

Chapter 8

A Vision for the Future

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Introduction

The progress made in reducing cigarette smoking in the United States over the past five decades represents one of the most notable public health achievements of the past century (Ward and Warren 2007; U.S. Department of Health and Human Services [USDHHS] 2014). Since the first Surgeon General's report on smoking and health was released in 1964, current cigarette smoking among U.S. adults 18 years of age and older has declined from 42.6% in 1964 to a low of 14.0% in 2017 (Wang et al. 2018). This decline has brought within reach USDHHS' national *Healthy People 2020* goal of reducing adult cigarette smoking prevalence to 12.0% (Office of Disease Prevention and Health Promotion n.d.). Similarly, current cigarette smoking among youth in grades 9–12 has declined from 36.4% in 1997 to 8.8% in 2017, a decline that has persisted in the two decades since the Master Settlement Agreement of 1998 and has surpassed the national *Healthy People 2020* target of 16.0% (Centers for Disease Control and Prevention [CDC] n.d.). This commendable progress has been accomplished through the implementation of evidence-based tobacco control programs and policies at the federal, state, and local levels that effectively combat the tobacco use epidemic in the United States (Figure 8.1 and Table 8.1) (USDHHS 2012, 2014). However, it is important to acknowledge that the tobacco product landscape has diversified in recent years. Although cigarettes remain the most commonly used tobacco product among U.S. adults (Wang et al. 2018), e-cigarettes have been the most commonly used tobacco product among youth since 2014, and recent increases in e-cigarette use have offset declines in cigarette smoking and led to a net increase in overall tobacco product use among youth (Gentzke et al. 2019).

The decline in cigarette smoking among adults have been driven, in part, by reductions in initiation among youth in recent years, especially over the past two decades (USDHHS 2012, 2014). For example, since 2002, cigarette smoking initiation and daily smoking initiation has decreased among youth 12–17 years of age of both sexes

and among nearly all races/ethnicities (Cantrell et al. 2018). Preventing tobacco use among youth is therefore critical to reduce the overall prevalence of tobacco use because the vast majority of adult smokers initiate tobacco use as youth or young adults (USDHHS 2012). However, despite these notable accomplishments, motivating and helping people to quit smoking remains essential to (a) protecting the nation's approximately 34 million adult cigarette smokers from a lifetime of addiction and tobacco-related disease and death (Wang et al. 2018) and (b) curbing the substantial financial costs incurred by society because of smoking-attributable healthcare spending and lost productivity (USDHHS 2014; Xu et al. 2015). Accordingly, sustained efforts to increase access to and use of evidence-based cessation treatments among adult smokers, in coordination with population-based interventions, are essential to effectively address the full continuum of tobacco use from initiation to intermittent or routine use (USDHHS 2012, 2014).

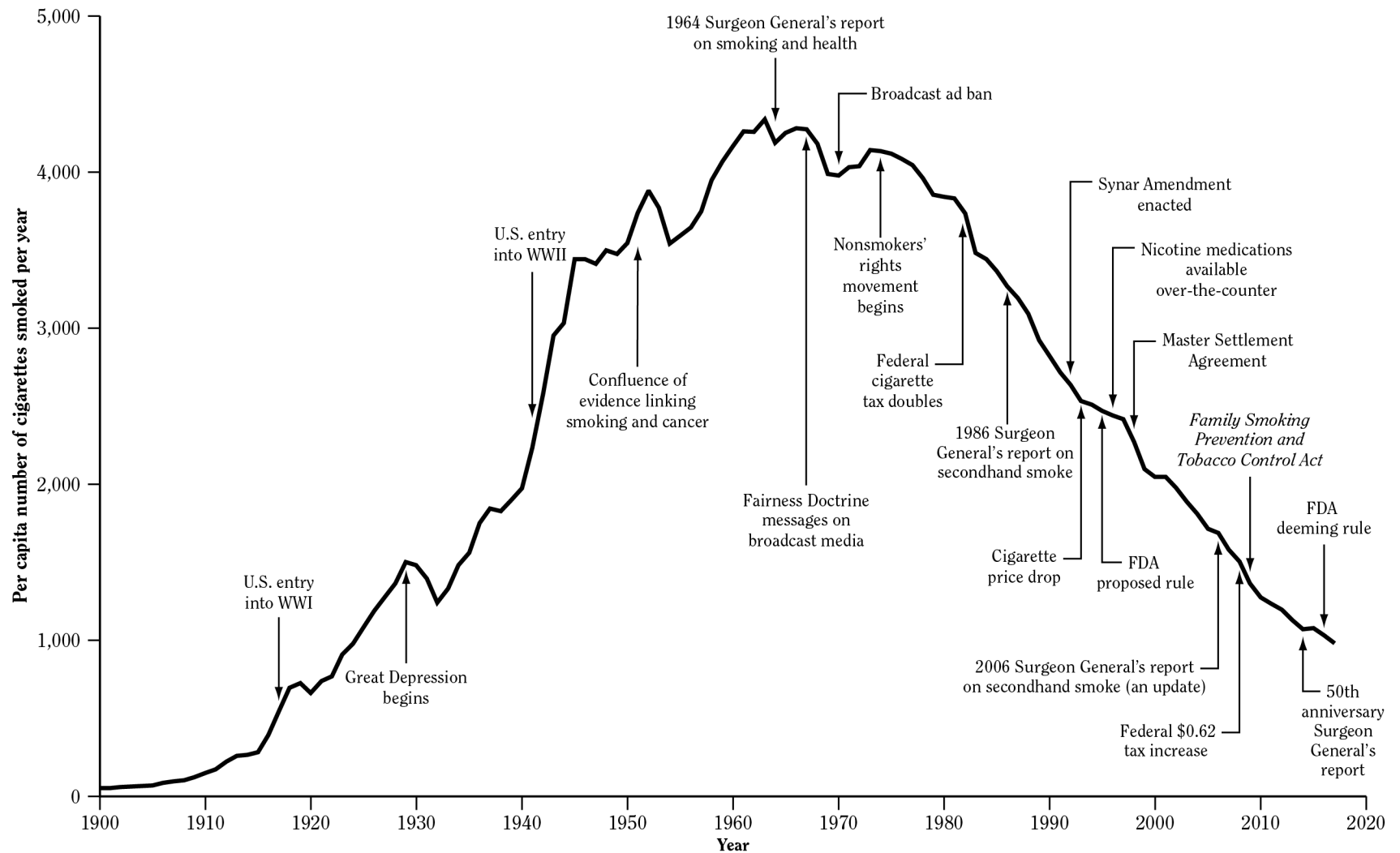
Three decades after the first Surgeon General's report to focus specifically on the health benefits of cessation, this report reviews and updates evidence on the importance of cessation in the context of a comprehensive tobacco control strategy. The report discusses historical patterns of smoking cessation in the United States, as well as the immediate and long-term health and economic benefits of smoking cessation at the individual and societal levels. The report also presents updated findings on biological insights into smoking cessation, including findings on nicotine addiction and genetic factors that may impact smoking behaviors. Finally, the report discusses the extensive array of clinical and population-based interventions that have been scientifically shown to effectively increase smoking cessation. The following sections discuss the past, present, and future of tobacco cessation in the United States. Specifically, these sections provide a historical perspective, discuss the current tobacco control landscape, and provide a vision for enhancing tobacco cessation in the United States.

Past: Historical Perspective

In 2010, USDHHS published the first tobacco control strategic action plan for the United States, *Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services* (USDHHS 2010). The main intent of this action plan was

to reinvigorate national momentum toward advancing tobacco prevention and control by applying proven methods to reduce the burden of tobacco use and dependence. The 50th anniversary Surgeon General's report provided further scientific evidence for the effectiveness of the interventions

Figure 8.1 Per capita annual cigarette consumption among adults, 18 years of age and older, and major smoking and health events in the United States, 1900–2017



Source: Adapted from Warner (1985) with permission from Massachusetts Medical Society, © 1985; as cited in USDHHS (2014).

Table 8.1 Summary of milestones aimed at increasing tobacco cessation in the United States

Year	Event
1964	<ul style="list-style-type: none"> The first Surgeon General's report, <i>Smoking and Health</i>, is released.
1967–1970	<ul style="list-style-type: none"> Regulation from the Federal Communications Commission requires broadcasters to apply the Fairness Doctrine to cigarette advertising to counter messages in advertising from the tobacco industry.
1971	<ul style="list-style-type: none"> Broadcast advertising of cigarettes ends. Surgeon General Jesse Steinfeld called for a national “Bill of Rights for the Non-Smoker.”
1979	<ul style="list-style-type: none"> The Surgeon General's report, <i>Smoking and Health</i>, is released. This report offers detailed reviews of major diseases and concludes that compared with smokers, risks are lower among former smokers for all-cause mortality, atherosclerosis and coronary heart disease, lung cancer, larynx cancer, lung function, and respiratory symptoms.
1984	<ul style="list-style-type: none"> Nicotine gum, available by prescription only, becomes the first FDA-approved cessation medication.
1986	<ul style="list-style-type: none"> The Surgeon General's report, <i>The Health Consequences of Involuntary Smoking</i>, is released.
1987	<ul style="list-style-type: none"> The United States House of Representatives passed an amendment to the <i>Federal Aviation Act</i>, making domestic flights of 2 hours or less smokefree.
1988	<ul style="list-style-type: none"> The Surgeon General's report, <i>The Health Consequences of Smoking—Nicotine Addiction</i>, is released.
1990	<ul style="list-style-type: none"> A congressionally mandated smoking ban takes effect on all domestic airline flights of 6 hours or less. The Surgeon General's report, <i>The Health Benefits of Smoking Cessation</i>, is released. San Luis Obispo, California, becomes the first city in the world to eliminate smoking in all public buildings, including bars and restaurants.
1992	<ul style="list-style-type: none"> California launches the first state-sponsored smoking cessation quitline.
1996	<ul style="list-style-type: none"> FDA approves the nicotine patch and gum for over-the-counter use and the nicotine nasal spray for prescription use. The U.S. Public Health Service issues the first clinical practice guideline on <i>Treating Tobacco Use and Dependence</i>.
1997	<ul style="list-style-type: none"> FDA approves the nicotine inhaler and bupropion for prescription use for cessation. (Bupropion had previously been available as an antidepressant and continues to be available for this indication.)
1998	<ul style="list-style-type: none"> Attorneys General of 46 states sign the Master Settlement Agreement with the four largest tobacco companies in the United States. Among its provisions, the agreement prohibits tobacco advertising that targets people younger than 18 years of age. California becomes the first state to pass a comprehensive statewide smokefree air law.
1999	<ul style="list-style-type: none"> CDC releases <i>Best Practices for Comprehensive Tobacco Control</i> with recommendations for tobacco cessation activities at the state level.
2000	<ul style="list-style-type: none"> The U.S. Public Health Service issues the second clinical practice guideline on <i>Treating Tobacco Use and Dependence</i>.
2002	<ul style="list-style-type: none"> The Joint Commission (on Accreditation of Healthcare Organizations) adds quality measures for treating tobacco dependence to accreditation requirements for hospitals. FDA approves the nicotine lozenge for over-the-counter use.
2003	<ul style="list-style-type: none"> NCI launches the smokefree.gov cessation website. University of California, San Francisco establishes the Smoking Cessation Leadership Center.
2004	<ul style="list-style-type: none"> USDHHS announces National Network of Quitlines; NCI's 1-800-QUIT-NOW portal becomes operational; and CDC begins to dedicate funding for state quitlines. The North American Quitline Consortium begins activities. The Surgeon General's report, <i>The Health Consequences of Smoking</i>, is released.
2006	<ul style="list-style-type: none"> The Surgeon General's report, <i>The Health Consequences of Involuntary Exposure to Tobacco Smoke</i>, is released. All 50 states, the District of Columbia, and Puerto Rico have publicly funded quitlines in place. Massachusetts implements an evidence-based, heavily promoted Medicaid cessation benefit. FDA approves varenicline for prescription use, making it the seventh FDA-approved cessation medication.
2007	<ul style="list-style-type: none"> The Multistate Collaborative for Health Systems Change is established.
2008	<ul style="list-style-type: none"> The U.S. Public Health Service issues the third clinical practice guideline on <i>Treating Tobacco Use and Dependence, 2008 Update</i>.
2009	<ul style="list-style-type: none"> Federal tax increase of \$0.62 per pack of cigarettes raises the federal tax to \$1.01 per pack of cigarettes. The <i>Family Smoking Prevention and Tobacco Control Act</i> is enacted.

