No. 18-119269-S

IN THE SUPREME COURT OF THE STATE OF KANSAS

DWAGFYS MANUFACTURING, INC., d/b/a The Vapebar Topeka and PUFFS 'N' STUFF, LLC, *Plaintiffs-Appellees*,

v.

CITY OF TOPEKA, KANSAS, a municipal corporation and the Governing Body of the City of Topeka, *Defendants-Appellants*.

BRIEF OF *AMICI CURIAE* THE GREATER KANSAS CITY CHAMBER OF COMMERCE and THE CAMPAIGN FOR TOBACCO-FREE KIDS, FILED ON THEIR BEHALF AND ON BEHALF OF CERTAIN OTHER PUBLIC HEALTH, MEDICAL, AND COMMUNITY ORGANIZATIONS

Appeal from the District Court of Shawnee County
Honorable Franklin R. Theis, Judge
District Court Case No. 2018-cv-35

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TABLE OF CONTENTS AND AUTHORITIES

NATURE OF THE CASE

This Court granted the Application to File *Amicus* Brief of the Greater Kansas City Chamber of Commerce (the Chamber) and the Campaign for Tobacco-Free Kids (Tobacco-Free Kids), in which the Chamber and Tobacco-Free Kids sought leave to file this brief on behalf of themselves and on behalf of "other public health, medical, and community organizations," by Order dated August 14, 2018. *Amici* submit this brief in support of the appeal brought by the City of Topeka from the grant of a permanent injunction enjoining the City's enforcement of 2017 Ordinance No. 20099 prohibiting the sale of cigarettes, electronic cigarettes, tobacco products or liquid nicotine to any person under the age of 21 (the Ordinance). In particular, *Amici* urge the Court that the Ordinance is a legitimate exercise of the City's police powers and not preempted by the Kansas Cigarette & Tobacco Products Act.

STATEMENT OF IDENTITY OF AND INTEREST BY *AMICI CURIAE*

Amici include the following national, state and local public health, medical, community and other interested organizations and entities, each of which works to protect the public from harms caused by tobacco products: The Greater Kansas City Chamber of Commerce, Campaign for Tobacco Free Kids, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Children's Mercy Kansas City, Health Care Foundation of Greater Kansas City, Healthier Lyon County, Metropolitan Healthy Communities Coalition, The Midwest Cancer Alliance, Oral Health Kansas, Inc., Preventing Tobacco Addiction Foundation, REACH Healthcare Foundation, Shawnee County Health Department, Tobacco Control Legal

Consortium, The Tobacco Free Kansas Coalition, Truth Initiative, Unified Government of Wyandotte County- Kansas City, Kansas - Public Health Department, and The University of Kansas Cancer Center.

Each of the *Amici* has a strong interest in the implementation of local tobacco control policies that will prevent the initiation of tobacco use by young people and save lives. By prohibiting the sale of tobacco products to persons under 21, the Ordinance would sharply reduce access to tobacco products by young people. Given that tobacco use predominately starts with the young, this measure will reduce the incidence of tobacco-related disease and death in Topeka for many years to come.

Amici submit this brief as a direct response to Appellees' assertions that (1) the Ordinance is not a legitimate exercise of the City's police power on the supposed basis that there has been no articulation of "a nexus between a legitimate governmental interest and the Ordinance . . . ." and (2) the Ordinance "is arbitrary without any requisite fact finding to support the exercise of the police power." Appellees' Brief, pp. 16-17. This brief also directly addresses the lower court's conclusion, in imposing a permanent injunction against the Ordinance, that the harm to Plaintiffs from enforcing the Ordinance "exceeds that to the public interest."

ARGUMENTS & AUTHORITIES

I. "Police powers" authorities, Ordinance background, common knowledge, and universally available statistics support enforcement of the Ordinance.

The *Cardarella* and *Mugler* "police powers" cases discussed in Appellees' brief do not, as Appellees urge, require a governing body to make findings or cite evidence in

some formalistic manner to establish a nexus between a legitimate governmental interest and an enactment intended to further that interest. Rather, both cases merely clarified that enactments must, *in fact*, bear a reasonable relationship to a valid exercise of the police power. *See Cardarella v. City of Overland Park*, 228 Kan. 698, 701-02, 620 P.2d 1122 (1980); *Mugler v. Kansas*, 123 U.S. 623, 661-662 (1887).

