under the IRC, the tobacco products that are subject to tax and TTB regulation are cigars, cigarettes, smokeless tobacco (chewing tobacco and snuff), pipe tobacco, and roll-your-own tobacco. Each of these tobacco products is defined with reference to “tobacco.” TTB also has regulatory authority over processed tobacco, which is not subject to tax. TTB regulations define processed tobacco to mean any tobacco that has undergone processing but that does not include tobacco products. The processing of tobacco includes, but is not limited to, stemming (i.e., removing the stem from the tobacco leaf); fermenting, threshing, cutting, or flavoring the tobacco; or otherwise combining the tobacco with nontobacco ingredients.</p> <p>To protect revenue, the IRC and its implementing regulations establish qualification criteria to engage in businesses related to manufacturing, importing, or exporting tobacco products or in manufacturing or importing processed tobacco, and they require that persons obtain permits to engage in these activities. Under the IRC, manufacturers of tobacco products and export warehouse proprietors must file a bond that relates to the tax liability for the tobacco products on the premises covered by the permit. The IRC and implementing regulations also include recordkeeping and reporting requirements designed to ensure that TTB can verify that the tax on tobacco products is paid or determined or that adequate documentation exists to confirm that a tax exemption applies. The IRC also provides TTB with certain enforced-collection options (e.g., liens and levies), civil and criminal penalties, permit suspension and revocation procedures, and forfeiture provisions to ensure that the tax is collected.</p> <p>ENDS that do not contain nicotine derived from tobacco are not tobacco products under the IRC and are not subject to taxation or TTB regulation. ENDS containing nicotine derived from tobacco may meet the definition of a tobacco product under the IRC, in which case they would be regulated by TTB and taxed accordingly.</p>	<p>TTB will collaborate with foreign-counterpart tax administrators to share information and best practices in the administration of tobacco excise taxes and their enforcement. Areas of possible technical assistance include setting up an auditing system and permitting regimen and conducting investigations.</p> <p>TTB’s tobacco laboratory provides technical assistance to TTB program offices on tobacco products for regulatory compliance and enforcement purposes. TTB’s tobacco laboratory develops and validates analytical methods and protocols on tobacco products. It also collaborates with national and international tobacco regulatory federal agencies and has established a collaborative partnership with the World Health Organization’s Tobacco Laboratory Network and the North America Tobacco Regulatory Laboratory Network.</p>

Table 5.2 Continued

Agency	Authority and description	Current	Potential
U.S. Department of Veterans Affairs (VA)	Can restrict the use of e-cigarettes and combustible cigarettes on facility grounds of the Veterans Health Administration to designated outdoor smoking areas only.	Public Law 102-585: Requires medical centers, nursing homes, and domiciliary care facilities of the Veterans Health Administration to establish smoking areas for patients and residents in a way that is consistent with medical requirements and limitations.	Include language about restrictions on the use of e-cigarettes in local and national guidance regarding smokefree policies.
U.S. Department of Veterans Affairs (VA)	Provides evidence-based tobacco cessation treatment to veterans receiving care in the VA health care system.	38 CFR Part 17: Eliminated in 2006 the copayment for smoking cessation counseling for veterans in care facilities of the Veterans Health Administration ( <i>Federal Register</i> 2006).	Continue to provide clinical guidance for the health care professionals and patients in facilities of the Veterans Health Administration on the evidence base of (a) potential health effects of e-cigarettes and (b) comparisons to FDA-approved NRT for cessation treatment.
U.S. Environmental Protection Agency (EPA)	Sets policies regarding the hazardous waste status of e-cigarettes under the RCRA.	Nicotine is a commercial chemical product listed in 40 CFR 261.33(e) and is an acute hazardous waste (EPA waste code P075) when disposed. EPA has concluded that nicotine is the sole active ingredient of the e-liquid in e-cigarettes and thus a commercial chemical product, that e-cigarettes are not manufactured articles, and that e-cigarette cartridges are considered containers of nicotine. Therefore, e-cigarettes may be regulated as acute hazardous waste code P075 when disposed. If the nicotine e-liquid is legitimately recycled, it is not considered a solid waste under 261.2 because it is considered a commercial chemical product, and therefore it is not subject to hazardous waste regulation. E-cigarettes that are disposed of by consumers at their residences are considered exempt household hazardous waste under 261.4(b)(1) and are not subject to regulation as hazardous waste under the federal RCRA regulations. <ul style="list-style-type: none"> <li>• Regulatory Citation(s): 261.2, 261.4(b)(1), 261.33.</li> <li>• Statutory Citation(s): 3006 Read U.S. Code 42, Chapter 82.</li> </ul>	—

Note: ATF = Bureau of Alcohol, Tobacco, Firearms and Explosives; BOP = Bureau of Prisons; CCTA = *Contraband Cigarette Trafficking Act*; CFR = Code of Federal Regulations; CMS = Centers for Medicare & Medicaid Services; DHS = U.S. Department of Homeland Security; DoD = U.S. Department of Defense; DOT = U.S. Department of Transportation; ED = U.S. Department of Education; ENDS = electronic nicotine delivery systems; EOP = Executive Office of the President; EPA = U.S. Environmental Protection Agency; EPSDT = Early and Periodic Screening, Diagnosis and Treatment; FAA = Federal Aviation Administration; FCC = Federal Communications

**Table 5.2 Continued**

Commission; FDA = Food and Drug Administration; FTC = U.S. Federal Trade Commission; FY = fiscal year; GSA = General Services Administration; HUD = U.S. Department of Housing and Urban Development; ICE = Bureau of Immigration and Customs Enforcement; IRC = Internal Revenue Code; NACDA = National Advisory Council on Drug Abuse; NDAA = *National Defense Authorization Act*; NIDA = National Institute on Drug Abuse; NIH = National Institutes of Health; NRT = nicotine replacement therapy; OMB = Office of Management and Budget; OPM = Office of Personnel Management; OSHA = Occupational Safety and Health Administration; PACT = *Prevent All Cigarette Trafficking Act*; PHS = Public Health Service; PIH = Public and Indian Housing; RCRA = *Resource Conservation and Recovery Act*; SAMHSA = Substance Abuse and Mental Health Services Administration; SNAP = Special Supplemental Nutrition Program; TTB = Alcohol and Tobacco Tax and Trade Bureau; U.S.C. = United States Code; USDA = U.S. Department of Agriculture; USTR = U.S. Trade Representative; VA = U.S. Department of Veterans Affairs; WIC = Women, Infants, and Children.

## Prevent Youth Access

Ensuring that laws on youth access include e-cigarettes is intended to protect youth from exposure to nicotine, which can lead to addiction and other health problems. Additionally, ensuring that these laws include e-cigarettes helps to capture the full diversity of the tobacco product landscape, including combustible, non-combustible, and electronic tobacco products. Effective strategies to deter access to e-cigarettes by youth and the use of these products in this population include restricting sales of e-cigarettes to minors, requiring verification of age, mandating clear signage about minimum age where sales take place, prohibiting the sale of e-cigarettes from vending machines, eliminating self-service displays of e-cigarettes, and actively enforcing existing laws with a focus on retailers. Compliance with laws that regulate the sale and distribution of e-cigarettes is facilitated by requiring retailers to be licensed. To date, 46 states have prohibited the sale of e-cigarettes to minors younger than a specified age (National Conference of State Legislatures 2015; The Council of State Governments 2015). Federally, aligning youth tobacco access control regulations with the statutory definition of tobacco products in the Tobacco Control Act, which includes e-cigarettes, could provide consistent framework to help ensure that restrictions on youth access to e-cigarettes are prioritized and enforced (*Federal Register* 2016). This could include modifications to the Synar regulation, which requires states, U.S. territories, and jurisdictions to enact and enforce laws prohibiting the sale or distribution of tobacco products to youth. Substance Abuse Prevention and Treatment Block Grant recipients must comply with the Synar amendment and implement regulations in order to receive their full awards (U.S. Food and Drug Administration, Center for Tobacco Products n.d.).