Table 8.1 Continued

Year	Event
2010	<ul style="list-style-type: none"> • President Obama signs the <i>Patient Protection and Affordable Care Act</i> into law. The law includes important provisions that expand tobacco cessation benefits and establishes the Prevention and Public Health Fund, which provides funds to prevent and reduce tobacco use. • Recording the smoking status in the electronic health records of all patients 13 years of age and older becomes a required measure to track and report as part of the <i>Patient Protection and Affordable Care Act</i>. • The first tobacco control strategic action plan for the United States, <i>Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services</i>, is published.
2011	<ul style="list-style-type: none"> • OPM implements an evidence-based cessation benefit for federal employees. • NCI launches SmokefreeTXT, a cessation program administered via mobile text messaging.
2012	<ul style="list-style-type: none"> • The Joint Commission's set of tobacco cessation measures for hospitals is strengthened to define required components of evidence-based treatment for tobacco dependence and becomes available for voluntary adoption by hospitals. • CDC launches <i>Tips From Former Smokers</i>, the first federally funded, national tobacco education campaign. • The University of California, San Diego, launches the Asian Smokers' Quitline.
2013	<ul style="list-style-type: none"> • NCI and CDC launch 1-855-DEJELLO-YA portal for Spanish speakers.
2014	<ul style="list-style-type: none"> • The Surgeon General's report <i>The Health Consequences of Smoking—50 Years of Progress</i> is released. • CDC publishes a new edition of <i>Best Practices for Comprehensive Tobacco Control Programs</i> that includes updated recommendations for tobacco cessation activities at the state level. • The U.S. Departments of Labor, Health and Human Services, and the Treasury issue subregulatory guidance that clarifies the tobacco cessation coverage requirements in the <i>Patient Protection and Affordable Care Act</i>. • Major components of the <i>Patient Protection and Affordable Care Act</i> are implemented, including new health insurance options and requirements that most private health plans must cover preventive services, including a comprehensive quit smoking benefit. As part of another key component, Medicaid is expanded to provide a comprehensive quit smoking benefit to millions of low-income Americans.
2015	<ul style="list-style-type: none"> • The U.S. Preventive Services Task Force issues updated recommendations for tobacco cessation. • CDC launches the 6/18 initiative, partnering with healthcare purchasers, payers, and providers to improve health and control costs. The initiative focuses on the reduction of tobacco use, which is a costly health condition with proven interventions.
2017	<ul style="list-style-type: none"> • Inpatient psychiatric facilities are required, as part of the Inpatient Psychiatric Facility Quality Reporting program, to report on the Joint Commission's set of tobacco cessation measures for hospitals.
2018	<ul style="list-style-type: none"> • FDA launches the <i>Every Try Counts</i> media campaign that encourages smokers to quit smoking.

Notes: **CDC** = Centers for Disease Control and Prevention; **FDA** = U.S. Food and Drug Administration; **NCI** = National Cancer Institute; **OPM** = Office of Personnel Management; **USDHHS** = U.S. Department of Health and Human Services.

described in the national action plan (USDHHS 2014). The report concluded that, "Comprehensive tobacco control programs and policies have been proven effective for controlling tobacco use. Further gains can be made with the full, forceful, and sustained use of these measures" (USDHHS 2014, p. 7). The evidence outlined in this Surgeon General's report reinforces that conclusion and provides compelling evidence related to the successes of these measures in the context of cessation:

- More than three out of every five U.S. adults who were ever cigarette smokers have quit smoking;
- More than two-thirds of U.S. adult cigarette smokers report interest in quitting cigarette smoking; and
- The majority of adult cigarette smokers in the United States have tried to quit during the past year, and

the percentage who have tried to quit has increased slowly over the past two decades.

However, several key findings of this report highlight the tragic public health history of tobacco use in this country, including the continued legacy of millions of lives prematurely lost from this deadly and completely preventable health risk factor:

- Each year, less than 1 in 10 U.S. adult cigarette smokers successfully quits smoking (defined as being quit for at least 6 months at the time of the survey interview);
- Disparities in cessation remain by age, race/ethnicity, educational attainment, socioeconomic status, healthcare insurance coverage, geography, and other factors;

- Interest in quitting is declining among high school students who are smokers, and the proportion who made a quit attempt during the past year has decreased over the past two decades;
- Support to quit smoking, in the form of advice from health professionals and assistance from clinicians, remains inadequate; and
- More than two-thirds of adult cigarette smokers in the United States who tried to quit during the past year did not use evidence-based cessation counseling or medication.

Despite progress over the past half century, challenges persist with regard to ensuring that the risks of cigarette smoking and the benefits of cessation are addressed by implementing evidence-based strategies in a timely manner and by sustaining these strategies over time. In 2000, Surgeon General Dr. David Satcher acknowledged a recurring theme that still plagues the tobacco control movement today: “Our lack of greater progress in tobacco control is more the result of failure to implement proven strategies than it is the lack of knowledge about what to do” (USDHHS 2000). To that end, several advances have been made to better understand the immediate and long-term benefits of smoking cessation and of effective cessation interventions. However, these strategies have not necessarily been implemented in a timely, equitable, and sustainable manner (USDHHS 2014). The comprehensive body of scientific evidence that has emerged since the first Surgeon General’s report on cessation nearly three decades ago (USDHHS 1990) makes it even more important that we act on this knowledge and immediately implement effective cessation strategies.

When first introduced in the U.S. marketplace in the mid-1980s and early 1990s, nicotine replacement therapy (NRT) was available only by prescription (USDHHS 1990; *JAMA: the Journal of the American Medical Association* 2000). However, a growing body of scientific evidence on the safety of NRT led the U.S. Food and Drug Administration (FDA) to make certain NRT products available over the counter. In 1996, FDA approved the transition of certain NRT products from being available by prescription only to being available over the counter to enhance their availability and use (*JAMA: the Journal of the American Medical Association* 2000). In the same year, the U.S. Agency for Health Care Policy and Research formally recommended that NRT be part of standard care for every adult smoker (Fiore et al. 1996).

As evidence on the efficacy of tobacco cessation interventions continued to grow, the U.S. Public Health Service (*JAMA: the Journal of the American Medical Association*

2000) released *A Clinical Practice Guideline for Treating Tobacco Use and Dependence*. As noted in the guideline, a considerable increase in research during the previous two decades had clarified the nature of tobacco dependence as a chronic disease, the addictive nature of nicotine, and the availability of multiple effective behavioral counseling and pharmacological strategies for treating tobacco use and dependence (*JAMA: the Journal of the American Medical Association* 2000). Based on this evidence, the guideline provided specific recommendations regarding brief and intensive tobacco cessation interventions, as well as systems-level changes designed to promote the assessment and treatment of tobacco use. These recommendations were updated in *Treating Tobacco Use and Dependence: 2008 Update* (Fiore et al. 2008). The 2008 guideline concluded that “tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit” (Fiore et al. 2008, p. vi). It provided healthcare professionals with additional effective treatment strategies that had not been identified in the 2000 guideline, such as stronger evidence on the effectiveness of counseling, evidence that quitline counseling is effective, and recommendations related to the efficacy of all seven first-line pharmacotherapies that are approved by FDA for smoking cessation. These seven medications include five nicotine-based medications (the nicotine patch, gum, lozenge, nasal spray, and oral inhaler) and two non-nicotine oral medications (bupropion and varenicline). Of note, the 2008 guideline also reinforced the increasing body of evidence demonstrating that the successful implementation of nicotine dependence treatment strategies depends on support from the healthcare system in which the strategies are embedded. To that end, the guideline presented new evidence about the critical role the healthcare system plays in increasing the likelihood that clinicians consistently identify and intervene with smokers and that smokers receive and use effective nicotine dependence treatments and successfully quit. The 2008 guideline also underlines the failure to fully implement proven tobacco cessation interventions: “Indeed, it is difficult to identify any other condition that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions” (Fiore et al. 2008, p. 12).

In 2009, following the release of the 2008 guideline, landmark advancements helped to shape the regulatory landscape for tobacco products in the United States. In June 2009, the *Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)* gave, for the first time in history, FDA the authority to regulate the manufacturing, marketing, and sale of tobacco products. The statute empowered FDA to regulate tobacco products in a manner that is “appropriate for the protection of public health” (*Tobacco Control Act* 2009, §907(a)(3)(A)), which

was an unprecedented and critical departure from the standard of safety and efficacy that had governed the regulation of human drugs and medical devices. For example, the *Tobacco Control Act* gives FDA the authority to promulgate regulations respecting the construction; components; ingredients; additives; constituents, including smoke constituents; and properties of cigarettes, but the Act prohibits the agency from reducing nicotine yields in these products to zero. The Act also requires FDA to consider the individual- and population-level health effects of its regulatory actions, including their impact on cessation. Despite these provisions, FDA has faced some legal challenges (Public Health Law Center 2019). Nonetheless, FDA authority over tobacco products has been, and continues to be, an instrumental lever to reduce tobacco use and its harms using a population-based standard. Ongoing FDA actions related to this authority have the potential to advance population-based cessation efforts, including

- Regulating existing tobacco products and their constituents;
- Conducting a premarket review of new tobacco products before they can be introduced into the marketplace;
- Evaluating modified risk claims and products and requiring premarket testing and postmarket surveillance to evaluate the potential consequences of introducing these products into the marketplace;
- Educating the public about the harms of tobacco products (Zeller 2012; USDHHS 2014).