The United States Supreme Court also explained in *Mugler* that in evaluating a governing body's exercise of police powers with respect to liquor regulation, it could not "shut out of view the fact, within the knowledge of all, that the public health . . . and the public safety, may be endangered by the general use of intoxicating drinks; nor" ignore other facts concerning dangers of liquor that were "established by statistics accessible to every one." *Id.* at 662.

Here the Ordinance was introduced by Councilmember Schwartz expressly "to protect children and help prevent underage smoking." Governing Body Minutes, Topeka City Council (Nov. 21, 2017), *available at* https://s3.amazonaws.com/cot-wp-uploads/wp-content/uploads/citycouncil/Minutes/112117m.pdf, at Appendix ("A") 2. At least seventeen individuals and entity representatives spoke in support of the Ordinance, presenting evidence of "health problems and statistics associated with" tobacco use "by people under the age of 21." *See id.* at A2-3; Governing Body Minutes, Topeka City Council (Dec. 5, 2017), *available at* https://s3.amazonaws.com/cot-wp-uploads/wp-content/uploads/citycouncil/Minutes/120517m.pdf, A6. *Amici* submit this brief to provide the Court with a full understanding, with "statistics available to every one," of the strong

connection between the Ordinance and the exercise of Topeka's police powers for the public health and welfare.

II. Tobacco use exacts disease and death tolls across the nation and in Kansas.

Each day, more than 350 children under the age of 18 become regular, daily smokers and almost one-third will eventually die from smoking. *See* U.S. Dep't of Health & Human Servs. ("HHS"), *Results from the 2016 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables* (2017), A12; HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, Fact Sheet (2012) ("2012 Fact Sheet"), A13. The 2014 Report of the Surgeon General projected that, if current trends continue, 5.6 million of today's youth will die prematurely from a smoking-related illness. *See* HHS, *The Health Consequences of Smoking: 50 Years of Progress, A Report of the Surgeon General* (2014) ("2014 SG Report"), A17.

In 2014 the Surgeon General reported that tobacco use remains the leading cause of preventable death in the United States, killing more than 480,000 people each year. *See* Centers for Disease Control and Prevention ("CDC), *Health Effects of Cigarette Smoking* (2018), at A41. Indeed, smoking kills more Americans than alcohol, HIV, car accidents, illegal drugs, and firearm-related incidents *combined. See id.* Smoking impacts nearly every organ of the body; more than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke. *See* 2014 SG Report, at A18. In addition to this staggering premature mortality, millions of Americans suffer from

debilitating medical conditions throughout their lives due to smoking. As of 2014, more than 16 million Americans were living with a disease caused by smoking. *See* 2014 SG Report, A36.

The continuing devastating impact of smoking on the nation's health is due, in large part, to the highly addictive nature of nicotine in tobacco products. Most smokers want to quit, but are unable to do so. The 2015 National Health Interview Survey revealed that 68% of adult smokers wanted to stop smoking and over 55% made an attempt to quit during the past year, but only 7.4% recently stopped smoking. *See* CDC, *Quitting Smoking Among Adults – United States, 2000-2015* (2017), A48.

Kansas communities are suffering greatly from tobacco-related disease and death. Recent data indicate that every year, tobacco takes the lives of approximately 4,400 Kansas residents, and that given recent smoking rates, 61,200 Kansas children alive today ultimately will die from smoking, or about one in every twelve Kansans now under 18. *See* CDC, *Best Practices for Comprehensive Tobacco Control Programs—2014* (2014), A59; 2014 SG Report, A30. Smoking costs the state over $2.2 billion annually in direct healthcare expenses and lost productivity. *See* Campaign for Tobacco-Free Kids (CTFK), *Toll of Tobacco in Kansas* (2018) ("CTFK Kansas Toll"), A60. Smoking continues at unacceptably high levels in Kansas communities, including among young people. Across the State, over 17% of Kansas adults smoked in 2016 and, the next year, over 7% of Kansas high school students smoked cigarettes. *See id.*; CDC, *Youth Risk Behavior Surveillance—United States 2017* (2018) ("2017 YRBS"), at A64. Indeed, approximately

9,200 Kansas young people under 18 who will try cigarettes for the first time each year and another 1,500 will become daily smokers. *See* CTFK Kansas Toll, at A60.