## Licensing

Licensing is used to regulate professional practice and business operations and represents one strategy to control the rising use of e-cigarettes among youth. In general, in the case of tobacco-related licensing, a business is authorized to manufacture, distribute, or sell tobacco products as long as it complies with all relevant laws (McLaughlin 2010). Typically, tobacco-related licensing requirements for retailers and/or manufacturers help to prevent evasion of excise taxes, ensure that licensees comply with tobacco-related laws, and promote safe manufacturing practices

(ChangeLab Solutions 2012). Repeat violators of relevant laws may be subject to suspension or permanent revocation of their license, an outcome that provides a strong incentive to comply with existing requirements. As in the conventional cigarette industry, licensing of e-cigarette retailers and manufacturers is designed in part to prevent the use of these products by youth and to facilitate safe manufacturing practices. Unlike traditional tobacco products, for which retailers sell prepackaged products and the number of manufacturers is limited, a growing number of businesses engage in both the retail sale and manufacturing of devices and liquids used in the devices (e-liquids). Stores devoted exclusively to the sale of e-cigarettes are known as “vape shops.” These shops frequently offer a social environment for using products, and they may also sell food and beverages (Sussman et al. 2014).

As of April 2015, 99 cities and counties in California required a retailer to obtain a license to sell e-cigarettes. The majority of these jurisdictions did so by broadening the definition of tobacco products to include “electronic smoking devices” (ChangeLab Solutions 2015a). The definition was purposely broadened to include products that do not include nicotine to decrease the complexity of enforcement and in recognition of the fact that e-cigarette devices are sometimes used with liquids that do not contain nicotine but may contain marijuana oil (The Center for Tobacco Policy & Organizing 2015a). Licensing requirements also may be used to restrict the sale of flavored products or to address issues of consumer and worker safety relative to the mixing of e-liquids.

Imposing a moratorium is another potential approach that has been used in some communities to stop new “vape shops” from entering the market while a more comprehensive approach was being considered. A moratorium is a land-use law that takes effect immediately to stop temporarily the issuance of a business license, building permit, or use permit. Typically, a moratorium is enacted to provide a jurisdiction with time to research and study how to regulate a type of business (ChangeLab Solutions 2015b). In California, several communities enacted moratoria that are initially 45 days but can be extended for up to 2 years (ChangeLab Solutions 2014, 2015b). A four-fifths vote, however, is required to establish a moratorium in California. Hayward and Union City, California, are examples of cities that have enacted moratoria and later adopted both retail licensing requirements for existing e-cigarette retailers and zoning restrictions to prohibit new vapor and hookah bars and lounges from opening within city limits (ChangeLab Solutions 2014; The Center for Tobacco Policy & Organizing 2015b).

## Taxation and Other Price Policies

Taxation and other price policies directed at making e-cigarettes more expensive may be implemented at multiple levels of government, from local to federal. Increasing the price of conventional cigarettes, including those increases resulting from excise taxes, significantly prevents and reduces tobacco use, particularly among youth and young adults (USDHHS 2014), and has potentially more impact on prevalence of current use in this population than on first use (Bader et al. 2011). Similarly, price policies are likely to reduce the use of e-cigarettes: a 10% increase in the price of e-cigarettes has been estimated to reduce sales of disposable e-cigarettes by approximately 12% and reusable products by about 19% (Bader et al. 2011; Huang et al. 2014). Data are currently lacking on the potential effects that taxing e-cigarettes might have on conventional cigarettes. Tobacco products are taxed in two main ways:

1. A “specific” excise tax is levied based on the quantity of the product sold (e.g., as measured by number of cigarettes, weight, or volume). This type of mechanism applies the same tax across low-end and premium brands and is generally simple to administer. The disadvantages to specific excise taxes are that the real value of the tax declines over time with inflation, making products more affordable, and that super-lightweight products—such as snus, orbs, sticks, and dissolvables—are grossly undertaxed if the tax is based on weight (Freiberg 2012; Boonn 2013; Shang et al. 2015).
2. The second tax mechanism is an ad valorem excise tax, which is levied on a percentage of the value of the tobacco product (e.g., the retailer’s, wholesaler’s, or manufacturer’s price). This type of tax keeps up with inflation and establishes a flat tax rate across all brands, product types, weights, and packaging. The disadvantages to this kind of tax include the potential for tax evasion through predatory (below-cost) or anticompetitive pricing; increasing the price differential between products with different pretax prices, leading to greater price variability and more opportunity for tax avoidance; a government-provided subsidy for manufacturers’ price cuts; and more expensive brands being subjected to a larger tax (Freiberg 2012; Boonn 2013; Shang et al. 2015).

Governments use uniform, tiered, and mixed-tax approaches to implement specific and ad valorem tobacco excise taxes. Uniform systems apply the same tax rate across all products; tiered systems levy taxes based on such product characteristics as toxicity, nicotine content,

type of production (handmade versus machine made), sales volume, packaging, or whether the products are domestic or imported; and mixed systems use a combination of uniform and tiered-tax approaches (Shang et al. 2015). Tiered-tax approaches, such as those based on nicotine content, could steer consumers to a less toxic product or one with lower nicotine (Benowitz 2014). Tiered-tax approaches are more complex to administer and may provide greater opportunity for tax evasion as a result of manipulation of the product or its packaging by the manufacturer (Shang et al. 2015). In recognition of nicotine’s toxicity, particularly to youth, several health groups have endorsed imposing excise taxes on e-cigarettes to discourage their use by youth (American Thoracic Society 2013; Association of State and Territorial Health Officials 2014; Bhatnagar et al. 2014; Brandon et al. 2015a; Crowley and Health Public Policy Committee of the American College of Physicians 2015; National Association of County and City Health Officials 2014). E-cigarettes are likely less toxic than combustible products (such as conventional cigarettes), and therefore, some contend should be taxed at a lower rate (Benowitz 2014; Bhatnagar et al. 2014). Yet others argue that e-cigarettes should be taxed at the same rate as other tobacco products (Freiberg 2012; American Thoracic Society 2013; National Association of County and City Health Officials April 2014).

As of January 2016, four states (Kansas, Louisiana, Minnesota, and North Carolina) and six localities (Juneau, Matanuska-Susitna, Petersburg, and Sitka, Alaska; Montgomery County, Maryland; and Chicago, Illinois) had enacted e-cigarette taxation policies. Minnesota’s ad valorem tobacco tax equates to 95% of the wholesale cost of any product containing or derived from tobacco (Minnesota Revenue 2014; Tobacco Control Legal Consortium 2015). It taxes e-liquids and e-cigarettes sold with nicotine cartridges that cannot be removed (i.e., disposables). In Minnesota, devices without a nicotine cartridge are not taxed as a tobacco product. On the other hand, North Carolina applies a specific excise tax, taxing e-liquids based on volume at 5 cents per milliliter (National Conference of State Legislatures 2015).

The Tobacco Control Legal Consortium, which is based at William Mitchell College of Law in St. Paul, Minnesota, recommends using an ad valorem tax for e-cigarettes applied at the retail level to the “essential” components of these devices. The tax is simple, captures both disposable and refillable devices, and could exclude accessories and universal parts sold separately, such as batteries or charging cords (Tobacco Control Legal Consortium 2015).