In March 2010, the *Patient Protection and Affordable Care Act (Affordable Care Act)* (2010) was signed into law. In the context of cessation, the law

- Requires most private insurance plans and all Medicaid expansion plans to cover in-network tobacco cessation with no cost-sharing;
- Requires state Medicaid programs to cover all seven FDA-approved tobacco cessation medications;
- Requires states to provide a comprehensive cessation benefit, including coverage of cessation counseling and medication, for pregnant women enrolled in Medicaid; and
- Provides Medicare beneficiaries with an annual wellness visit that includes referrals for tobacco cessation services.

By contributing to improved Medicaid and private cessation coverage and increasing the number of smokers who have insurance coverage, the *Affordable Care Act* has increased smokers' access to proven cessation treatments, which will improve their chances of quitting (McAfee et al. 2015). Specifically, the Act requires Grade A or B recommendations from the U.S. Preventive Services Task Force to be covered without cost-sharing. Since the implementation of the *Affordable Care Act*, some progress has occurred in traditional state Medicaid coverage of proven tobacco cessation treatments: The number of states covering individual and group counseling and all seven FDA-approved cessation medications increased from 7 states at the end of 2008 to 15 states at the end of 2018, and the number of states covering all seven FDA-approved cessation medications increased from 20 states at the end of 2008 to 36 states at the end of 2018. However, cessation coverage still falls short of a comprehensive benefit across all 50 states and the District of Columbia, and nearly all states retain barriers—such as prior authorization, duration limits, and copayments—that make it difficult for Medicaid enrollees to access cessation treatments (DiGiulio et al. 2018).

Effective August 2016, FDA finalized a rule that extended its regulatory authority to all tobacco products, except for accessories of newly deemed products, including electronic cigarettes (e-cigarettes), cigars, hookah and pipe tobacco, and future tobacco products, as part of its goal to improve public health. Known as the “deeming rule,” the rule makes these products subject to regulatory requirements imposed by or authorized under the *Tobacco Control Act*, including federal prohibition on free sampling for most tobacco products, federal requirements for health warnings, and the requirement that tobacco manufacturers register with FDA and seek the agency's review of new tobacco products (FDA 2018a). Of important note, the deeming rule does not preempt states and localities from implementing laws related to tobacco product sales, use, distribution, and advertising, as long as the laws are in addition to, or more stringent than, the requirements of the *Tobacco Control Act* (FDA 2018a). Expanding the diversity of tobacco products under the regulatory jurisdiction of FDA enhanced the agency's ability to effectively regulate these products in a manner that is appropriate for the protection of public health, as directed by the U.S. Congress. As was concluded in the 50th anniversary Surgeon General's report, “The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products” (USDHHS 2014, p. 7), thus reinforcing the importance of regulatory actions to address the variety of combustible tobacco products being sold and used in the United States. The report further noted that “the cigarette is also a defective product, meaning not just dangerous but unreasonably dangerous,

killing half of its long-term users” (Proctor 2013, p. i27, as cited in USDHHS 2014). The report also noted that a variety of noncombustible and electronic tobacco products with the potential for modified risk are being developed and aggressively marketed. Further, it noted that the shift in patterns of tobacco use could have several potential impacts, ranging from the positive effect of accelerating the rates of complete cessation among adult smokers to the negative effects of delaying cessation and diminishing progress in reducing the use of all forms of tobacco products, especially among youth and young adults. However, the impact of these products on population health is considerably more likely to be beneficial in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combustible tobacco products are being rapidly reduced and effectively regulated, most notably among youth and young adults (USDHHS 2014).

These major developments in the federal regulatory landscape since the release of the last Surgeon General’s report on cessation in 1990, coupled with the extensive and growing body of science documenting evidence-based clinical and population-based strategies for reducing tobacco use and motivating and helping tobacco users to quit, have created a strong foundation for achieving success in helping the nation’s 34 million adult cigarette smokers quit for good. Increased implementation of proven tobacco

control strategies would accelerate progress; however, the present levels of implementation of these strategies are unacceptably low and fall well below optimally effective levels based on the existing body of scientific evidence. Of particular note, state funding for tobacco control programs has been declining for more than a decade (CDC 2014; Campaign for Tobacco-Free Kids 2018); this funding includes support for state cessation interventions, which is one of CDC’s five recommended components of a comprehensive state tobacco control program (CDC 2014). For example, in fiscal year 2019, states will collect \$27.3 billion from taxes and payments as a result of the tobacco Master Settlement Agreement of 1998. However, states will spend just 2.4% of this revenue—\$655 million—on tobacco control programs, including efforts to help smokers quit (Campaign for Tobacco-Free Kids 2018). The enormous health and financial burden of smoking-attributable disease, disability, and death in the United States will continue for decades unless comprehensive, meaningful, sufficiently funded, and evidence-based actions take hold at the national, state, and local levels. Although the nation is on the cusp of reaching the *Healthy People 2020* objective of reducing the prevalence of smoking among adults 18 years of age and older to 12.0% (Wang et al. 2018), more can and should be done to help implement the proven interventions that are readily available.

Present: Health Benefits of Cessation

Even more than 50 years after the first Surgeon General’s report on smoking, the number of diseases and other adverse health effects caused by smoking continues to grow as the available scientific evidence has expanded with time (U.S. Department of Health, Education, and Welfare 1964; USDHHS 2004, 2010, 2014). The conclusions in earlier Surgeon General’s reports on tobacco use have focused primarily on causal associations between smoking and increased risk of disease and other adverse health outcomes, largely because of the lack of a sufficient body of scientific evidence at the time on the link between smoking cessation and decreased risk of such outcomes. The 1990 report was the first Surgeon General’s report to comprehensively synthesize the available scientific evidence on the health benefits of smoking cessation. That report concluded that smoking cessation has major and immediate health benefits for men and women of all ages (USDHHS 1990). Specifically, the report concluded that compared with continued smoking, smoking cessation reduces rates of respiratory symptoms and respiratory infections, such as bronchitis and pneumonia. The report also reached conclusions related to the short- and

long-term benefits of cessation. For example, smoking cessation improves pulmonary function by about 5% in only a few months after quitting smoking. Moreover, with sustained abstinence from smoking, the rate of decline in pulmonary function among former smokers returns to that of never smokers, and mortality rates from chronic obstructive pulmonary disease decline among former smokers compared with rates among persons who continue to smoke (USDHHS 1990). This report expands on the findings of the 1990 report, reaching several important new conclusions about the specific health benefits of smoking cessation, including

- Smoking cessation benefits persons at any age, but the benefits are greater at younger ages compared with older ages;
- Smoking cessation improves well-being, including higher quality of life and improved health status;
- Smoking cessation reduces the risk of the following cancers: lung, larynx, oral cavity and pharynx,

esophagus, pancreas, bladder, stomach, liver, cervix, kidney, colorectal, and acute myeloid leukemia;

- Smoking cessation substantially reduces the risk of coronary heart disease among men and women of all ages and reduces risk of morbidity and mortality from stroke and cardiovascular diseases; and
- Smoking cessation by pregnant women benefits their health and that of their fetuses and newborns.

In addition to significant health benefits to individual smokers and society, smoking cessation also has considerable economic benefits. Smoking cessation can reduce the costs of smoking for individual smokers, health systems, and society. Moreover, the report finds that smoking cessation interventions are cost-effective. The report documents an array of effective clinical and health systems interventions for increasing smoking cessation and treating tobacco use and dependence:

- Behavioral counseling and cessation medication interventions increase smoking cessation compared with self-help materials or no treatment.
- Behavioral counseling and cessation medications are each effective alone in treating tobacco use and nicotine addiction but are most effective when used in combination.
- Combination pharmacotherapy, including combining short- and long-acting forms of NRT, increases smoking cessation compared with the use of single forms of NRT.
- Tobacco quitline counseling increases smoking cessation, when provided alone or in combination with medication.
- Insurance coverage of cessation interventions that are comprehensive, barrier-free, and evidence-based increases the availability and utilization of treatment services for smoking cessation.

This report further reinforces the importance of interventions promoting cessation at the individual and population levels. Specifically, actions at the clinical and health system levels are typically designed to integrate tobacco cessation interventions into routine clinical care, increase the use and effectiveness of smoking cessation treatments, or directly help smokers quit. However, such interventions should not function in isolation. Instead, they should complement population-based interventions that have already been shown in multiple previous

Surgeon General's reports (USDHHS 2004, 2014) and other major reports to reduce tobacco use and tobacco-related morbidity and mortality. Given the critical importance and impact of population-based interventions in combating the tobacco use epidemic, King and Graffunder (2018) described the importance of such strategies in the context of a "tobacco control vaccine," whose ultimate impact on public health is contingent on its combination of individual components (including a "cessation access" component), robust population-level protection, and the extent to which these components are supported and advanced by key stakeholders at an adequate dose. In addition to preventing initiation of tobacco product use, population-based interventions can also influence cessation at a macro level by motivating tobacco users to quit and by providing an environment that makes it easier for them to do so (CDC 2014). Although previous Surgeon General's reports have documented the efficacy of these interventions for reducing tobacco use, this is the first Surgeon General's report to document the impact of such interventions on smoking cessation:

- Increasing the price of cigarettes reduces cigarette consumption, reduces the prevalence of smoking, and increases smoking cessation;
- Mass media campaigns increase the number of calls to quitlines and increase smoking cessation;
- Smokefree policies lead to decreased prevalence of smoking, decreased cigarette consumption, and increased smoking cessation among adults; and
- Comprehensive state tobacco control programs reduce the prevalence of smoking and increase smoking cessation.

Predictive models described in this report show that evidence-based tobacco control policies can yield substantial reductions in the prevalence of smoking. Moreover, cessation treatment policies and other policies—including tax increases, smokefree laws, and media campaigns—have complementary effects by increasing quit attempts and improving quitting success. Taken together, the preponderance of available data on the benefits of cessation and the efficacy of available clinical and population-based interventions reinforces the importance of a comprehensive approach to promoting tobacco cessation in the United States. While acknowledging the importance of the individual components, it is critical to recognize that these individual components must work together synergistically to most effectively prevent initiation of tobacco use and promote cessation (CDC 2014; USDHHS 2014).

Future: Ending the Tobacco Use Epidemic

Progress and Challenges

Tobacco use could remain the leading cause of preventable disease, disability, and death in the United States unless the prevalence of tobacco use, especially use of combustible products, is reduced more rapidly than the current trajectory (USDHHS 2014). Such reductions will require coordinated efforts to prevent initiation of tobacco use and nicotine addiction among young people and to create an environment that promotes and supports cessation among current tobacco users (USDHHS 2014). Considerable progress has been made but more can be done—and with enhanced expediency. To end the tobacco use epidemic, the evidence-based strategies articulated in this report must be implemented fully and sustained with sufficient intensity and duration. If this does not happen, nearly half a million Americans will continue to die each year from smoking-related diseases and exposure to secondhand smoke, and millions of Americans will continue to live with serious smoking-related diseases, costing society hundreds of billions of dollars in smoking-attributable healthcare expenditures and lost productivity (USDHHS 2014).