Although cigarettes take the greatest toll in tobacco-related disease and death, smokeless tobacco (moist snuff, chewing tobacco, and dry snuff) also poses significant health risks, causing oral, pancreatic and esophageal cancer and lesions in the mouth, in addition to being addictive. *See Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products*, 82 Fed. Reg. 8004, 8011 (Jan. 23, 2017), A72. And although cigarette smoking in the U.S. has been on the decline, usage of smokeless tobacco among high school adolescents (7.7% among boys and 3.0% among girls in 2017) remains steady. *See* CDC, *Tobacco Use Among Middle and High School Students—United States, 2011-2017* (2018) ("CDC 2011-2017"), A75. In Kansas that same year, 9.1% of high school boys used smokeless tobacco. *See* 2017 YRBS, A68.

Finally, in the past five years, e-cigarettes, which generally deliver a nicotine-containing aerosol to the user, have become the fastest growing segment of the tobacco market. Although much is still uncertain about the long-term health risks from e-cigarettes, there is little doubt that many e-cigarettes generate toxins, including cancer-causing agents, although generally at lower levels than cigarettes. *See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning for Tobacco Products*, Final Rule, 81 Fed. Reg. 28,974, 29,029-32 (May 10, 2016), A81-84. The vast majority of e-cigarettes, like traditional cigarettes, contain highly addictive nicotine, often at the same

levels as traditional cigarettes. *Id.* at A81, A83. As the Surgeon General concluded, "The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe." *See* HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of the Surgeon General* (2016), A91.

E-cigarette usage among high school students has surged in recent years, rising from 1.5% in 2011 to 11.7% in 2017. *See* CDC 2011-2017, A76-77. Last year in Kansas, 10.6% of high school students used e-cigarettes. *See* 2017 YRBS, A66.

New e-cigarette devices are indeed being made to resemble everyday objects, like computer flash drives, that can easily avoid detection in schools and other places where young people can use them surreptitiously. For example, a new device called JUUL "fits easily in a pocket and looks nondescript when plugged into a laptop's USB drive to recharge or sitting on a desk." *See* Anne M. Chaker, *Schools & Parents Fight a Juul E-Cigarette Epidemic*, W.S.J. (updated Apr. 4, 2018), www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246, at A93. As FDA Commissioner Scott Gottlieb recently noted, JUUL-like products "have become wildly popular with kids" and are "more difficult for parents and teachers to recognize or detect . . . ." *See* FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D. on new enforcement actions and a youth tobacco prevention plan to stop youth use of, and access to, JUUL and other e-cigarettes* (2018), at A99. JUUL's manufacturer claims that the device "delivers a nicotine experience truly akin to a cigarette, with two times the nicotine strength . . . of leading competitive products." *See* Business Wire, *PAX Labs, Inc. Introduces Revolutionary Technologies with Powerful E-Cigarette JUUL*, Apr. 21, 2015,

www.businesswire.com/news/home/20150421005219/en/PAX-Labs-Introduces-Revolutionary-Technologies-Powerful-E-Cigarette, at A103. E-cigarettes may also lead to use of other more hazardous tobacco products like cigarettes. A Report of the National Academies of Sciences, Engineering & Medicine, *Public Health Consequences of e-Cigarettes* (2018) ("NASEM Report"), recently concluded: "There is substantial evidence that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults." *See* A108. Thus, in addition to the direct harm of e-cigarettes to young people's health, their increasing use threatens to undermine the progress of communities across the nation, and in Kansas, in curbing youth smoking.

III. The Ordinance, by prohibiting sales to persons under 21, will reduce tobacco-product use by young people, prevent disease, and save lives.

A landmark 2015 Report of the Institute of Medicine (now the National Academy of Medicine) of the National Academy of Science, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products* (2015) ("IOM Report"), predicted that raising the minimum age for tobacco sales "will reduce tobacco initiation, particularly among adolescents 15 to 17 years of age, will improve health across the life span, and will save lives." *See* IOM Report, at A122. Topeka's prohibition of the sale of tobacco products to persons under 21 years of age is a science-based measure that will reduce tobacco-related disease and save lives in this community by helping to protect young people from tobacco addiction.