Numerous major health organizations support raising the price of e-cigarettes through non-tax options, such as limiting rebates, discounts, and coupons (Freiberg

2012; Association of State and Territorial Health Officials 2014; Bhatnagar et al. 2014; Huang et al. 2014; Brandon et al. 2015a).

Finally, Chaloupka and colleagues (2015) have proposed that differential taxation of tobacco products can be used to incentivize a move away from combustible products to less hazardous noncombustible products, including e-cigarettes. They have argued that taxation could be part of a harm-reduction system. In their view, future determinations by FDA as to whether a product poses a substantially reduced risk would be one criterion in determining the relative rate of taxation.

## Restrictions on Marketing

As described in Chapter 4, the marketing of e-cigarettes drives consumer demand for these products. Such marketing also may promote misperceptions about the safety and efficacy of these products for use as cessation devices (Choi and Forster 2014; Mark et al. 2015; Pokhrel et al. 2015). For some populations—such as pregnant women, adolescents, former smokers, and young adults—the adverse health consequences of nicotine intake are substantial. Several groups have supported extending marketing restrictions that apply to conventional cigarettes and other tobacco products to e-cigarettes (Association of State and Territorial Health Officials 2014; Bam et al. 2014; Bhatnagar et al. 2014; Partnership for Prevention 2014; Brandon et al. 2015a). Significant barriers still exist to regulating commercial speech, including the First Amendment rights of the e-cigarette companies (Laird-Metke 2010).

Additionally, for traditional tobacco products, partial advertising bans and voluntary agreements have generally been ineffective in reducing consumption because the tobacco industry circumvents the restrictions by shifting the marketing platforms used to unregulated platforms (National Cancer Institute 2008). This response would be expected to be similar with regard to e-cigarettes. Therefore, despite the numerous barriers, public health groups and state, local, tribal, and territorial governments should take steps to stem the proliferation of e-cigarette marketing likely to appeal to young people by using tools designed to curb youth-oriented tobacco marketing and expanding evidence to inform future restrictions on the marketing of e-cigarettes to youth and young adults.

Surveillance of e-cigarette marketing, performing content analyses of the messages used, and conducting studies to assess the link between exposure to e-cigarette marketing and the use of e-cigarette products, particularly among youth and young adults, will facilitate the development of an evidence base of the type that informed prior

federal and Master Settlement Agreement restrictions on tobacco advertising. Observations of retailers' practices, assessments of outdoor advertising, and identification of event sponsorships and promotional activities at bars and community events are actions that state, local, tribal, and territorial public health agencies have taken related to traditional tobacco products. Many of these actions can be adapted to monitor and document the presence of e-cigarette marketing in communities (Pucci et al. 1998; Feighery et al. 2001; Rigotti et al. 2005; Roeseler et al. 2010; Rose et al. 2014).

In the absence of legal restrictions on e-cigarette marketing, and apart from the issue of the previous promulgation by some companies of unsubstantiated health and cessation claims, public health groups can advocate for television and radio broadcasters, print and outdoor media companies, the management of event venues and sports events, digital media outlets, retailers, and others to voluntarily refuse to air or place e-cigarette advertising, offer sponsorships, or give out free samples at fairs and festivals. Although the impact of a voluntary approach may be low, such actions raise awareness, build concern, and help to denormalize the proliferation of e-cigarette marketing. In California, surveillance plus voluntary efforts to promote restrictions on sponsorship of events by the tobacco industry facilitated a modest decline in tobacco industry-sponsored events and youth-oriented activities at those events that promoted the interests of the tobacco companies, and it led to a productive partnership with the tobacco litigation unit of the California attorney general's office that resulted in several settlements with tobacco companies (Roeseler et al. 2010).

State, local, tribal, and territorial public health agencies may be able to contribute to the stimulation of enforcement and compliance with existing rules that constrain marketing. Some states have brought lawsuits against e-cigarette companies, alleging that distributors of these products violated state law by selling to minors or making unsubstantiated health claims; some of those lawsuits resulted in financial damages and agreements to stop making claims that e-cigarettes are safer than conventional cigarettes unless confirmed by rigorous science (Center for Public Health and Tobacco Policy 2013).

Finally, another area to address is the use of "advertorials" employed by e-cigarette retailers to promote cessation and health claims. Advertorials are paid advertisements designed to look like an independent editorial. Although there are no specific rules for how a publisher should distinguish actual editorial content from paid editorial content in terms of their appearance, the Federal Trade Commission (FTC) stated in an advisory opinion that disclosure of the source is necessary when content "uses the format and has the general appearance of a news

feature and/or article for public information which purports to give an independent, impartial and unbiased view” (*Federal Register* 1972, p. 154). Additionally, paid advertising must be disclosed clearly and conspicuously in a manner that is understandable to consumers (FTC 1984). State and local public health agencies can play an important role by monitoring and providing substantiation to their state attorney general or FTC regarding advertising that makes improper claims or is not clearly identified as advertising.

## **Educational Initiatives**

The extensive data reviewed in Chapter 2 highlighted the limited knowledge that members of the general public, particularly adolescents and young adults, have about e-cigarettes and their potential for nicotine addiction and other adverse health consequences. FDA has jurisdiction for product warnings that can reach users, but that agency, along with other federal entities and state and local governmental and nongovernmental organizations, can also carry out educational campaigns to enhance such limited knowledge levels. Potentially effective initiatives with youth and young adults to prevent smoking were reviewed in the 2012 Surgeon General’s report and may be applicable to preventing e-cigarette use. That report concluded that sufficient evidence exists to conclude that mass media campaigns, comprehensive community programs, comprehensive statewide tobacco control programs, and school-based programs that have shown evidence of effectiveness, if they contain specific components, can produce at least short-term effects and reduce the prevalence of tobacco use among school-aged youth (USDHHS 2012).

## **Implications for Health Care Practice**

Although the issues are not well documented, health care practitioners face questions about e-cigarettes from

their patients and their communities, including what are the risks of using e-cigarettes, how do these risks compare with those of cigarettes or other combustible products, and is e-cigarette use an effective way to quit smoking? Chapter 3 set out the limited evidence base related to these questions. Clinicians need to respond to these questions and guide their patients in the context of considerable uncertainty. At this time, practitioners can turn to the various statements from medical organizations, which generally urge caution regarding e-cigarettes and do not find the evidence to be supportive of their use for cessation or for formal harm-reduction strategies (Table 5.3). In fact, any recommendation to use e-cigarettes for the cessation of smoking is not supported by the bulk of the available scientific evidence (Hartmann-Boyce et al. 2016). Both the American Association of Cancer Research and the American Society of Clinical Oncology recommend against advising the use of e-cigarettes for cessation (Brandon et al. 2015b). The U.S. Preventive Services Task Force found that there is insufficient evidence that e-cigarettes are an effective smoking cessation tool in adults, including pregnant women (Agency for Healthcare Research and Quality 2015).

The clinical care setting is a critical venue for taking evidence-based approaches for enhancing smoking cessation and increasing the protection of susceptible groups against exposure to secondhand smoke (USDHHS 2014). However, research on e-cigarettes in relation to this set of venues is lacking and urgently needed. Regardless, some pragmatic approaches have been proposed. For example, the American Academy of Pediatrics (AAP) gives advice on how pediatricians can approach questioning about the use of e-cigarettes. As of October 2015, the AAP’s position on e-cigarettes is that sales to minors should be prohibited; flavors that appeal to youth should be prohibited; and measures against the use of e-cigarette products need to be included in requirements for maintaining smoke-free environments, such as in restaurants and workplaces (AAP 2015a).