Challenges remain to accomplish the goal of a society free of tobacco-related death and disease. For example, marked disparities exist in the use of tobacco products, and some subpopulations face a considerably higher burden of tobacco use and tobacco-associated morbidity and mortality. Use of tobacco products remains higher among males, middle-aged adults, American Indians/Alaska Natives, persons with lower levels of education, persons living below the poverty level, persons living in the Midwest and South, persons with no health insurance or who are insured through Medicaid, sexual and gender minorities, persons with disabilities, and persons with behavioral health conditions (Wang et al. 2018). Additionally, as noted in this report, marked disparities in cessation persist across population groups. Disparities also persist regarding access to and use of proven cessation treatments (National Cancer Institute [NCI] 2017). The prevalence of key indicators of cessation—quit attempts, advice to quit from a health professional, and access to cessation therapies—varies across populations, with lower prevalence among some vulnerable subgroups. For example, uninsured smokers and Hispanic smokers are less likely than their respective counterparts to report receiving advice to quit from a health professional; uninsured smokers, Hispanic smokers, and gay/lesbian/bisexual smokers are less likely than their counterparts to report using cessation counseling and/or medication as part of a quit attempt (Babb et al. 2017). To eliminate tobacco-related disparities,

tobacco control programs and policies, including barrier-free access to cessation treatments, must be implemented in a way that achieves equitable benefits for all (CDC 2014). Such efforts would ultimately enhance access to effective cessation treatments and accelerate the decline in the prevalence of smoking across all population groups, thus alleviating the disproportionate health and economic burden experienced by vulnerable population groups (CDC 2014; NCI 2017).

Disparities in tobacco use and cessation are compounded by the fact that the tobacco industry continues to aggressively market and promote addictive and lethal products with the goals of retaining current users of these products and of recruiting new consumers, including youth and young adults (USDHHS 2012). Such marketing and promotional activities, including decades of coordinated efforts targeting various vulnerable population groups, have contributed to the disparities in cigarette smoking and cessation that exist in the United States (USDHHS 1998, 2014; NCI 2008, 2017). The 50th anniversary Surgeon General's report further underscored the deceptive nature of the tobacco industry's efforts, reaching the following major conclusion: "The tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes" (USDHHS 2014, p. 7).

The landscape of tobacco products continues to evolve to include an array of combustible, noncombustible, and electronic products (Cullen et al. 2018; Wang et al. 2018). For example, heated tobacco products have recently reentered the U.S. marketplace, with IQOS being authorized by FDA for sale in April 2019 (FDA 2019). More research is needed to better understand the long-term health effects of heated tobacco products. Although preliminary data from the tobacco industry suggest certain heated tobacco products generally have lower levels of harmful ingredients than conventional cigarettes (St. Helen et al. 2018), concerns remain around sustained dual use of heated products and conventional cigarettes, youth initiation, and the limited number of independent studies assessing the constituents in these products and the potential population-level health risks (Leigh et al. 2018; Max et al. 2018; McKelvey et al. 2018; Nabavizadeh et al. 2018). At present, data are not available on the long-term health effects of these products.

The continued diversification of the tobacco product landscape could have several different potential impacts, ranging from accelerating the rates of complete cessation among adult smokers to delaying cessation and

diminishing progress in reducing the use of all forms of tobacco products among youth and young adults (USDHHS 2014). Moreover, as the landscape of tobacco products continues to evolve, so does the tobacco industry. For example, during the past decade, three categories of e-cigarette brands have emerged in the U.S. market: brands developed by cigarette manufacturers, brands that were ultimately acquired by cigarette manufacturers, and brands that have no affiliation with cigarette manufacturers (USDHHS 2016). In recent years, the majority of e-cigarettes sold in traditional retail stores are those manufactured by major cigarette companies (King et al. 2018). More recently, the tobacco industry has also made more prominent efforts to acquire a stake in e-cigarette companies not previously affiliated with the traditional tobacco industry. For example, in December 2018, Altria Group, the parent company of Philip Morris USA, purchased a 35% stake in JUUL Labs, the maker of the most commonly sold e-cigarette in the United States (Altria Group 2018).

The increasing availability and use of novel tobacco products, most notably e-cigarettes, raise questions about the potential impact that such products could have on efforts to eliminate the individual- and population-level disease and death caused by tobacco use. However, when considering the impact of e-cigarettes on public health, it's critical to acknowledge their potential benefits and their potential risks, including the recognition that population-level increases in youth using e-cigarettes and becoming addicted to nicotine could offset any potential benefits realized among adult smokers using these products to quit. Additionally, e-cigarette, or vaping, product use may be associated with other health risks beyond youth initiation and use. For example, CDC, FDA, state and local health departments, and public health and clinical partners have been investigating a multistate outbreak of e-cigarette, or vaping, product use associated lung injury (EVALI) (Siegel et al. 2019). The latest national and state findings show e-cigarette, or vaping, products containing THC—particularly those from informal sources, such as friends, family, or in-person or online dealers—are linked to most of the cases of lung injury and play a major role in the outbreak (Moritz et al. 2019; Navon et al. 2019). In particular, vitamin E acetate is closely associated with EVALI (Blount et al. 2019). Vitamin E acetate has been identified in several tested products used by EVALI patients, and has been identified in bronchoalveolar lavage (BAL) fluid samples from 48 of 51 assessed EVALI patients, but not in the BAL fluid from a control group. However, as of January 2020, evidence is not yet sufficient to rule out the contribution of other chemicals of concern among some EVALI patients.

The *Tobacco Control Act* is governed by a requirement to protect the overall public health. Such a

population-level public health standard is essential because exposure to harmful toxicants from e-cigarettes at the individual level could adversely affect public health at the population level by (a) increasing initiation of e-cigarette use and nicotine addiction among vulnerable populations, including young people, and (b) increasing the number of adult users of both combustible tobacco products and e-cigarettes (i.e., dual users) without necessarily increasing the number of successful adult quitters. Weighing the relative benefits and risks to individuals and the population as a whole is essential when considering the potential role that any noncombustible tobacco product may play in reducing the occurrence of smoking-attributable disease and death (USDHHS 2014). E-cigarettes could help individual adult smokers if they completely switch from conventional cigarettes to e-cigarettes. Among those who have transitioned completely, the ultimate goal should be to also quit the use of e-cigarettes completely to achieve the maximal individual and public health benefit. However, at the population level, any potential benefits these products confer in terms of increasing cessation among adult smokers would need to outweigh potential risks related to increased initiation of tobacco product use among youth (USDHHS 2014). E-cigarette use among U.S. high school students increased 78% during 2017–2018, as 1 in 4 high school students reported currently using e-cigarettes in 2019 (Cullen et al. 2019). This increase coincided with the growing popularity of e-cigarettes shaped like a USB flash drive, including JUUL (King et al. 2018; Gentzke et al. 2019). Many of these e-cigarettes deliver nicotine in the form of nicotine salts, which allow users to inhale particularly high levels of nicotine more easily and with less irritation than the freebase nicotine that is used traditionally in tobacco products, including older generation e-cigarettes (USDHHS 2018). These high levels of nicotine introduce additional population-level risks because nicotine is extremely addictive, can harm the developing brain in adolescents, and can prime the brain for addiction to other drugs (USDHHS 2016).

It is also critical to acknowledge that for e-cigarettes or other noncombustible tobacco products to be effective harm-reduction tools, they must help smokers completely quit conventional cigarettes. Specifically, users must transition completely from combustible tobacco products to lower risk alternatives in order to realize a reduction in risk at the individual level. As noted in the major conclusions of this report, e-cigarettes, a continually changing and heterogeneous group of products, are used in a variety of ways; and there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation. Moreover, the available evidence indicates that a majority of e-cigarette users also smoke conventional cigarettes—a pattern of use that does not confer a substantial

risk reduction benefit to the individual (USDHHS 2014; Goniewicz et al. 2018). However, the number and scientific rigor of studies on e-cigarettes and smoking cessation among adults continue to increase (Hajek et al. 2019), and a growing body of scientific evidence suggests that multiple factors related to e-cigarettes—including product type, frequency of use, and efficiency of nicotine delivery—could affect the efficacy of these products for successful smoking cessation. Of note, the diversification of the e-cigarette landscape is especially important to consider in the context of cessation efficacy, as various aspects of these products—including their ability to efficiently deliver nicotine to the user—have evolved with each generation of e-cigarette product that has entered the marketplace. For example, although justifiable concerns exist that nicotine salts could promote initiation of e-cigarette use among youth, this new product formulation also has the potential to enhance the dose and efficiency with which nicotine is delivered to adult smokers who may be attempting to quit smoking, thus potentially increasing the likelihood that they are able to transition completely to e-cigarettes. However, this formulation could also make it more difficult for those who fully transition to e-cigarettes to eventually quit using these products completely.

Studies on the relationship between e-cigarettes and smoking cessation continue to emerge, including randomized clinical trials that will be critical to providing a comprehensive and evidence-based understanding of this topic. When considering current and future studies on e-cigarettes, it is important to note that findings may not be generalizable to all settings, including smokers who have different levels of dependency than those included in the reported research; smokers who try or use e-cigarettes for reasons other than quitting smoking; and smokers who live in countries that have different policy and regulatory environments, including limitations on the amount of nicotine permitted in e-cigarettes and restrictions on e-cigarette advertising and marketing. Also, e-cigarettes are not a uniform product category; the generalizability of research on their efficacy for smoking cessation is complicated by the diversity of products available, the volatile nature of the marketplace, and the extent to which the products can be modified by the user—including modifications that affect the level of nicotine the products deliver. More longitudinal research is needed on the long-term health effects of using e-cigarettes and on the effects of e-cigarette use on cessation, including research addressing internal validity and generalizability to real-world usage. Additionally, given the volatility of the e-cigarette landscape, including the introduction of nicotine salts, research on different types of e-cigarette products and frequency of use is essential.

As studies on e-cigarettes and cessation continue to emerge, it is critical that public health recommendations be based on a robust and scientifically rigorous evidence base that takes into account the potential detrimental impacts that the widespread availability and promotion of e-cigarettes for cessation could have on youth initiation of e-cigarettes, as well as other tobacco products (USDHHS 2016). When considering public health, in order for a net gain to occur, any benefit of e-cigarette use among adult smokers would have to outweigh the risks of increased initiation among young people at the population level.

End-Game Strategies

Faced with the challenge of realizing the vision of a society free of tobacco-related death and disease, and especially given the increasing variety of tobacco products in the marketplace, the patterns of use of these products among adults and youth, and the changing demographics of users of these products, the 50th anniversary Surgeon General's report summarized several potential end-game strategies and emphasized those judged most relevant for the United States (Table 8.2) (USDHHS 2014). These proposed strategies, in conjunction with the accelerated implementation of proven tobacco control interventions, are intended to end the epidemic of disease and premature death caused by tobacco use. The development of various end-game strategies by scholars around the world has taken place in the absence of a broad consensus on how to define the *end* related to tobacco. For example, some end-game strategies have focused on the elimination of all tobacco use and the use of any nicotine-containing products, including e-cigarettes; others have focused on eliminating the use of combustible tobacco products because to date, these products have been responsible for the overwhelming burden of death and disease caused by tobacco use (USDHHS 2014). Nonetheless, there is generally broad recognition and consensus that the overriding objective is to maximize health (USDHHS 2014).