A. Tobacco initiation starts with young people under 21, who are particularly vulnerable to nicotine addiction.

The Ordinance's critical importance to public health in Topeka becomes clear when it is understood that, according to national data, 80% of adult smokers begin smoking by age 18 and about *95% of adult smokers begin smoking before they turn 21.* *See* IOM Report, A124. The 18-20 year-old age range is a pivotal time of transition to regular use of cigarettes. According to one national survey, the prevalence of current smoking among 18-20 year olds is more than double that of 16-17 year olds (21.2% vs. 9.2%). CTFK, *Increasing the Minimum Legal Sale Age for Tobacco Products to 21* (2018), A134. Because the brain is not fully developed until about age 25, and adolescence is a time of high sensation seeking and peer influence, adolescents and young adults are more likely to engage in risky behaviors such as smoking. *See* IOM Report, A113, A126-127, A130-132.

Adolescents are particularly vulnerable to the addictive effects of nicotine. According to the IOM Report, "the parts of the brain most responsible for decision making, impulse control, sensation seeking, . . . and peer susceptibility and conformity continue to develop and change through young adulthood," and "[a]dolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction." *Id.* at A113. As a result of nicotine addiction, about three out of four teen smokers end up smoking into adulthood, even if they intended to quit after a few years. *See* 2012 Fact Sheet, A13.

Delaying the age when young people first experiment or begin using tobacco can reduce the risk of addiction and transition to regular or daily tobacco use and increase

their chances of successfully quitting if they do become regular users. Noting that the age of initiation is critical, the IOM Report predicts that "increasing the minimum age of legal access to tobacco products will likely prevent or delay initiation of tobacco use by adolescents and young adults." *See* IOM Report, at A114.

B. Youth vulnerability to nicotine addiction and tobacco use is exacerbated by youth-targeted tobacco industry marketing.

Tobacco companies have heavily targeted young people through a variety of marketing activities – such as music and sporting events, bar promotions, college scholarships, and parties. *See United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 663-672, 691-692 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied,* 130 S.Ct. 3501 (2010), at A143-154. In 2006, after a nine-month trial involving thousands of internal tobacco industry documents, the U.S. District Court for the District of Columbia found by clear and convincing evidence "and beyond any reasonable doubt – that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying that they do so." *See id.* at A153.

In 2014, the Surgeon General found that the industry's youth marketing continued: "the root cause of the smoking epidemic is also evident: the tobacco industry aggressively markets and promotes lethal and addictive products, and continues to recruit youth and young adults as new consumers of these products." *See* 2014 SG Report, A37. Moreover, as the FDA wrote while defending its extension of regulatory jurisdiction to e-cigarettes and other tobacco products, "[e]vidence indicates that e-cigarette marketing specifically targets youth, mimicking the strategies historically used by the tobacco

industry to devastating effect." *See* Brief of Appellees, *Nicopure Labs, LLC v. FDA*, No. 17-5196, Doc. #1729233 (D.C. Cir. May 2, 2018), A167. These tactics include advertising their products during events with large youth viewership and in magazines with substantial youth readership, providing free samples at concerts, music festivals, and sporting events, and even marketing e-liquids to resemble kid-friendly products like juice boxes and candy. *Id.* at A167-168.

These marketing tactics make it all the more imperative that communities like Topeka be able to implement tools like raising the minimum age for tobacco sales to help protect their young people from being victimized by predatory industry activities.

C. The Ordinance will reduce tobacco-product availability to young people by removing 18- to 20-year olds as sources of such products.

In addition to protecting 18- to 20-year olds from the adverse health effects of tobacco products, raising the minimum age for tobacco sales will make individuals in that age group less available as supply sources for younger children, thus reducing the prevalence of tobacco use among children below the age of 18.

To the extent those below 18 are able to get access to tobacco products despite current restrictions on their legal sale, research shows that they rely on social sources such as friends and classmates. Data from the federal Population Assessment of Tobacco and Health study show that about three in four smokers aged 15-17 obtain cigarettes from social sources, including giving them money to buy cigarettes from a store or simply asking them for cigarettes. *See* Andrew Hyland, *Highlighted Findings from Wave 1 of the*

Population Assessment of Tobacco and Health (PATH) Study, Society for Research on Nicotine and Tobacco Annual Conference (Mar. 2016), A175.