Table 5.3 Medical organizations

## A. Positions of professional organizations

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Academy of Pediatrics (2015b)	—	<ul style="list-style-type: none"> <li>• “Concentrated nicotine solution for electronic nicotine delivery systems should be sold in child-resistant containers with amounts limited to that which would not be lethal to a young child if ingested.”</li> <li>• “Prohibitions on smoking and use of tobacco products should include prohibitions on use of electronic delivery systems.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The promotion and sale of electronic nicotine delivery systems to youth should be prohibited by federal, state, and local regulations.”</li> <li>• “Prohibitions on promotion should include all media that can be viewed by youth, including broadcast, print, and electronic (Web- or Internet-based) media.”</li> <li>• “Prohibitions on promotion should include prohibitions on sponsorships, such as sports, cultural event, and entertainment sponsorships. Any promotional activities that can be accessed by children and/or adolescents should be considered promoting to children.”</li> <li>• “Electronic nicotine delivery systems should be subject to the same restrictions on advertising and promotion at least as restrictive as that on combustible cigarettes. Until government agencies institute these prohibitions, media companies, entertainment companies, sports teams, and promoters should voluntarily institute these prohibitions.”</li> <li>• “Celebrities should not use their privileged position to model tobacco product use, including electronic nicotine delivery systems and other existing or emerging tobacco products.”</li> </ul>	—

**Table 5.3 A Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (2015) (continues on next page)	<ul style="list-style-type: none"> <li>FDA has not approved e-cigarettes as smoking cessation aids, and current data are inconclusive with regard to their efficacy as quit-smoking products.</li> <li>“Oncologists would be wise to refrain from recommending e-cigarettes to patients as a first-line therapy for smoking cessation.”</li> </ul>	<ul style="list-style-type: none"> <li>“The evidence regarding the risks and benefits of e-cigarettes is difficult to interpret, and data on the long-term consequences of e-cigarette use are not yet available.”</li> <li>“Chemicals and ultrafine particles known to be toxic and carcinogenic and/or to cause respiratory and heart distress have been identified in e-cigarettes.”</li> <li>“Studies find the levels of the toxicants in e-cigarette aerosol to be significantly lower than in cigarette smoke and, in many cases, comparable with trace amounts found in a medicinal nicotine inhaler. It is unclear what effects these toxicants might have on e-cigarette users after chronic and frequent use.”</li> <li>“The vast majority of e-cigarette users use products containing nicotine. Nicotine is an addictive chemical, adversely affects maternal and fetal health during pregnancy, has adverse consequences for fetal brain development, and may adversely affect the adolescent brain. It is unclear what effect nicotine intake via e-cigarettes has on health or on the addictiveness of these products.”</li> </ul>	<ul style="list-style-type: none"> <li>“The FDA CTP should regulate all ENDS that meet the statutory definition of tobacco products and their component parts. ENDS delivery systems and e-liquids containing tobacco-derived nicotine should be regulated whether they are sold together or separately.”</li> <li>“ENDS manufacturers should be required to register with FDA and report all product and ingredient listings, as well as the nicotine concentration in the ENDS solution.”</li> <li>“ENDS packaging and advertising should be required to carry health warnings and safety labels—including a warning regarding nicotine addiction.”</li> <li>“Youth-oriented ENDS advertising and marketing should be prohibited, including: self-service ENDS displays, the provision of gifts and other giveaways with purchase of ENDS, the sale and distribution of items such as hats or t-shirts with ENDS brand logos, brand name sponsorship of social or cultural events, or of any team entry into those events, and youth-oriented advertising of tobacco products.”</li> <li>“Internet and other mail-order sellers of ENDS should be required to check the age and identification of customers at the point of purchase and delivery; to comply with all laws in the purchaser’s state or local jurisdiction; and pay all applicable federal, state, and local taxes.”</li> <li>“Childproof caps should be required for all e-liquid containers.”</li> <li>“ENDS and ENDS liquid containing candy and other youth-friendly flavors should be banned unless there is evidence demonstrating that these products do not encourage youth uptake.”</li> <li>“ENDS use should be prohibited in places where combustible tobacco product use is prohibited by federal, state, or local law until the safety of second- and thirdhand aerosol exposure is established.”</li> </ul>	<ul style="list-style-type: none"> <li>“There are insufficient data on health consequences of e-cigarette use, their value as tobacco cessation aids, and their effects on the use of combustible tobacco products by smokers and nonsmokers.”</li> <li>“Oncologists should advise all smokers to quit smoking combustible cigarettes, encourage use of FDA-approved cessation medications, refer patients for smoking cessation counseling, and provide education about the potential risks and lack of known benefits of long-term e-cigarette use.”</li> </ul>

Table 5.3 A Continued

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
(continued from previous page) American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (2015)	—	<ul style="list-style-type: none"> <li>• “Data from the [CDC] showed a significant increase in e-cigarette-related calls to poison centers between 2010 and 2014 as a result of accidental ingestion or absorption of e-cigarette liquid.”</li> <li>• “Secondhand exposure to toxicants and nicotine from e-cigarette aerosol has been documented, though there are not current data suggesting that exposure to the aerosol has adverse health effects.”</li> <li>• “There are no published studies evaluating thirdhand (i.e., residue that builds up on surfaces over time) exposure to e-cigarette aerosol in indoor environments, although preliminary data suggest that nicotine from e-cigarettes can stick to surfaces.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Funding generated through tobacco product taxes, including any potential taxes levied on ENDS, should be used to help support research on ENDS and other tobacco products, but should not preclude the allocation of federal funding for this research.”</li> <li>• “All data related to ENDS composition, use, and health effects should be disclosed for dissemination and independent review as well as to enhance policy decisions for ENDS product regulation.”</li> <li>• “Tobacco products should be taxed proportionate to their harm; therefore, ENDS should not be taxed at equal or higher rates than combustible cigarettes.”</li> <li>• “State and local governments should implement ENDS regulations within their authorities that are appropriate for protecting the public health, including restricting the sale, distribution, marketing, and advertising of ENDS to youth.”</li> <li>• “International cooperation is needed to develop standards for the regulation of ENDS, and these regulations should prioritize protection of the public’s health and draw upon the best available scientific evidence whenever possible.”</li> </ul>	—
American Association for Respiratory Care (AARC) (2015)	<ul style="list-style-type: none"> <li>• “Even though the concept of using the e-cigarettes for smoking cessation is attractive, they have not been fully studied and the use among middle school children is increasing year after year.”</li> </ul>	<ul style="list-style-type: none"> <li>• “There is no evidence as to the amount of nicotine or other potentially harmful chemicals being inhaled during use or if there are any benefits associated with using these products.”</li> </ul>	—	<ul style="list-style-type: none"> <li>• Date effective: April 2014</li> <li>• “The [AARC] opposes the use of the electronic cigarette (e-cigarette).”</li> </ul>