Benowitz and Henningfield (1994) made one of the first end-game proposals, describing a policy approach of gradually reducing the levels of nicotine content in cigarettes to nonaddictive levels, so as to prevent the development of nicotine addiction in youth. The authors also noted that this strategy could increase the likelihood that adult smokers would stop smoking—as cigarettes would become “less satisfying.” In the decades since that 1994 publication, several studies have assessed the potential impact of experimental very-low-nicotine-content cigarettes on adult smokers. Based on these studies, this report finds that reducing the level of nicotine content in cigarettes could have the potential to reduce smoking:

Table 8.2 Potential end-game strategies discussed in the 50th anniversary Surgeon General’s report, 2014

Potential end-game strategy	Description
Reduce nicotine yield in cigarettes and other tobacco products	Use government regulations to gradually reduce the level of nicotine in cigarettes, and possibly other tobacco products, to nonaddictive levels
Reduce toxicity in tobacco products	Implement regulatory standards that require manufacturers to create tobacco products with very low toxicity
Gradually reduce the supply of tobacco products	Phase out over time the use of tobacco products via systematic reduction of supply to zero or to some other minimal level
Prohibit the sale of tobacco products to future generations	Prohibit the sale of tobacco products to persons born after a specific date, essentially creating tobacco-free cohorts that progressively increase in coverage and size over time
Prohibit cigarettes and/or cigarettes and other tobacco products	Prohibit the production and sale of cigarettes and possibly other types of tobacco products
Sell tobacco products through a not-for-profit agency	Transfer control of the supply and sales of tobacco products to a not-for-profit agency that has the goal of reducing consumption

Sources: Benowitz and Henningfield 1994, 2013; Borland 2003, 2013; Callard et al. 2005a,b; Daynard et al. 2010; Hatsukami et al. 2010, 2012, 2013; Khoo et al. 2010; Thomson et al. 2010; Proctor 2011, 2013; Berrick 2013; Callard and Collishaw 2013; Wilson et al. 2013; USDHHS 2014.

The evidence is suggestive but not sufficient to infer that very-low-nicotine-content cigarettes can reduce smoking and nicotine dependence and increase smoking cessation when full-nicotine cigarettes are readily available; the effects on cessation may be further strengthened in an environment in which conventional cigarettes and other combustible tobacco products are not readily available.

Moreover, a simulation model by Apelberg and colleagues (2018) suggested that if conventional cigarettes were not available, lowering the level of nicotine content in cigarettes to minimally addictive levels in the United States would decrease the prevalence of cigarette smoking to 1.4% by 2060, prevent 16 million people from initiating smoking, and avert an estimated 2.8 million tobacco-related deaths. Of all end-game strategies proposed to date, nicotine reduction has received the greatest interest and attention in the United States, in part because the regulatory structure required to implement it is already in place and is explicitly articulated in the *Tobacco Control Act*. In 2018, FDA issued an advance notice of proposed rulemaking that specifically requested data and other information to inform a potential tobacco product standard to reduce nicotine in cigarettes to minimally addictive or nonaddictive levels for the protection of public health (*Federal Register* 2018; FDA 2018a). The *Tobacco Control Act* gives FDA several tools to regulate cigarettes, including the ability to establish product standards, which could include reducing nicotine content to levels so low that they would be insufficient to cause or sustain nicotine addiction, but the Act expressly prohibits FDA from requiring the reduction of nicotine yields of

cigarettes to zero. However, questions of potential interest related to a standard could include whether such a nicotine standard would lead to smokers inhaling more deeply to compensate for the reduced nicotine yield; would lead to illicit trade in products with higher nicotine yield; and would impact vulnerable populations with higher rates of smoking, such as those with mental illness and substance use disorders (USDHHS 2014; Gottlieb and Zeller 2017).

In addition to a potential standard around the level of nicotine content, several other end-game proposals also have the potential to contribute to increases in smoking cessation and reductions in the disease and premature death caused by tobacco. For example, strict standards for ingredients in tobacco products could be established to make some or all tobacco products less toxic and less appealing, particularly to young people (Table 8.2). The *Tobacco Control Act* authorizes FDA to implement product standards to control levels of chemicals and other ingredients in tobacco products or their emissions for the protection of public health (USDHHS 2014). Other potential end-game strategies could aim to reduce the supply of tobacco products, which could also influence cessation among current users of such products, or to prohibit the sale of cigarettes and/or other tobacco products. Although the *Tobacco Control Act* prohibits FDA from banning the sale of cigarettes, it does authorize the agency to set standards for tobacco products that could significantly impact the marketing of tobacco products. Specifically, the act allows FDA to issue a product standard to prohibit menthol in cigarettes, or any other tobacco product, to protect public health. Moreover, the *Tobacco*

Control Act does not preempt states and localities from prohibiting the sale of cigarettes or other tobacco products. However, other factors may preclude such actions, including state constitutions or other state laws, which could prevent the implementation of such measures at the local level. Additionally, prohibiting specific types of tobacco products (e.g., flavored tobacco products) could also impact population-level cessation. In November 2018, FDA indicated its intent to prohibit menthol in combustible tobacco products, prohibit flavored cigars, and prohibit flavored e-cigarettes (excluding tobacco and menthol flavors), except those sold in age-restricted, in-person locations (FDA 2018b). Several jurisdictions in California, Illinois, Massachusetts, Minnesota, New York, and Rhode Island have restricted the sale of flavored tobacco products, with some of these policies not exempting menthol flavors (Campaign for Tobacco-Free Kids 2019). Prohibiting flavors, including menthol, in tobacco products can benefit public health by reducing initiation among young people and promoting cessation among adults (USDHHS 2014). For example, studies show that a sizable portion of adults who smoke menthol cigarettes report that they would try to quit smoking if menthol cigarettes were prohibited (O'Connor et al. 2012; Pearson et al. 2012). In 2011, the Tobacco Product Scientific Advisory Committee (TPSAC) to the FDA conducted an extensive review of the state of the science on menthol, concluding that the “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States” (TPSAC 2011, p. 225). Furthermore, FDA conducted a subsequent independent review of the science and concluded, “From the available studies, the weight of evidence supports the conclusion that menthol in cigarettes is likely associated with reduced success in smoking cessation, especially among African American menthol smokers” (FDA n.d., p. 6).

But end-game strategies cannot function in isolation and should not be seen as a panacea or as a substitute for the accelerated implementation of established population-based strategies. To that end, an integrated national tobacco control strategy is essential—one that is based on a foundation of enhanced implementation of the traditional strategies that have been shown to be effective, including taxation, smokefree policies, barrier-free cessation support, and hard-hitting mass media campaigns (USDHHS 2014; King and Graffunder 2018). The most feasible end-game strategies—such as reducing the nicotine content in cigarettes to make them less addictive and placing greater restrictions on sales of tobacco products, including prohibitions on entire categories of tobacco products—could then be integrated into this foundational platform (Van der Eijk 2015). Using this paradigm, a more aggressive implementation of the proven population-based interventions outlined in Chapter 7 would reinforce

cessation efforts nationally and enhance the feasibility and impact of end-game strategies.

The pursuit of an integrated strategy of accelerated implementation of proven interventions coupled with the introduction of novel end-game interventions is likely to encounter unique challenges (Isett 2013; Rabe 2013; Thomas and Gostin 2013). These challenges are likely to come from two key groups. The first group is those with a financial stake in the continued widespread use of cigarettes and other tobacco products, including the traditional tobacco industry and the emerging array of e-cigarette companies and related entities advocating for their interests (USDHHS 2014). The tobacco industry has an extensive history of attempting to influence decision makers to oppose evidence-based tobacco control strategies, and because local control is so integral to galvanizing evidence-based policies and shifting social norms, the tobacco industry and its allies have used strategies to preempt local smokefree laws and other types of tobacco control policies (USDHHS 2014). The second group is users of tobacco products and others who would be ideologically opposed to any policy or strategy that would jeopardize the availability and sale of cigarettes and other tobacco products and the ability of adults to obtain and consume these products (USDHHS 2014). However, innovation spurred by the proliferation of subnational policies has been a hallmark of tobacco control for decades, at times giving rise to approaches that have been emulated by practitioners in other disciplines. As noted in the 50th anniversary Surgeon General’s report, “It is important to remember that many policy innovations, once thought inconceivable, have now become the law of the land” (USDHHS 2014, p. 858). Just two decades ago, it would have been difficult to envision that more than half of U.S. states and more than 1,000 communities would be covered by comprehensive smokefree laws, and even a decade ago, most public health experts would not have predicted that more than a dozen states and several hundred communities would increase the legal age of sale for tobacco to 21 years of age (CDC 2018). Indeed, the profound and dynamic history of tobacco control over more than 50 years suggests that continued innovation is a key tenet of success. Therefore, the public health community must remain nimble and capable of evolving as quickly as the rapidly changing landscape of tobacco products. New developments and innovations will continue to occur, as has been the case for decades, but the public health community need not reinvent the wheel. Proven interventions can continue to be modernized with time. Additionally, new end-game strategies offer unprecedented opportunities to complement these interventions to end the epidemic of disease and premature death caused by tobacco use.

Advancing Cessation

As documented in Chapter 6, a comprehensive body of scientific evidence, which has grown stronger over time, supports the use of behavioral counseling and pharmacologic interventions for smoking cessation, with the combination of both being the most effective approach. Effective counseling interventions include an array of behavioral treatments that can be delivered effectively by a variety of qualified personnel in many formats, including individual, group, and telephone counseling. Additionally, emerging evidence suggests that text messaging and web interventions are also effective modalities for delivering cessation behavioral interventions. As documented in Chapter 5, strong evidence exists for the cost-effectiveness of both behavioral and pharmacologic tobacco cessation treatments. However, although more than half of current smokers try to quit each year, the success rate of these quit attempts remains low, and successful cessation is typically preceded by multiple prior attempts (Babb et al. 2017). Moreover, despite gains over the past three decades, both the reach and use of existing smoking cessation interventions also remain low, with less than one-third of smokers using behavioral and/or pharmacologic interventions when trying to quit. The current state of the cessation landscape in the United States underscores the fact that more can and should be done to help smokers quit for good.

Two factors drive the rate of cessation in the population: the rate of quit attempts and the rate of successful cessation among smokers who try to quit. Thus, increases in quit attempts and quit success rates can each drive increases in population-level cessation. Moreover, increasing the reach and intensity of cessation interventions can each increase the cessation rate in the population (CDC 2014). Of note, some strategies address only one of these factors, and others address both. For example, a mass media campaign can motivate more smokers to try to quit, and the development of a new, more effective cessation medication can increase the success rate for smokers who try to quit. In contrast, a mass media campaign that drives smokers to a quitline or a promotional campaign that drives smokers enrolled in Medicaid to take advantage of newly improved Medicaid cessation coverage in their state can (a) motivate more smokers to try to quit and (b) by connecting these smokers with proven cessation treatments, increase their chances of quitting successfully. Therefore, strategies that increase the rate of quit attempts and the rate of successful cessation are especially important.