Research shows that underage smokers generally turn to persons close in age to them as supply sources. A study of the sources of cigarettes for minors, based on the California Tobacco Survey, found that the majority of adolescents who smoke primarily depend on others for their cigarettes and that "[a]dolescents seemed most likely to get cigarettes from persons that were approximately their own age." *See* Martha M. White, *et al.*, *Facilitating Adolescent Smoking: Who Provides the Cigarettes?*, 19 Am. J. Health Promotion 355, 358 (2005) ("White"), A179. "In particular," according to this study, "16- to 17-year olds were more likely to obtain cigarettes from 18- to 20-year olds than were younger adolescents." *Id.* Moreover, "[t]he majority . . . of people approached by adolescents to purchase cigarettes were of legal age to do so (18+ years)." *Id.* Another study of the age groups most likely to be asked to furnish cigarettes to minors found that the subgroups "with the highest rates of being asked to provide tobacco to minors were smokers aged 18 and 19 years, smokers aged 20 to 24 years, and nonsmokers aged 18 and 19 years." *See* Kurt M. Ribisl, *et al.*, *Which Adults Do Underaged Youth Ask for Cigarettes?*, 89 Am. J. Pub. Health 1561, 1562 (Oct. 1999), A183. Older age groups were far less likely to be asked. *See id.*

Raising the tobacco sale age to 21 would significantly limit these social sources of tobacco for minors because it "would increase the age gap between adolescents taking up smoking and those who can legally provide them with cigarettes." *See* White, at A180. For example, it would limit tobacco availability in high schools, where 15- to 17-year

olds may have school or social connections to 18- and 19-year olds who can legally buy cigarettes. With the minimum legal sale age set at 21, legal purchasers would be less likely to be in the same social networks as high school students and therefore less able to sell or give them cigarettes. In turn, the supply of cigarettes to younger teens would be diminished as well because their older teen suppliers would have reduced access to tobacco products. The IOM Report anticipated that the greatest impact of raising the legal age to 21 would be on social sources for adolescents between 15-17 years of age. *See* IOM Report, at A116. That is the age group where adolescents are at greatest risk of becoming established smokers. *See* White, at A180.

Thus, the Ordinance here can be expected to reduce the supply of tobacco products from social sources to the adolescent population in Topeka.

D. Raising the tobacco sale minimum age to 21 will reduce the prevalence of tobacco-related disease and death in Topeka.

Reviewing the existing scientific literature and predictive modeling, the Institute of Medicine concluded that raising the minimum age for tobacco sales:

- will likely lead to substantial reductions in smoking prevalence;
- will likely lead to substantial reductions in smoking-related mortality;
- will likely reduce the number of adolescents with smoking-caused diminished health status; and
- will likely improve maternal, fetal and infant outcomes by reducing the likelihood of maternal and paternal smoking. *See* IOM Report, at A117-119.

The IOM Report found that raising the minimum age for tobacco products to 21 on a national scale will, over time, reduce the overall smoking rate by about 12% and smoking-related deaths by 10%, which translates into 249,000 fewer premature deaths and 4.2 million fewer years of life lost. *Id.* at A118-119.

Therefore, the Ordinance, by reducing access of young people to tobacco products, can be expected to lower the prevalence of tobacco use in Topeka, reduce the risk of tobacco-related disease, and save lives in the community. By any measure, the Ordinance represents a valid exercise of Topeka's police power to protect community health and welfare.

CONCLUSION

The Ordinance is a science-based law that will reduce the prevalence of youth usage of tobacco products in the Topeka community and prevent countless local residents from the debilitating and often fatal effects of tobacco-related disease. Compelling public health reasons thus support the authority of local Kansas communities like Topeka to enact and implement such life-saving measures.

Dated: September 12, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 12th day of September, 2018, the above and foregoing Brief of *Amici Curiae* and its attached Appendix were electronically filed with the Supreme Court of the State of Kansas through its electronic filing system, which will generate a notice constituting service thereof on the following:

Kansas Attorney General 120 SW 10th Ave., Second Floor Topeka, KS 66612-1597 *Attorney for* Amicus Curiae *The State of Kansas*	Robert E. Duncan, II 212 SW 8th Ave., Suite 202 Topeka, KS 66603 *Attorney for Appellee Dwagfys Mfg., Inc.*
W. Robert Alderson Alderson Law Firm 2101 SW 21st St. P.O. Box 237 Topeka, KS 66604 *Attorney for* Amicus Curiae *Petroleum Marketers and Convenience Store Assoc.*	Mary Feighny 3540 SW Oak Parkway Topeka, KS 66614 *Attorney for Appellant City of Topeka, KS*
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APPENDIX INDEX

Governing Body Minutes – November 21, 2017

CITY COUNCIL CHAMBERS, Topeka, Kansas, Tuesday, November 21, 2017. The Governing Body members of the City of Topeka met in regular session at 6:00 P.M., with the following Councilmembers present: Hiller, Clear, Ortiz, Emerson, De La Isla, Jensen, Schwartz, Coen and Harmon -9. Mayor Larry E. Wolgast presided -1.