**Table 5.3 A Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American College of Physicians (ACP) (Crowley and Health Public Policy Committee of the ACP 2015)	<ul style="list-style-type: none"> <li>• “ENDS, which include electronic cigarettes, or e-cigarettes, are growing in popularity, but their safety and efficacy as a smoking cessation aid are not well understood.”</li> </ul>	<ul style="list-style-type: none"> <li>• “[There is concern] that the health effects of ENDS use are unknown, that they may appeal to young people, and that they may encourage dual use of ENDS and traditional tobacco products.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The Food and Drug Administration [should] extend its regulatory authority granted through the <i>Family Smoking Prevention and Tobacco Control Act</i> to cover electronic nicotine delivery systems (ENDS).”</li> <li>• “Characterizing flavors should be banned from all tobacco products, including ENDS.”</li> <li>• “The [ACP] supports taxing tobacco products, including ENDS devices and nicotine liquids, to discourage use among children and adolescents. Local governments should be permitted to establish higher tax rates for ENDS and related products than state levels.”</li> <li>• “The [ACP] supports legislative or regulatory efforts to restrict promotion, advertising, and marketing for ENDS products in the same manner as for combustible cigarettes, including a prohibition on television advertising.”</li> <li>• “Youth tobacco prevention efforts, such as antismoking media campaigns and school-based interventions, should include information about the potential risks of ENDS use.”</li> <li>• “The federal, state, and local regulators should take action to extend indoor and public place clean air laws that prohibit smoking in public places, places of employment, commercial aircraft, and other areas to ENDS products.”</li> <li>• “The federal government should authorize and appropriate funding to rigorously research the health effects of ENDS use, chemical content, and toxicity; effects of ENDS vapor exposure; dual-use rates; and effects of ENDS-derived nicotine on human health.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The [ACP] supports strong regulations to ensure product safety and transparency, policies that prevent use among young people, increased research to better determine their health effects, strong limits on marketing and promotion to discourage interest among young people, and application of indoor air laws to protect the health of bystanders.”</li> <li>• “This paper is not intended to offer clinical guidance or serve as an exhaustive literature review of existing ENDS-related evidence but to help direct the [ACP], policymakers, and regulators on how to address these products.”</li> </ul>

Table 5.3 A Continued

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Thoracic Society (2013, 2015) (continues on next page)	<ul style="list-style-type: none"> <li>• “The new CDC data show that Big Tobacco is once again peddling a new product intended to get youth hooked on nicotine, and that e-cigarettes are not about harm reduction or smoking cessation, but about addiction.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The short- and long-term health risks of these nicotine-delivery devices are largely unknown.”</li> </ul>	<ul style="list-style-type: none"> <li>• “States should regulate e-cigarettes as tobacco products. E-cigarettes should not be sold to those younger than 18, and regulations requiring identification and proof of age at the time of purchase should apply. Internet sales of e-cigarettes should be strictly regulated.”</li> <li>• “E-cigarettes should be taxed at rates equivalent with traditional cigarettes and other tobacco products.”</li> <li>• “E-cigarettes should be subject to the same restrictions regarding public use as combustible tobacco products, and e-cigarettes should not be used in smoke-free areas.”</li> <li>• “The FDA should deem regulatory authority over e-cigarettes.”</li> <li>• “Candy and menthol flavored e-cigarettes should be banned.”</li> <li>• “E-cigarette packaging should include warning labels, similar in size and scope to those required of combustible tobacco packaging. Where risks are known, the consumer should be informed of those risks in clear and direct language. Where data regarding risk is [<i>sic</i>] unavailable or inconclusive, the consumer should be informed of the lack of reliable safety testing data.”</li> <li>• “The FDA should regulate the form and content of e-cigarette advertising.”</li> <li>• “Both direct and implied health and safety claims by e-cigarette manufacturers should be subject to the same evidentiary review process currently required for other products making such claims.”</li> <li>• “The FDA should require e-cigarette manufacturers to adopt Good Manufacturing Processes similar to those that exist for other regulated products, including lot numbers, securing packaging, etc.”</li> <li>• “Given that nicotine is an addictive drug, with the dependence liability related to the pharmacokinetic characteristics of the delivery device, delivery characteristics of the e-cigarette should be evaluated and disclosed, and periodically monitored to ensure consistency of the product’s dependence potential over time.”</li> </ul>	<ul style="list-style-type: none"> <li>• “[E]-cigarettes need to be subject to the same marketing and manufacturing restrictions as tobacco products.”</li> <li>• “For the first time, e-cigarette use among young people is higher than for any other tobacco product.”</li> </ul>

**Table 5.3 A Continued**

<b>Organization</b>	<b>Organizational position on cessation</b>	<b>Organizational position on harm</b>	<b>Organizational position on regulation</b>	<b>General comments</b>
(continued from previous page) American Thoracic Society (2013, 2015)	—	—	<ul style="list-style-type: none"> <li>• “Content of e-cigarette cartridges should be disclosed and regulated.”</li> <li>• “The nicotine content of the e-cigarette cartridge should not exceed that of similar user volume of combustible tobacco.”</li> <li>• “Deliverable nicotine levels should be consistent between cartridges.”</li> <li>• “Researchers and clinicians, along with scientific societies and publications, receiving funding from e-cigarette manufacturers should disclose this relationship and the potential for conflict of interest in a manner equivalent to disclosures required for funding from the remainder of the tobacco industry.”</li> </ul>	—

Table 5.3 A Continued

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
European Respiratory Society (ERS) (2014)	<ul style="list-style-type: none"> <li>“Electronic cigarettes are designed for the purpose of direct nicotine delivery to the respiratory system, and they fall into a regulatory gap in most countries, escaping regulation as medicinal products and avoiding the controls applicable to tobacco products.”</li> </ul>	<ul style="list-style-type: none"> <li>“For ERS, the priority of the Revision of the Tobacco Products Directive is to protect children and youth from becoming smokers by preventing them from picking up their first cigarette.”</li> <li>“There is no adequate scientific research available on the overall health risk or the long-term effects of electronic cigarette use on humans.”</li> </ul>	<ul style="list-style-type: none"> <li>“Mandatory reporting system of ingredients used in tobacco products.”</li> <li>“Harmonised regulation of the ingredients of tobacco products.”</li> <li>“80% pictorial health warnings, covering the front and back of packages. Based on evidence, the larger the pictorial health warnings are, the more effective they are.”</li> <li>“Plain/standardised packaging of tobacco products.”</li> <li>“Introduction of both visible and invisible security features on tobacco packaging and ensuring that the storage and access to such data is [<i>sic</i>] independent from tobacco companies.”</li> <li>“Prohibition on the cross-border distance sale of tobacco products.”</li> <li>“Strong regulatory framework and independent research for electronic cigarettes. Any regulation of electronic nicotine delivery systems should be science based.”</li> <li>“Ensuring the adoption of delegated acts is not exposed to the interests of the tobacco industry, which would jeopardise the achievement of high level of health protection.”</li> </ul>	<ul style="list-style-type: none"> <li>“ERS supports the European Commission’s Proposal for the Tobacco Products Directive and Rapporteur Linda McAvan’s efforts to improve it.”</li> <li>“Introduction of standard packs with increased health warnings.”</li> <li>“Prohibition of characterizing flavours.”</li> <li>“Strengthening of traceability and security features for combating illicit trade.”</li> <li>“Prohibiting misleading features, including slim cigarettes.”</li> <li>“Approximately 700,000 EU citizens die prematurely every year because of tobacco consumption.”</li> </ul>