As noted in this report, increasing quit rates requires several strategies that include increasing the appeal and reach of existing evidence-based interventions to smokers. Promising directions to increase appeal and reach could

include expanding treatment targets, leveraging emerging technologies to enhance the initial and sustained engagement of smokers in treatment, and accelerating the integration of cessation services across multiple platforms and in healthcare systems. Given shifts in the manner in which people communicate and obtain information, possible emerging technologies that could be considered include (a) mobile health platforms with applications that involve adaptive interventions that are tailored to the needs of each person and (b) social media and other applications that deliver behavioral treatment and improve adherence to medication.

In addition to enhancing the reach of behavioral support, the enhanced availability of generic versions of FDA-approved brand-name drugs could enhance access to and the reach of these medications, particularly with regard to increased affordability among persons in lower socioeconomic groups, who traditionally have high rates of smoking (Wang et al. 2018). It is anticipated that health insurers would be more likely to cover generic cessation medications with no or minimal barriers because generic medications are typically less expensive; this would increase the affordability of and access to these medications among smokers, especially low-income smokers. Additionally, Leischow (2019) proposed enhancing access to and the reach of proven pharmacotherapies by making varenicline and other prescription medications for smoking cessation available over the counter. The conversion of pharmacotherapies to over-the-counter medicines requires careful weighing of risks and benefits at the individual and population levels.

Increasing quit rates could also be achieved by increasing the effectiveness of existing interventions. Chapter 6 of this report concluded, “The evidence is sufficient to infer that combining short- and long-acting forms of nicotine replacement therapy increases smoking cessation compared with using single forms of nicotine replacement therapy.” Emerging evidence also suggests that combining varenicline with bupropion or NRT may be more effective than taking varenicline alone, particularly among heavy smokers. In addition, combination therapy involving bupropion and NRT has been shown to produce better outcomes than either medication used by itself. Reaching a better understanding of both behavioral and pharmacological interventions that can safely and effectively promote cessation among youth is becoming increasingly important because of the dearth of evidence on this issue and because of recent surges in e-cigarette use and frequency among youth, particularly products that utilize nicotine salts (USDHHS 2018).

Efforts can also be made to increase quit rates through the development of cessation interventions that have greater reach and/or effectiveness than existing

interventions or that appeal to and are used by different populations of smokers. For example, according to this report, evidence is suggestive but not sufficient to conclude that cytisine is effective for smoking cessation (Chapter 6). Cytisine is used for cessation in several Eastern European countries but is not yet approved by FDA for use as a cessation medication in the United States. More research is needed to further assess the safety and efficacy of cytisine for smoking cessation and its possible utility in the United States.

Similarly, more research is needed on the potential of using e-cigarettes as a smoking cessation aid, including determining what types of e-cigarettes and what aspects of use may maximize positive cessation outcomes and minimize adverse consequences, especially related to use among young people. Chapter 6 of this report concluded that the evidence is inadequate to infer that e-cigarettes, in general, increase smoking cessation. It also concluded that the evidence is suggestive but not sufficient to infer that the use of e-cigarettes containing nicotine is associated with increased smoking cessation compared with the use of e-cigarettes not containing nicotine, and the evidence is suggestive but not sufficient to infer that more frequent use of e-cigarettes is associated with increased smoking cessation compared with less frequent use of e-cigarettes. It is also important to note that the e-cigarette landscape continues to evolve, and existing research has not assessed newer types of e-cigarettes, including those that use nicotine salts. Such products may deliver nicotine content more efficiently and, therefore, may be more effective for smoking cessation than earlier generations of e-cigarettes. However, this formulation could also make it more difficult for those who fully transition to e-cigarettes to eventually quit using these products completely.

The aforementioned individual treatments for smoking cessation are necessary but not sufficient to fully achieve meaningful population-based cessation outcomes. As discussed in Chapter 7, these interventions are most effective when complemented by actions taken at the clinical and health systems levels to create environments that support the use of cessation treatments and successful cessation by smokers—including policies to transform systems of care to better address tobacco use and dependence, the promotion of evidence-based treatments for tobacco use and dependence, and the implementation of policies (e.g., covering all evidence-based cessation treatments; removing barriers to treatments, such as prior authorization; and promoting covered treatments to smokers and providers so that they are aware of and use these treatments) to increase smokers' access to clinical interventions and cessation treatments that could help them quit. Although considerable progress has been made to integrate nicotine dependence treatment into clinical

health systems over the past several decades, substantial opportunities for improvement remain, for example:

- Embedding policies and protocols for tobacco use screening and interventions into the clinical workflow;
- Embedding prompts, decision support, and documentation tools into health records, including electronic health records; and
- Distributing specific components of the intervention across the broader healthcare team to reduce the burden on time-constrained physicians and to reinforce the importance of cessation to patients.

Because cigarette smoking remains high and quitting smoking may be more difficult among certain subpopulations in the United States, including persons of lower socioeconomic status and those with comorbid mental health and other substance use disorders (Wang et al. 2018), specific types of healthcare providers or clinical environments could become increasingly important in promoting cessation and delivering targeted cessation support. In addition to policies that seek to make the delivery of clinical cessation interventions in health systems more consistent and routine, policies that remove cost and other barriers to access for patients are also essential to increase the delivery and utilization of nicotine dependence treatment, especially when barrier-free coverage is well promoted to health plan beneficiaries. Timely and relevant clinical guidelines and clinical quality measures also play critical roles in ensuring that clinicians and staff from healthcare systems intervene consistently with tobacco users. Improving and promoting insurance coverage of treatment for tobacco use and dependence are also essential. Cessation benefits should cover all evidence-based cessation interventions, including brief and intensive counseling and all FDA-approved medications, including combination NRT therapy. This coverage should be provided with no or minimal barriers, such as prior authorization, duration limits, or cost-sharing. Regardless of how well designed a coverage benefit may be, coverage alone, without promotion, is not sufficient. Benefits for smoking cessation, whether offered through a health insurer or an employee wellness program, must be promoted to increase awareness.

In addition to the individual and clinical health systems interventions cited previously, population-based policy and program actions also serve critical roles in broadly influencing the behavior of smokers as they try to quit or think about quitting smoking. As noted in Chapter 7, population-level policy and program actions

can facilitate the integration of individual treatments into routine clinical care, thus making cessation interventions available and accessible to individual smokers and motivating smokers to use them. Such actions can occur at multiple levels—national, state, and local—and may involve government and nongovernment entities. These policies and programs include quitlines, which are an evidence-based, population-level strategy to increase the accessibility and uptake of scientifically proven cessation support, including the optimal combination of cessation counseling and medication.

Tobacco quitlines have typically been funded at the state level, but they can also be used by and funded through employers, health plans, and health systems. Quitlines offer convenient mechanisms through which health insurers and employers can partially meet federal requirements for coverage of tobacco cessation and reduce tobacco-related health expenditures. Employers can offer a tobacco quitline as an employee benefit to promote tobacco cessation and to help increase the productivity of employees who use tobacco by helping them to quit. Health systems can use quitlines as a complement to clinical care and to provide more intensive follow-up to patients engaged in a quit attempt. Provider referrals offer a less expensive and potentially more sustainable approach to drive smokers to quitline services, although developing and maintaining relationships with health systems and putting referral systems in place can be time- and staff-intensive. As described in Chapter 6, quitlines are increasingly linked to the delivery of cessation treatment by primary care providers, and enhanced use of electronic health records to electronically refer patients who smoke to quitlines is warranted. Beyond quitline e-referrals, electronic health records can be a critical tool for improving the frequency, quality, and consistency of screening and treatment for tobacco use and dependence, thereby increasing adherence to clinical practice guidelines. However, it is important that careful and intentional efforts must be made to integrate appropriate, evidence-based cessation content into the electronic health record system and to make parallel changes to the clinical work flow.

Although telephone quitlines are a clinical treatment, they are supported through broad policies at the local, state, and national levels and are designed to be accessed on a population-wide basis to address quit attempts, successful quitting, and the prevalence of smoking. Supportive policies include price increases (e.g., increasing excise taxes); restrictions on where tobacco can be used (e.g., smokefree policies); adequately funding state programs for tobacco control; carrying out mass media campaigns (e.g., CDC's *Tips From Former Smokers* campaign [*Tips*], FDA's *Every Try Counts*

campaign); and developing product regulations, such as requiring pictorial health warnings. Additionally, promising policies discussed in Chapter 7 include those focused on limiting retail density and point-of-sale tobacco advertising and on policies seeking to regulate the nicotine content in cigarettes to very low, nonaddictive levels.

Population-level policies have a broad impact, can change the context and environment to make it easier for persons to quit, and are more likely to help people quit and stay quit when coupled with clinical interventions at the individual level. Specifically, combining clinical and health system-based and population-level policy actions can improve cessation outcomes. For example, in addition to motivating smokers to make a quit attempt, a mass media campaign, such as the *Tips* campaign and the *Every Try Counts* campaign, can connect smokers to evidence-based resources for cessation treatment, such as a quitline or, in some cases, a healthcare provider. Therefore, clinicians and public health practitioners should connect clinical work with macro-level policy work to maximize the impact of tobacco-control interventions at the population level on tobacco cessation and to facilitate the implementation of these interventions.

Accelerating National Momentum to Promote Cessation

As noted in the 50th anniversary Surgeon General's report, the scientific evidence is undeniable: inhaling the combusted compounds from tobacco smoke is deadly (USDHHS 2014). Although substantial progress has been made to reduce smoking in the United States over the past five decades, by increasing adult smoking cessation and by reducing youth smoking initiation, more can and should be done. The following major conclusions from this report provide evidence that points to an urgent need for intensified and coordinated actions to reduce the considerable—and preventable—human and financial burden of smoking in the United States:

- More than three out of five U.S. adults who have ever smoked cigarettes have quit. Although a majority of cigarette smokers make a quit attempt each year, less than one-third use FDA-approved cessation medications or behavioral counseling to support these attempts.
- Smoking places a substantial financial burden on smokers, healthcare systems, and society. Smoking cessation reduces this burden, including smoking-attributable healthcare expenditures.

- Considerable disparities exist in the prevalence of smoking across the U.S. population; such prevalence is higher in some subgroups. Similarly, the prevalence of key indicators of smoking cessation—quit attempts, receiving advice to quit from a health professional, and using cessation therapies—also varies across the population, with lower prevalence among some subgroups.

To increase smoking cessation and reduce smoking in the United States, this report outlines a broad range of well-defined and effective population-based interventions that are necessary, at present, to help the 34 million American adults who currently smoke cigarettes quit:

- Fully funded, comprehensive statewide tobacco control programs;
- Higher average retail prices of cigarettes—at least \$10 a pack;
- Complete protection of the entire U.S. population from exposure to secondhand smoke through comprehensive indoor smokefree policies in workplaces, restaurants, and bars;
- High-impact media campaigns, such as CDC's *Tips From Former Smokers*, that run with sufficient reach, frequency, and duration—ideally for 12 months a year; and
- Product regulations, such as requiring pictorial health warnings.