AFTER THE MEETING was called to order, Councilmember Ortiz gave the invocation.

THE PLEDGE OF ALLEGIANCE was recited by those present in the chamber.

A PRESENTATION on the 2017 Visit Topeka Inc., Annual Report was presented by Brett Oetting, Visit Topeka Inc., Chief Executive Officer.

Councilmember Schwartz asked Mr. Oetting to provide Quarterly Reports to the Governing Body in 2018.

Councilmember Coen questioned if the closing of the Ramada Inn West hotel would have an effect on the number of occupancy taxes generated and how the creation of the Greater Topeka Partnership (GTP) would work in regards to planning community events.

Brett Oetting reported they do not anticipate the closing of the Ramada Inn West hotel to have an effect on occupancy numbers in the City; however, they do anticipate the numbers to increase in 2018 with the opening of other hotels. He noted the combined efforts of the many organizations that makeup GTP has been going well.

BOARD APPOINTMENT recommending the appointment of Ivan Weichert to the Citizens Advisory Council for a term ending November 22, 2020, was presented.

Councilmember De La Isla moved to approve the board appointment. The motion seconded by Councilmember Hiller carried unanimously. (9-0-0)

THE CONSENT AGENDA was presented as follows:

Councilmember De La Isla asked if all agencies had the opportunity to apply for funding.

Max Wilson stated all organizations were given the same opportunity to apply for the funds; however, the organizations that received the highest score are being recommended for funding.

Georgianna Wong and Kinsley Searles, Topeka Youth Project, spoke in opposition of the major funding cuts to the Topeka Youth Project program and asked the Governing Body to reconsider the allocation of funds for the program.

DISCUSSION concerning a local amendment to the Uniform Public Offense Code concerning the sale or furnishing of cigarettes, electronic cigarettes, tobacco products and liquid nicotine to any person under the age of 21 was presented.

Councilmember Schwartz reported the amendment would prohibit the sale or furnishing of cigarettes and other tobacco-related products to adults between the ages of 18 and 20. She spoke about her personal health issues related to smoking and asked the Governing Body to support the proposal being presented to protect children and help prevent underage smoking.

Councilmember Jensen spoke in support of preventing children from smoking; however, he questioned if the proposal should be combined with other courses of action such as funding an educational program through taxes. He questioned what would prevent children from going out of the area to purchase the products; should the issue be part of a larger educational program; and how are similar bans working in other cities.

Tanya Dorf Brunner, Oral Health Kansas; Alice Weingartner, GraceMed Health Clinic; Tracy Russell; Missty Lechner, Heartland Health Neighborhoods and United Way; Craig Barnes; Linda Ochs, Shawnee County Health Department; Kristi Pankratz, Safe Streets & Prevention Services; Mary Jayne Hellebust; Dr. Gianfranco Pezzino and Shawnee County Commissioner Bob Archer spoke in support of the "Tobacco 21" effort. They discussed the health problems and statistics

associated with the use of tobacco by people under the age of 21. They asked the Governing Body to support the proposed ordinance restricting the sale of tobacco products by those between the ages of 18 and 20 to help change the overall culture of the state.

Yasmarie Rodriguez spoke in opposition of the lack of transparency and accountability by elected government officials, Topeka Police Officers and other City officials in regards to the death of Dominique White and asked the Governing Body to change the processes in place that regulate these issues.

Spencer Duncan, Kansas Vapers Association, spoke in opposition of the age limit being presented. He stated there are laws in place to prevent under-aged children from buying tobacco as well as the proposal appears to be flawed, and in violation of State law. He asked the Governing Body to conduct an economic assessment of the law and how it relates to small business owners and taxes the City would receive from tobacco sales.

Councilmember Schwartz requested staff provide a report on the social economic impact of tobacco sales.

Councilmember Coen asked if the proposal would ban smoking or consuming tobacco products for people under 21 as well as the purchase of tobacco products.

Lisa Robertson, City Attorney, stated the proposal does not address consumption of tobacco products.

Councilmember Clear spoke in support of the proposal and stated she believes it would be a good first step towards better health.

Councilmember Jensen asked if the statement "prohibit the possession of tobacco" should be added to the proposal.