**Table 5.3 A Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
Forum of International Respiratory Societies (American College of Chest Physicians 2014; Schraufnagel et al. 2014)	<ul style="list-style-type: none"> <li>“Studies looking at whether electronic cigarettes can aid smoking cessation have had inconsistent results.”</li> </ul>	<ul style="list-style-type: none"> <li>“The safety of electronic cigarettes has not been adequately demonstrated.”</li> <li>“The addictive power of nicotine and its untoward effects should not be under-estimated.</li> <li>“Potential benefits to an individual smoker should be weighed against harm to the population of increased social acceptability of smoking and use of nicotine.”</li> <li>“Adverse health effects for third parties exposed to the emissions of electronic cigarettes cannot be excluded.”</li> </ul>	<ul style="list-style-type: none"> <li>“Health and safety claims regarding electronic nicotine delivery devices should be subject to evidentiary review.”</li> <li>“If ENDS devices are permitted, they should be regulated as tobacco products.”</li> <li>“Research, supported by sources other than the tobacco or electronic cigarette industry, should be carried out to determine the impact of electronic nicotine delivery devices on health in a wide variety of settings.”</li> <li>“The use and population effects of END devices should be monitored.”</li> <li>“All information derived from this research should be conveyed to the public in a clear manner.”</li> </ul>	<ul style="list-style-type: none"> <li>“ENDS should be restricted or banned, at least until more information about their safety is available.”</li> </ul>

Table 5.3 Continued

**B. Voluntary health organizations**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Cancer Society (ACS) (2014)	<ul style="list-style-type: none"> <li>• “Because the American Cancer Society doesn’t yet know whether e-cigarettes are safe and effective, we cannot recommend them to help people quit smoking.”</li> <li>• “There are proven methods available to help people quit, including pure forms of inhalable nicotine as well as nasal sprays, gums, and patches.”</li> </ul>	<ul style="list-style-type: none"> <li>• “[E]-cigarettes are not labeled with their ingredients, so the user doesn’t know what’s in them.”</li> <li>• “Inhaling a substance is not the same as swallowing it.”</li> <li>• “Studies have shown that e-cigarettes can cause short-term lung changes that are much like those caused by regular cigarettes.”</li> </ul>	<ul style="list-style-type: none"> <li>• “E-cigarettes need to be researched and regulated.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Until electronic cigarettes are scientifically proven to be safe and effective, ACS will support the regulation of e-cigarettes and laws that treat them like all other tobacco products.”</li> </ul>

**Table 5.3 B Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Heart Association (AHA) (Bhatnagar et al. 2014) (continues on next page)	<ul style="list-style-type: none"> <li>• “Current evidence evaluating the efficacy of these products as a cessation aid is sparse, confined to 2 randomized controlled trials and 1 large cross-sectional study, anecdotal reports, and Internet-based surveys.”</li> <li>• “[R]eports are confounded by a self-selection bias in that the respondents are often e-cigarette enthusiasts.”</li> <li>• “The AHA maintains that e-cigarette use should be part of tobacco screening questions incorporated into clinical visits and worksite/community health screenings that are tied into healthcare delivery.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Low levels of harmful or potentially harmful metals such as lead, nickel, and chromium are listed as having been detected.”</li> <li>• “Trace levels of tobacco-specific N-nitrosamines, polycyclic aromatic hydrocarbons, and volatile organic compounds in the e-liquid and vapor have been reported.”</li> <li>• “The FDA has issued warnings to several e-cigarette companies for selling e-cartridges with [diethylene glycol, weight-loss chemical rimonabant (Zimulti), and the erectile dysfunction medication tadalafil (active ingredient in Cialis)] contaminants.”</li> <li>• “There are no reports of e-cigarette safety in patients with known cardiovascular disease.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The regulation should allow for quality-controlled products for adults who want to transition from conventional cigarettes to e-cigarettes or to quit or reduce smoking.”</li> <li>• “Bottles containing nicotine refill liquids can be toxic if swallowed, so cartridges and bottles should have proper warning labeling and child-proofing packaging.”</li> <li>• “It is important that the relevant government agency monitor whether these devices are used for delivery of other drugs and medications.”</li> <li>• “Companies should not be able to claim that e-cigarettes are a cessation aid unless they are approved by the FDA for that purpose.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The [AHA] supports effective regulation that addresses marketing, labeling, quality control of manufacturing, and standards for contaminants.”</li> <li>• “[It] also supports including e-cigarettes in smoke-free air laws and prohibiting the sales of e-cigarettes to youth.”</li> </ul>

**Table 5.3 B Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
(continued from previous page) American Heart Association (AHA) (Bhatnagar et al. 2014)	<ul style="list-style-type: none"> <li>• “Clinicians should be educated about e-cigarettes and should be prepared to counsel their patients who are using combustible tobacco products to use e-cigarettes as a primary cessation aid.”</li> <li>• “For patients with existing cardiovascular disease and stroke, or at risk of a cardiovascular disease event, intensive cessation counseling should be offered as soon as possible.”</li> </ul>	—	—	—

**Table 5.3 B Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
American Lung Association (2014, 2015)	<ul style="list-style-type: none"> <li>• “Until and unless the FDA approves a specific e-cigarette for use as a tobacco cessation aid, the American Lung Association does not support any direct or implied claims that e-cigarettes help smokers quit.”</li> </ul>	<ul style="list-style-type: none"> <li>• “There is currently no scientific evidence establishing the safety of e-cigarettes.”</li> <li>• “FDA found detectable levels of toxic cancer-causing chemicals, including an ingredient used in anti-freeze, in two leading brands of e-cigarettes and 18 various cartridges.”</li> <li>• “The lab tests also found that cartridges labeled as nicotine-free had traceable levels of nicotine.”</li> <li>• “Nicotine is believed to contribute to increased incidence of premature birth, and low birth weight.”</li> <li>• “Research has also shown a negative impact on pulmonary function in newborns.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The FDA has not approved any e-cigarettes as a safe or effective method to help smokers quit.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Including e-cigarettes in smokefree laws and ordinances.”</li> <li>• “State laws that would prohibit the sale of any flavored e-cigarette product.”</li> <li>• “Taxing e-cigarettes at a rate equivalent with all tobacco products, including cigarettes.”</li> <li>• “Eliminating e-cigarette sales to youth, otherwise restricting youth access to e-cigarettes and requiring e-cigarette retailers to be licensed.”</li> <li>• “E-cigarettes should be defined as tobacco products.”</li> <li>• “Opposes creating new definitions for ‘vapor products’ and/or ‘alternative nicotine products’ in state laws.”</li> </ul>

Table 5.3 B Continued

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
Americans for Nonsmokers' Rights (ANR) (n.d.a; n.d.b)	<ul style="list-style-type: none"> <li>• “ESDs are not proven cessation devices.”</li> <li>• “Many people become ‘stable dual-users’ who use both cigarettes and ESDs.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Americans for Nonsmokers’ Rights recommends that e-cigarettes not be used in areas where people will be exposed to the vapors they emit.”</li> <li>• “Electronic smoking device aerosol is not water vapor. . . . The aerosol (incorrectly called vapor) contains nicotine, hazardous ultrafine particles that lodge deeply in the lungs . . . and toxins known to cause cancer.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Electronic smoking devices are currently unregulated products.”</li> <li>• “[ANR] . . . encourages municipalities and states to prohibit the use of ESDs in all smokefree venues.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Electronic cigarettes are not a safe alternative!”</li> </ul>

### C. World Health Organization

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
World Health Organization (WHO) (Bates 2014; WHO 2014b) (continues on next page)	<ul style="list-style-type: none"> <li>• “Prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids.”</li> <li>• “The regulatory standard for cessation claims and approval as cessation aids should remain an appropriate body of evidence, based on well-controlled clinical trials.”</li> </ul>	<ul style="list-style-type: none"> <li>• “ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined. If smoke-free legislation is not fully developed according to Article 8 of the WHO FCTC and the guidelines for its implementation, this should be done as soon as possible.”</li> <li>• “Health warnings should be commensurate with proven health risks.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Parties should contemplate putting in place an effective restriction on ENDS advertising, promotion and sponsorship.”</li> <li>• “Protection from vested commercial interests.”</li> <li>• “Governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Overall, in its public communication WHO portrays e-cigarettes as a threat to public health.”</li> <li>• “Encourage smoking cessation and provide a quitline number if one exists.”</li> </ul>