However, these population-based actions and the more aggressive use of the evidence-based policies and programs reviewed in Chapter 7 are not enough. An array of effective clinical and health system-based interventions should also be implemented to increase smoking cessation and treat tobacco use and dependence in the United States:

- Increasing the appeal and reach of existing evidence-based interventions to individuals, including leveraging emerging technologies and accelerating the integration of cessation services across multiple platforms and in healthcare systems;
- Increasing the effectiveness of existing interventions, including recommending the combination of short- and long-acting forms of NRT, combined with behavioral support interventions, as first-line treatment for tobacco use;

- Conducting research to develop and better understand cessation interventions that have the potential for greater reach and/or effectiveness than existing interventions or that appeal to and are used by different populations of smokers;
- Conducting research to develop and better understand cessation interventions that are safe and effective among both youth and adults, including those that address the diversity of tobacco products being used by these populations, including e-cigarettes;
- Embedding policies and protocols for tobacco use screening and intervention into the clinical workflow; embedding prompts, decision support, and documentation tools into health records, such as electronic health records; and distributing specific components of the intervention across the broader healthcare team to reduce the burden on time-constrained physicians and to reinforce the importance of cessation to patients;
- Adopting policies to make the provision of cessation care in health systems more routine, as well as policies that remove cost and barriers to access for patients to increase the delivery and utilization of tobacco dependence treatment;
- Providing timely and relevant clinical guidelines and clinical quality measures to ensure that clinicians and health systems intervene consistently with tobacco users;
- Providing barrier-free cessation insurance coverage—without prior authorization, duration limits, cost-sharing, or other barriers that impede smokers' access to cessation treatments—to increase the availability and utilization of treatment services for smoking cessation;
- Ensuring comprehensive cessation insurance benefits for all smokers that include coverage of all evidence-based cessation interventions, including brief and intensive counseling and all FDA-approved medications, including combination NRT therapy;
- Promoting cessation coverage and services, whether offered through a health insurer or an employee wellness program, to smokers and healthcare providers to increase awareness and use of the covered treatments; coverage alone, without promotion, is not sufficient; and

- Adequately funding and promoting tobacco quitlines to enable their operations and services to function at levels sufficient to maximize their reach and impact.

The implementation of scientifically proven interventions has been a hallmark of the successes made in combating the tobacco use epidemic in the United States for more than 50 years. However, the tobacco control community must remain nimble and vigilant in conducting and disseminating timely, high-quality scientific studies on best practices; in modernizing existing interventions to keep pace with the rapidly diversifying landscape of tobacco products; and in identifying emerging strategies to ensure more rapid elimination of the health and economic burden of tobacco use in the United States. To that end, several end-game strategies could help to increase cessation and reduce the disease and premature death caused by tobacco use. Strategies that have been proposed include:

- Implementing a tobacco product standard to lower the level of nicotine in cigarettes to minimally addictive or nonaddictive levels, and
- Restricting the sale of tobacco products, such as prohibitions on entire categories of flavored tobacco products, including menthol.

Such actions have the potential to accelerate increases in smoking cessation and declines in the prevalence of smoking in the United States, thus hastening the end of the tobacco epidemic. However, these actions and the extensive body of evidence-based clinical, health system, and population-based tobacco prevention, control, and cessation strategies that are outlined in this report are a necessary but insufficient means to end the tobacco epidemic. Reaching the finish line will require coordination across federal government agencies and other stakeholders at the national, state, and local levels. To achieve success, we must work together to maximize resources and coordinate efforts across a wide range of stakeholders. Stakeholders who have a role to play include federal, state, local, tribal, and territorial governments; voluntary health agencies; nongovernmental and community-based organizations; civic and community leaders; public health and healthcare professionals; researchers; and individuals

(USDHHS 2016). Stakeholders must also continue to hold the tobacco industry accountable for its role in creating, obscuring, and perpetuating the tobacco use epidemic in the United States (USDHHS 2014). For example, beginning in 2017, the major U.S. tobacco companies were required by the U.S. District Court for the District of Columbia to run “corrective statements” via television and newspaper ads and to publish statements on their websites and cigarette packs that tell the American public the truth about the dangers of smoking and secondhand smoke (U.S. Department of Justice 2017; Farber et al. 2018). The tobacco control movement has achieved remarkable progress over time through coordinated actions by diverse stakeholders. The most effective interventions frequently originate at the local level before percolating to higher levels and ultimately becoming recognized as evidence-based practices (CDC 2014; USDHHS 2014). Action at the federal level is a key lever to success, but such action must be complemented by subnational and nongovernmental efforts to continue to denormalize tobacco use and advance the strategies that we know work to combat the devastating effects of tobacco use on society (USDHHS 2014). Each stakeholder can make unique and critical contributions toward reducing tobacco-related disease and death in the United States. In particular, there are opportunities for practitioners, experts, and researchers who have traditionally focused primarily on population-based tobacco control policy interventions, to collaborate more closely with their counterparts who have traditionally focused on cessation interventions as part of a broader effort to build linkages.

We are at the precipice of a critical period in the more-than-half-century history of the tobacco control movement in the United States. The considerable reduction in the prevalence of smoking since the mid-1960s is an important public health achievement, which has been driven in part by increases in adult smoking cessation and the multiple advances in smoking cessation interventions since the last Surgeon General’s report on this topic nearly three decades ago (USDHHS 1990). However, we cannot rest on our laurels. More work must be done, and we have the experience and wherewithal to do it. Equipped with both science and resolve, we will continue to move forward to end the tobacco epidemic in the United States. Working together, we can make tobacco-related disease and death a thing of the past.

References¹

- Altria Group. Altria makes \$12.8 billion minority investment in JUUL to accelerate harm reduction and drive growth [press release], December 20, 2018; <<http://investor.altria.com/file/Index?KeyFile=396169695>>; accessed: March 11, 2019.
- Apelberg BJ, Feirman SP, Salazar E, Corey CG, Ambrose BK, Paredes A, Richman E, Verzi SJ, Vugrin ED, Brodsky NS, et al. Potential public health effects of reducing nicotine levels in cigarettes in the United States. *New England Journal of Medicine* 2018;378(18):1725–33.
- Babb S, Malarcher A, Schauer G, Asman K, Jamal A. Quitting smoking among adults—United States, 2000–2015. *Morbidity and Mortality Weekly Report* 2017;65(52):1457–64.
- Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. The implications for tobacco regulation. *New England Journal of Medicine* 1994;331(2):123–5.
- Benowitz NL, Henningfield JE. Reducing the nicotine content to make cigarettes less addictive. *Tobacco Control* 2013;22(Suppl 1):i14–i17.
- Berrick AJ. The tobacco-free generation proposal. *Tobacco Control* 2013;22(Suppl 1):i22–i26.
- Blount BC, Karwowski MP, Shields PG, Morel-Espinosa M, Valentin-Blasini L, Gardner M, Braselton M, Brosius CR, Caron KT, Chambers D, et al. Vitamin E acetate in bronchoalveolar-lavage fluid associated with EVALI. *New England Journal of Medicine* 2019.
- Borland R. A strategy for controlling the marketing of tobacco products: a regulated market model. *Tobacco Control* 2003;12(4):374–82.
- Borland R. Minimising the harm from nicotine use: finding the right regulatory framework. *Tobacco Control* 2013;22(Suppl 1):i6–i9.
- Callard C, Thompson D, Collishaw N. Transforming the tobacco market: why the supply of cigarettes should be transferred from for-profit corporations to non-profit enterprises with a public health mandate. *Tobacco Control* 2005a;14(4):278–83.
- Callard CD, Thompson D, Collishaw N. *Curing the addiction to profits: a supply-side approach to phasing out tobacco*. Ottawa (Ontario, Canada): Canadian Centre for Policy Alternatives, 2005b.
- Callard CD, Collishaw NE. Supply-side options for an endgame for the tobacco industry. *Tobacco Control* 2013; 22(Suppl 1):i10–i13.
- Campaign for Tobacco-Free Kids. *Broken Promises to Our Children: A State-by-State Look at the 1998 Tobacco Settlement 20 Years Later*, 2018; <<https://www.tobaccofreekids.org/what-we-do/us/statereport>>; accessed: January 15, 2019.
- Campaign for Tobacco-Free Kids. *States & Localities that Have Restricted the Sale of Flavored Tobacco Products*, January 22, 2019; <<https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>>; accessed: March 13, 2019.
- Cantrell J, Bennett M, Mowery P, Xiao H, Rath J, Hair E, Vallone D. Patterns in first and daily cigarette initiation among youth and young adults from 2002 to 2015. *PLoS One* 2018;13(8):e0200827.
- Centers for Disease Control and Prevention. *Best Practices for Comprehensive Tobacco Control Programs—2014*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014; <https://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive.pdf>; accessed: July 26, 2017.
- Centers for Disease Control and Prevention. *STATE System Smokefree Indoor Air Fact Sheet*, August 28, 2018; <<https://chronicdata.cdc.gov/Legislation/STATE-System-Smokefree-Indoor-Air-Fact-Sheet/vgq2-kkcg>>; accessed: October 18, 2018.
- Centers for Disease Control and Prevention. 1991–2017 High School Youth Risk Behavior Survey data, n.d.; <<https://nccd.cdc.gov/youthonline/App/Default.aspx>>; accessed: March 11, 2019.
- Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the field: use of electronic cigarettes and any tobacco product among middle and high school students—United States, 2011–2018. *Morbidity and Mortality Weekly Report* 2018;67(45):1276–7.
- Cullen KA, Gentzke AS, Sawdey MD, Chang JT, Anic GM, Wang TW, Creamer MR, Jamal A, Ambrose BK, King BA. E-cigarette use among youth in the United States, 2019. *JAMA: the Journal of the American Medical Association* 2019.
- Daynard RA. Doing the unthinkable (and saving millions of lives). *Tobacco Control* 2009;18(1):2–3.
- DiGiulio A, Jump Z, Yu A, Babb S, Schecter A, Williams KS, Yembra D, Armour BS. State Medicaid coverage for tobacco cessation treatments and barriers to accessing treatments—United States, 2015–2017. *Morbidity and Mortality Weekly Report* 2018;67(13):390–5.
- Family Smoking Prevention and Tobacco Control Act*, Public Law 111-31, 123 U.S. Statutes at Large 1776 (2009).

¹For reference entries that contain URLs, those URLs were active on the access date presented in the respective reference entry.