Councilmember Hiller asked what the intent of the proposal would be and when the proposal would be presented before the Governing Body for consideration.

Councilmember Ortiz questioned if the City has the authority to pass the proposal and referenced issues mentioned by Spencer Duncan. She stated she supports the proposal; however, she would like to ensure the City would be in compliance with State law.

Brent Trout, City Manager, reported the ordinance would be considered at the December 5, 2017, Governing Body meeting and staff would provide the requested information to the Governing Body as soon as possible.

DISCUSSION regarding legislative priorities identified by the Governing Body to be addressed or monitored during the 2018 Legislative Session was presented.

Whitney Damron, City Lobbyist, provided an overview of anticipated major issues in 2018 including budget/revenue and education. He also highlighted the following points of possible interest to the City of Topeka for the 2018 Legislative Session:

1. Revisit Abandoned Housing Legislation
2. Additional Funding for Mental Health Service Delivery
3. Expanding Sales Opportunities for Certain Liquor Products (6% Alcohol Content by Volume)
4. Changes to the Tax Lid Law
5. Expansion of Medicaid to Help Kansas Hospitals
6. Asset Forfeiture Laws
7. Kansas Department of Transportation (KDOT) New Transportation Plan
8. School Finance Fix
9. Halt any New STAR Bond Projects In Order To Revise the Policy

Councilmember Emerson commented on abandoned houses in the city. He asked if it was possible to streamline the process by taking small steps to expedite the ability for the City to take control of these properties.

Governing Body Minutes – December 5, 2017

CITY COUNCIL CHAMBERS, Topeka, Kansas, Tuesday, December 5, 2017. The Governing Body members of the City of Topeka met in regular session at 6:00 P.M., with the following Councilmembers present: Hiller, Clear, Ortiz, Emerson, De La Isla, Jensen, Schwartz, Coen and Harmon -9. Mayor Larry E. Wolgast presided -1.

AFTER THE MEETING was called to order, Councilmember Emerson gave the invocation.

THE PLEDGE OF ALLEGIANCE was recited by those present in the chamber.

A PRESENTATION on the Topeka Metropolitan Transit Authority (TMTA) 2017 Annual Report was provided by Susan Duffy, TMTA General Manager and Jim Ogle, Topeka Metropolitan Planning Organization (MTPO) Policy Board member.

Councilmember Jensen asked how much increase to the mill levy would be needed to provide essential services.

Jim Ogle reported approximately $4 million would be needed.

Councilmember Jensen expressed the importance of helping citizens understand what was actually needed in terms of additional tax dollars to provide essential services.

Councilmember Ortiz commended TMTA for their work and the services they provide to the community.

Nickie Lee, Administrative and Financial Services Director, reported TMTA has a unique financial structure in that it falls under the City's mill levy cap; therefore, the mill levy must be shifted or divided, increased through a public vote or propose a change in State law.

Jason Peek, Public Works Director, recognized Joe Singer, Manager of Survey and Design/Records for his 47 years of service with the City.

THE CONSENT AGENDA was presented as follows:

fundamental issues that need to be worked out as well as setting a timeline to draft a plan incorporating the recommendations for consideration of the Governing Body.

Councilmember Hiller moved to defer the Downtown Comprehensive Parking Plan for one week. The motion seconded by Councilmember Ortiz carried unanimously. (10-0-0)

ORDINANCE NO. 20099 introduced by Councilmember Elaine Schwartz, amending Section 59.05.080 of the Code of the City of Topeka, adding a local amendment to the Uniform Public Offense Code concerning the sale or furnishing of cigarettes, electronic cigarettes, tobacco products and liquid nicotine to any person under age 21 was presented.

Dr. Kim Richter, Kansas University Medical Center; Dr. Eric Voth, Stormont Vail Health Center; Ben Scott; Lauren Smith; Mia Weiler; Shawnee County Commissioner Bob Archer; Mary Jane Hellebust; Jim Barnett; Dr. Gianfranco Pezzino; Linda Ochs and Esther Lane spoke in support of the ordinance prohibiting the purchase of tobacco products to persons under the age of 21. They discussed the health impacts of smoking over time; the minimal financial impact it would have on the community; and the importance of changing the health culture across the state.

Bob Alderson, Casey's General Stores, Inc., and Tom Palace spoke on behalf of convenience stores across the state. They spoke in opposition of the ordinance and stated they believe the proposed ordinance was in direct conflict of State law and lacks personal accountability.