**Table 5.3 C Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
(continued from previous page) World Health Organization (WHO) (Bates 2014; WHO 2014b)	<ul style="list-style-type: none"> <li>• “For ENDS products to be approved for smoking cessation by the suitable regulatory agency, the appropriate balance should be reached between providing accurate scientific information to the public about the risk of ENDS use and its potential benefits as compared with smoking.”</li> </ul>	—	—	—

Table 5.3 Continued

## D. Government health

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
European Union (EU) (European Parliament and Council 2014; WHO Framework Convention on Tobacco Control 2014)	—	<ul style="list-style-type: none"> <li>• “Certain additives used to create the impression that tobacco products have health benefits, as well as those with [carcinogenic, mutagenic, or reprotoxic] properties in unburnt form, should be prohibited in order to ensure uniform rules throughout the Union and a high level of protection of human health.”</li> <li>• “Electronic cigarettes and refill containers could create a health risk when in the hands of children—it is necessary to ensure products are child and tamperproof.”</li> <li>• “Nicotine-containing liquid should only be placed on the market in electronic cigarettes or in refill containers that meet certain safety and quality requirements.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The prohibition of tobacco products with characterizing flavours does not preclude the use of individual additives outright, but it does oblige manufacturers to reduce the additive or the combination of additives.”</li> <li>• “Electronic cigarettes and refill containers should be regulated by this Directive.”</li> <li>• “Where the manufacturer of the relevant product is not established in the Union, the importer of that product should bear the responsibilities relating to the compliance of those products with this Directive.”</li> <li>• “Nicotine-containing liquid should only be allowed to be placed on the market, where the nicotine concentration does not exceed 20 mg/ml.”</li> <li>• “Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market.”</li> <li>• “The labeling and packaging of [e-cigarettes] should display sufficient and appropriate information on their safe use.”</li> </ul>	<ul style="list-style-type: none"> <li>• New directive: May 2014.</li> <li>• New rules applied: First half of 2016.</li> <li>• “Aims at ensuring equal treatment across the EU for nicotine-containing e-cigarettes (products that do not contain nicotine are not covered by the Directive).”</li> <li>• “Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers.”</li> </ul>

**Table 5.3 D Continued**

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
CAP/BCAP (UK) (2014)	—	<ul style="list-style-type: none"> <li>• “Ads cannot convey health benefits or claim that they are safer or healthier than smoking tobacco.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Ads must not be likely to appeal particularly to people under 18, especially by reflecting or being associated with youth culture.”</li> <li>• “People shown using e-cigarettes or playing a significant role must neither be, nor seem to be, under 25.”</li> <li>• “Ads must not be directed at people under 18 through the selection of media or the context in which they appear.”</li> <li>• “Ads must not encourage nonsmokers or nonnicotine users to use e-cigarettes.”</li> <li>• “Ads must make clear that the product is an e-cigarette and not a tobacco product.”</li> <li>• “Ads on TV and radio will be subject to scheduling restrictions to reduce the chance of e-cigarette advertisements being seen or heard by children.”</li> </ul>	<ul style="list-style-type: none"> <li>• Effective date: November 10, 2014.</li> <li>• “The rules place an emphasis on the protection of young people and ads must avoid containing anything that promotes the use of a tobacco product or that shows the use of a tobacco product in a positive light.”</li> <li>• CAP: Write and maintain the UK advertising codes.</li> </ul>
Public Health England (UK) (Britton and Bogdanovica 2014; CAMQUIT n.d.)	—	—	<ul style="list-style-type: none"> <li>• “Under the terms of the new Tobacco Product Directive (TPD) . . . advertising of nicotine-containing devices that are not licensed as medicines will be prohibited, products will be required to carry health warnings, meet purity and emission standards that are yet to be defined.”</li> </ul>	<ul style="list-style-type: none"> <li>• Effective date: 2016.</li> <li>• “The UK [Medicines and Healthcare products Regulatory Agency] announced that from 2016, it intended to regulate electronic cigarettes and other nicotine-containing products as medicines by function, and thus require manufacture to medicinal purity and delivery standards, and proactive controls on advertising.”</li> </ul>

Table 5.3 D Continued

Organization	Organizational position on cessation	Organizational position on harm	Organizational position on regulation	General comments
International Union Against Tuberculosis and Lung Cancer (2013)	<ul style="list-style-type: none"> <li>• “The benefits of e-cigarettes have not been scientifically proven.”</li> <li>• “Very few studies have assessed ECs/ENDS as a harm reduction and cessation aid and with conflicting findings.”</li> </ul>	<ul style="list-style-type: none"> <li>• “The safety of ECs or ENDS has not been scientifically demonstrated.”</li> <li>• “Adverse health effects for [secondhand smoke] cannot be excluded because the use of electronic cigarettes leads to emission of fine and ultrafine inhalable liquid particles, nicotine and cancer-causing substances into indoor air.”</li> </ul>	<ul style="list-style-type: none"> <li>• “A range of current and proposed legislative and regulatory options exists.”</li> <li>• “Brazil, Norway, and Singapore have banned ECs/ENDS completely.”</li> <li>• “ENDS could undermine the implementation of WHO FCTC Article 12 (de-normalisation of tobacco use).”</li> <li>• “Use of ENDS could also hamper the implementation of Article 8 (protection from exposure to tobacco smoke).”</li> </ul>	<ul style="list-style-type: none"> <li>• “The Union strongly supports the regulation of the manufacture, marketing and sale of Electronic cigarettes (ECs) or electronic nicotine delivery systems (ENDS); the preferred option is to regulate ECs or ENDS as medicines.”</li> <li>• “The Union is concerned that the marketing, awareness and use of ECs or ENDS is growing rapidly.”</li> </ul>

*Note:* AARC = American Association for Respiratory Care; ACP = American College of Physicians; ACS = American Cancer Society; AHA = American Heart Association; ANR = Americans for Nonsmokers’ Rights; CAP/BCAP = Committees of Advertising Practice/Broadcast Committee of Advertising Practice; CDC = Centers for Disease Control and Prevention; CTP = Center for Tobacco Products; ECs = electronic cigarettes; ENDS = electronic nicotine delivery systems; ERS = European Respiratory Society; ESDs = electronic smoking devices; EU = European Union; FCTC = Framework Convention for Tobacco Control; FDA = U.S. Food and Drug Administration; UK = United Kingdom; WHO = World Health Organization.

## Case Studies

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Case studies in California and North Dakota demonstrate how e-cigarette policies have been enacted at the local and state levels, and they provide potential models

of how cities, counties, and other states might address e-cigarettes in their jurisdictions.

### **City of Hayward Takes Bold Steps to Address Tobacco Products Aimed at Kids**

In response to the “D” grade that the city of Hayward received in 2011 from the American Lung Association in California for its efforts to protect youth from tobacco sales, the city council directed its staff to develop regulations to address the problem of youth tobacco sales. Draft regulations were presented at a city planning meeting in 2012, followed by a series of community meetings and hearings that culminated in the Hayward city council’s adoption of a 45-day moratorium to begin in January 2014 on the issuance of business licenses or building permits for any new tobacco retailers. The following month, the moratorium was extended another 15 months to provide more time to research and consider the issue (City of Hayward 2014).