- Farber HJ, Neptune ER, Ewart GW. Corrective statements from the tobacco industry: more evidence for why we need effective tobacco control. *Annals of the American Thoracic Society* 2018;15(2):127–30.
- Federal Register. U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Tobacco product standard for nicotine level of combusted cigarettes, 83 *Fed. Reg.* 11818 (2018).
- Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, Heyman RB, Holbrook J, Jaen CR, Kottke TE, et al. *Smoking Cessation: Clinical Practice Guideline No. 18*. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, 1996. AHCPR Publication No. 96-0692.
- Fiore MC, Jaén CR, Baker TB, Bailey WC, Benowitz NL, Curry SJ, Dorfman SF, Froelicher ES, Goldstein MG, Heaton CG, et al. *Treating Tobacco Use and Dependence: 2008 Update. U.S. Public Health Service Clinical Practice Guideline*. Rockville (MD): U.S. Department of Health and Human Services, 2008.
- Genzke AS, Creamer M, Cullen KA, Ambrose BK, Willis G, Jamal A, King BA. Vital signs: tobacco product use among middle and high school students, United States, 2011–2018. *Morbidity and Mortality Weekly Report* 2019;68(6):157–64.
- Goniewicz ML, Smith DM, Edwards KC, Blount BC, Caldwell KL, Feng J, Wang L, Christensen C, Ambrose B, Borek N, et al. Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes. *JAMA Network Open* 2018;1(8):e185937.
- Gottlieb S, Zeller M. A nicotine-focused framework for public health. *New England Journal of Medicine* 2017;377(12):1111–4.
- Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine* 2019;380(7):629–37.
- Hatsukami DK. Ending tobacco-caused mortality and morbidity: the case for performance standards for tobacco products. *Tobacco Control* 2013;22(Suppl 1):i36–i37.
- Hatsukami DK, Benowitz NL, Donny E, Henningfield J, Zeller M. Nicotine reduction: strategic research plan. *Nicotine and Tobacco Research* 2013;15(6):1003–13.
- Isett KR. In and across bureaucracy: structural and administrative issues for the tobacco endgame. *Tobacco Control* 2013;22(Suppl 1):i58–i60.
- JAMA: the Journal of the American Medical Association*. A clinical practice guideline for treating tobacco use and dependence: A U.S. Public Health Service report. *JAMA: the Journal of the American Medical Association* 2000;283(24):3244–54.
- Khoo D, Chiam Y, Ng P, Berrick AJ, Koong HN. Phasing-out tobacco: proposal to deny access to tobacco for those born from 2000. *Tobacco Control* 2010;19(5):355–60.
- King BA, Gammon DG, Marynak KL, Rogers T. Electronic cigarette sales in the United States, 2013–2017. *JAMA: the Journal of the American Medical Association* 2018;320(13):1379–80.
- King BA, Graffunder C. The tobacco control vaccine: a population-based framework for preventing tobacco-related disease and death. *Tobacco Control* 2018;27(2):123–4.
- Leigh NJ, Palumbo MN, Marino AM, O'Connor RJ, Goniewicz ML. Tobacco-specific nitrosamines (TSNA) in heated tobacco product IQOS. *Tobacco Control* 2018;27(Suppl 1):S37–S38.
- Leischow SJ. Increasing smoking cessation in the United States: expanding the availability of over-the-counter medication. *JAMA: the Journal of the American Medical Association* 2019;321(6):541–2.
- Max WB, Sung HY, Lightwood J, Wang Y, Yao T. Modelling the impact of a new tobacco product: review of Philip Morris International's Population Health Impact Model as applied to the IQOS heated tobacco product. *Tobacco Control* 2018;27(Suppl 1):S82–S86.
- McAfee T, Babb S, McNabb S, Fiore MC. Helping smokers quit—opportunities created by the Affordable Care Act. *New England Journal of Medicine* 2015;372(1):5–7.
- McKelvey K, Popova L, Kim M, Chaffee BW, Vijayaraghavan M, Ling P, Halpern-Felsher B. Heated tobacco products likely appeal to adolescents and young adults. *Tobacco Control* 2018;(Suppl 1):S41–S47.
- Moritz ED, Zapata LB, Lekiachvili A, Glidden E, Annor FB, Werner AK, Ussery EN, Hughes MM, Kimball A, DeSisto CL, et al. Update: characteristics of patients in a national outbreak of e-cigarette, or vaping, product use-associated lung injuries—United States, October 2019. *Morbidity and Mortality Weekly Report* 2019;68(43):985–9.
- Nabavizadeh P, Liu J, Havel CM, Ibrahim S, Derakhshandeh R, Jacob P III, Springer ML. Vascular endothelial function is impaired by aerosol from a single IQOS HeatStick to the same extent as by cigarette smoke. *Tobacco Control* 2018;27(Suppl 1):S13–S19.
- National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use*. Smoking and Tobacco Control Monograph No. 19. Bethesda (MD): U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, 2008. NIH Publication No. 07-6242.
- National Cancer Institute. *A Socioecological Approach to Addressing Tobacco-Related Health Disparities*. National Cancer Institute Tobacco Control Monograph 22. Bethesda (MD): U.S. Department of Health and Human

- Services, National Institutes of Health, National Cancer Institute, 2017. NIH Publication No. 17-CA-8035A.
- Navon L, Jones CM, Ghinai I, King BA, Briss PA, Hacker KA, Layden JE. Risk factors for e-cigarette, or vaping, product use-associated lung injury (EVALI) among adults who use e-cigarette, or vaping, products—Illinois, July–October 2019. *Morbidity and Mortality Weekly Report* 2019 Nov 15;68(45):1034–9.
- O'Connor RJ, Bansal-Travers M, Carter LP, Cummings KM. What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand. *Addiction* 2012;107(7):1330–8.
- Office of Disease Prevention and Health Promotion. Tobacco use: objectives, n.d.; <<https://www.healthypeople.gov/2020/topics-objectives/topic/tobacco-use/objectives>>; accessed: July 26, 2017.
- Patient Protection and Affordable Care Act*, Public Law 111-148, *U.S. Statutes at Large* 124 (2010):100.
- Pearson JL, Abrams DB, Niaura RS, Richardson A, Vallone DM. A ban on menthol cigarettes: impact on public opinion and smokers' intention to quit. *American Journal of Public Health* 2012;102(11):e107–14.
- Proctor RN. *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition*. Berkeley (CA): University of California Press, 2011.
- Proctor RN. Why ban the sale of cigarettes? The case for abolition. *Tobacco Control* 2013;22(Suppl 1):i27–i30.
- Public Health Law Center. Lawsuits challenging the FDA's deeming rule (2019), March 5, 2019; <<https://www.publichealthlawcenter.org/resources/lawsuits-challenging-fda-deeming-rule>>; accessed: May 14, 2019.
- Rabe BG. Political impediments to a tobacco endgame. *Tobacco Control* 2013;22(Suppl 1):i52–i54.
- Siegel DA, Jatlaoui TC, Koumans EH, Kiernan EA, Leyer M, Cates JE, Kimball A, Weissman DN, Petersen EE, Reagan-Steiner S, et al. Update: interim guidance for health care providers evaluating and caring for patients with suspected e-cigarette, or vaping, product use associated lung injury—United States, October 2019. *Morbidity and Mortality Weekly Report* 2019;68:919–27.
- St. Helen G, Jacob P III, Nardone N, Benowitz NL. IQOS: examination of Philip Morris International's claim of reduced exposure. *Tobacco Control* 2018;27(Suppl 1):S30–S36.
- Thomas BP, Gostin LO. Tobacco endgame strategies: challenges in ethics and law. *Tobacco Control* 2013;22(Suppl 1):i55–i57.
- Thomson G, Wilson N, Blakely T, Edwards R. Ending appreciable tobacco use in a nation: using a sinking lid on supply. *Tobacco Control* 2010;19(5):431–5.
- Tobacco Products Scientific Advisory Committee. *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*. Washington (DC): U.S. Food and Drug Administration, 2011.
- U.S. Department of Health, Education, and Welfare. *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*. Washington: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, 1964. PHS Publication No. 1103.
- U.S. Department of Health and Human Services. *The Health Benefits of Smoking Cessation: A Report of the Surgeon General*. Rockville (MD): U.S. Department of Health and Human Services, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1990. DHHS Publication No. (CDC) 90-8416.
- U.S. Department of Health and Human Services. *Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics. A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1998.
- U.S. Department of Health and Human Services. Reducing Tobacco Use: A Report of the Surgeon General. Highlights: At a Glance, 2000; <https://www.cdc.gov/tobacco/data_statistics/sgr/2000/highlights/ata glance/index.htm>; accessed: March 12, 2019.
- U.S. Department of Health and Human Services. *The Health Consequences of Smoking: A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.
- U.S. Department of Health and Human Services. *Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services*. Washington (DC): Office of the Assistant Secretary for Health, 2010.
- U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.
- U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

- U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health 2016.
- U.S. Department of Health and Human Services. *Surgeon General's Advisory on E-Cigarette Use Among Youth*, 2018; <<https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>>; accessed: January 9, 2019.
- U.S. Department of Justice. Print corrective statements—exhibit 3: newspaper exemplars, October 2, 2017; <<https://www.justice.gov/opa/press-release/file/1013581/download>>; accessed: April 11, 2019.
- U.S. Food and Drug Administration. FDA's deeming regulations for e-cigarettes, cigars, and all other tobacco products, 2018a; <<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm>>; accessed: March 11, 2019.
- U.S. Food and Drug Administration. Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018b; <<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>>; accessed: March 12, 2019.
- U.S. Food and Drug Administration. FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway [press release], April 30, 2019; <<https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>>; accessed: June 13, 2019.
- U.S. Food and Drug Administration. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*, n.d.; <<https://www.fda.gov/downloads/ucm361598.pdf>>; accessed: November 15, 2018.
- U.S. Public Health Service. *Treating Tobacco Use and Dependence: 2008 Update. Tobacco Use and Dependence Guidelines Panel*. Rockville (MD): U.S. Department of Health and Human Services, 2008; <<https://www.ncbi.nlm.nih.gov/books/NBK63952/>>; accessed: January 30, 2019.
- Van der Eijk Y. Development of an integrated tobacco end-game strategy. *Tobacco Control* 2015;24(4):336–40.
- Wang TW, Asman K, Gentzke AS, Cullen KA, Holder-Hayes E, Reyes-Guzman C, Jamal A, Neff L, King BA. Tobacco product use among adults—United States, 2017. *Morbidity and Mortality Weekly Report* 2018;67(44):1225–32.
- Ward JW, Warren C, editors. *Silent Victories: The History and Practice of Public Health in Twentieth-Century America*. New York (NY): Oxford University Press, 2007.
- Warner KE. Cigarette advertising and media coverage of smoking and health. *New England Journal of Medicine* 1985;312(6):384–8.
- Wilson N, Thomson GW, Edwards R, Blakely T. Potential advantages and disadvantages of an endgame strategy: a 'sinking lid' on tobacco supply. *Tobacco Control* 2013;22(Suppl 1):i18–i21.
- Xu X, Bishop EE, Kennedy SM, Simpson SA, Pechacek TF. Annual healthcare spending attributable to cigarette smoking: an update. *American Journal of Preventive Medicine* 2015;48(3):326–33.
- Zeller M. Three years later: an assessment of the implementation of the Family Smoking Prevention and Tobacco Control Act. *Tobacco Control* 2012;21(5):453–4.