On July 1, 2014, the Hayward city council unanimously adopted an ordinance that requires sellers of tobacco products and “electronic smoking devices” to obtain annually a \$400 tobacco retailer license that covers the cost of an annual inspection for compliance with federal, state, local, tribal, and territorial tobacco control laws. The ordinance allowed the city’s existing 142 tobacco retailers, 8 e-cigarette retailers, and 2 hookah lounges to continue operating at their current locations; however, new sellers must obtain a conditional use permit, are restricted to special commercial zones, and may not locate within 500 feet of residential areas or child-sensitive areas (e.g., schools and parks) or within 500 feet of an existing tobacco seller. It also prohibits new hookah lounges or vaping lounges from opening within the city.

The ordinance also contains provisions to prohibit self-service displays of tobacco products and e-cigarettes and to regulate the sales of cigars, flavored products, and imitation tobacco products. Cigars selling for less than \$5 each are required to be sold in pack sizes of five or more, and the sale of flavored traditional tobacco products, e-cigarettes, and imitation tobacco products (e.g., candy cigarettes, bubble gum chew) is prohibited within 500 feet of schools for any business not selling these products before July 1, 2014.

Penalties range from \$1,500 for a first violation and possible suspension to a complete revocation of a license after three violations within a 3-year period (City of Hayward 2014; n.d.a.). Active enforcement of the ordinance began in April 2015 (City of Hayward n.d.b.).

Throughout the process, Hayward officials and staff relied heavily on materials from the American Lung Association, the Center for Tobacco Policy and Organizing, and ChangeLab Solutions to provide the public health and legal rationale for supporting the provisions. Hayward’s tobacco retail licensing effort was also supported by the tobacco control program of the Alameda County public health department, which used monies from its Master Settlement Agreement to fund the Hayward police department to conduct youth decoy operations and local community and youth organizations to conduct educational outreach (City of Hayward 2014). Collectively, these resources informed the Hayward city council’s decision-making process.

## North Dakota's Statewide Clean Indoor Air Law Prohibits Conventional Tobacco Products and E-Cigarettes

In November 2012, North Dakota achieved a remarkable victory for statewide clean indoor air (BreatheND n.d.a.) despite major obstacles, including a harsh winter climate, an adult smoking rate of 21.9% (CDC 2013), and several prior failed legislative attempts to close exemptions in the state's 2005 clean indoor air law (CDC 2014). Despite these impediments, two-thirds of the state voted to prohibit both the smoking of conventional tobacco products and use of e-cigarettes in all non-hospitality workplaces; restaurants; bars; hotel guest rooms and communal areas; health care facilities; assisted living facilities; all licensed child and adult day care facilities; gaming facilities; indoor areas of sports arenas; and within 20 feet of entrances, exits, operable windows, air intakes, and ventilation systems of enclosed areas where smoking is not allowed (BreatheND n.d.b.). Additionally, the law provided no exemptions for tobacco-only retail or "vape shops" (Americans for Nonsmokers' Rights Foundation 2015, n.d.).

The 2012 ballot initiative on statewide clean indoor air resulted from the lack of progress in working with the legislature to try to close smoking exemptions in the state law. The initiative's sponsors, Tobacco Free North Dakota and the American Lung Association in North Dakota, worked closely with the Tobacco Control Legal Consortium to draft policy language, which included prohibiting the use of e-cigarettes anywhere smoking was prohibited. The sponsors approached stakeholders and assessed public support. Little opposition was encountered to prohibiting the use of e-cigarettes indoors. In addition to the sponsors' efforts, the North Dakota Center for Tobacco Prevention and Control Policy conducted a media campaign and worked with local partners to educate their communities, resulting in 11 smokefree ordinances prior to the issuing of the statewide ballot initiative. The landslide victory (66% vs. 33%) in favor of clean indoor air, with the initiative successfully carried in every one of North Dakota's 53 counties, demonstrated widespread public support for clean indoor air (Ballotpedia 2012).

Only a few years later, the law continues to enjoy strong public support from nonsmokers (84.4%) and smokers (58%) alike. Compliance with the law is comparable to cigarette smoking; just 16.8% of North Dakotans reported having observed smoking indoors in areas where it was prohibited, and 23.2% reported having seen e-cigarettes used indoors in such places. Local enforcement personnel confirm a high level of compliance, reporting violations primarily related to smoking within 20 feet of entrances. To date, the only prosecuted violation of the law involved the sampling of an e-cigarette product inside a "vape shop" (BreatheND 2014). In hindsight, the decision to include e-cigarettes in North Dakota's smokefree law was helpful, given increasing concerns about involuntary exposure to nicotine and other aerosolized e-cigarette emissions.

## Summary and Recommendations

The Surgeon General has long played a leading role in identifying the harms of tobacco use and documenting the most effective ways to reduce them. This report comes amid the rising use of e-cigarettes among the nation's youth and young adults. It calls attention to this problem and the need to implement immediately a comprehensive strategy to minimize any negative public health impact now and in the future, giving consideration to the potential for youth to be harmed from e-cigarettes while, simultaneously, acknowledging that gains might be made if the use of combustible tobacco products fell among adult smokers. Chapters 1–4 documented the particular challenges posed by the rapid emergence and dynamic nature of e-cigarette use among youth and young adults. The marketplace is diverse, and although it includes the large tobacco companies, e-cigarettes are sold in thousands of "vape shops"

and other small commercial locations and on the Internet. Marketing strategies exploit social media, reaching widely and with tailored targeting to consumers.

The differences notwithstanding, the principles and strategies articulated in the 2014 Surgeon General's report and prior reports remain relevant to e-cigarettes. The 2014 report was written not long after the use of e-cigarettes began to surge dramatically; that report commented on the need for rapid elimination of conventional cigarettes and other combustible tobacco products but did not specify a role for e-cigarettes or discuss strategies to minimize adverse effects among youth and young adults (USDHHS 2014). The report's final chapter, however, set out an evidence-based strategy for the future. The present report builds on this foundation, adding recommendations related to e-cigarettes.

## Conclusions

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1. The dynamic nature of the e-cigarette landscape calls for expansion and enhancement of tobacco-related surveillance to include (a) tracking patterns of use in priority populations; (b) monitoring the characteristics of the retail market; (c) examining policies at the national, state, local, tribal, and territorial levels; (d) examining the channels and messaging for marketing e-cigarettes in order to more fully understand the impact future regulations could have; and (e) searching for sentinel health events in youth and young adult e-cigarette users, while longer-term health consequences are tracked.
2. Strategic, comprehensive research is critical to identify and characterize the potential health risks from e-cigarette use, particularly among youth and young adults.
3. The adoption of public health strategies that are precautionary to protect youth and young adults from adverse effects related to e-cigarettes is justified.
4. A broad program of behavioral, communications, and educational research is crucial to assess how youth perceive e-cigarettes and associated marketing messages, and to determine what kinds of tobacco control communication strategies and channels are most effective.
5. Health professionals represent an important channel for education about e-cigarettes, particularly for youth and young adults.
6. Diverse actions, modeled after evidence-based tobacco control strategies, can be taken at the state, local, tribal, and territorial levels to address e-cigarette use among youth and young adults, including incorporating e-cigarettes into smoke-free policies; preventing the access of youth to e-cigarettes; price and tax policies; retail licensure; regulation of e-cigarette marketing that is likely to attract youth and young adults, to the extent feasible under the law; and educational initiatives targeting youth and young adults. Among others, research focused on policy, economics, and the e-cigarette industry will aid in the development and implementation of evidence-based strategies and best practices.

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