Councilmember Schwartz spoke in support of the ordinance. She stated a smoke-free environment provides for a much healthier approach for the community as a whole and it will have a very small financial impact on businesses.

Councilmember Jensen spoke in support of the ordinance. He stated a person's health should be considered in every aspect of government because there are many health issues that need to be

addressed. He noted this would be the first step in addressing the issue and believes education as well as other options should be reviewed and determined.

Councilmember Ortiz asked the City Attorney to provide a legal opinion on the City's authority to implement the law.

Lisa Robertson, City Attorney, stated the City has a solid legal standing to move forward with the ordinance.

Councilmember De La Isla referenced the many health issues related to smoking and the importance of making healthy decisions for the community at a municipal level by adopting laws that promote good health.

Councilmember Emerson stated he understands smoking causes many health issues; however, he believes government should not intrude on a person's personal choices.

Councilmember Coen stated he concurs with Councilmember Emerson and supports personal liberties.

Councilmember Clear spoke in support of the ordinance because it would help young adults make good decisions about their health.

Councilmember Hiller asked if there were other cities supporting this type of issue.

Councilmember Schwartz reported many cities are passing similar laws with the hope that the State will do the same, similar to the Clean Air Act. She suggested the issue be added to the City's 2018 Legislative Agenda.

Councilmember Schwartz moved to adopt the ordinance. The motion seconded by Councilmember Jensen carried. Councilmembers Emerson and Coen voted "no." (8-2-0)

The ordinance was adopted on roll call vote as follows: Ayes: Hiller, Clear, Ortiz, De La Isla, Jensen, Schwartz, Harmon and Mayor Wolgast -8. Noes: Emerson and Coen -2.

RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES

PREVALENCE ESTIMATES, STANDARD ERRORS, *P* VALUES, AND SAMPLE SIZES

Substance Abuse and Mental Health Services Administration
Center for Behavioral Health Statistics and Quality
Rockville, Maryland 20857

September 7, 2017

RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES

PREVALENCE ESTIMATES, STANDARD ERRORS, *P* VALUES, AND SAMPLE SIZES

Contract No. HHSS283201300001C
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For questions about these tables, please e-mail Peter.Tice@samhsa.hhs.gov.

Prepared for Substance Abuse and Mental Health Services Administration, Rockville, Maryland

Prepared by RTI International, Research Triangle Park, North Carolina

September 7, 2017

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Introduction

Results from the 2016 National Survey on Drug Use and Health: Detailed Tables is a collection of tables presenting national estimates from the National Survey on Drug Use and Health (NSDUH).[1] These tables present information for youths aged 12 to 17 and adults 18 or older (separately and combined) on drug, alcohol, and tobacco use, as well as substance use disorder (SUD) (also referred to as dependence or abuse), risk and availability of substance use, treatment, health topics, and alcohol consumption.[2] For youths, additional topics include youth experiences and measures on mental health service utilization, major depressive episode (MDE), and treatment for depression (among youths with MDE). For adults, additional topics include measures on any mental illness (AMI), serious mental illness (SMI), AMI excluding SMI, mental health service utilization (i.e., treatment or counseling for mental health issues), suicidal thoughts and behaviors, MDE, treatment for depression (among adults with MDE), and serious psychological distress (SPD). Measures such as the co-occurrence of mental disorders with substance use or with SUDs also are presented for both adults and youths. Measures of these behaviors and characteristics are presented by a variety of demographic, geographic, and other variables. The estimates in the tables include prevalence rates of the behaviors, numbers of persons engaging in these behaviors, and other measures. A small number of measures are no longer comparable with measures from previous years, but the 2-year trend table format was retained in the detailed tables in order to help illustrate this lack of comparability.

A summary report, *2016 National Survey on Drug Use and Health: Methodological Summary and Definitions*, accompanies these detailed tables.[3] In that report, information on key definitions (i.e., see the glossary in its Section D) can be found for many of the measures and terms used in these detailed tables and in other 2016 NSDUH documents, along with further analytic details on these measures (see its Section B in particular) and the survey. Where relevant, the glossary provides cross-references between terms and specific question wording for clarity.

In addition to these detailed tables, three first findings reports (FFRs) from the 2016 NSDUH that are focused on key substance use and mental health indicators, receipt of services for substance use and mental health issues among adults, and risk and protective factors and initiation of substance use are scheduled to be made available online in September 2017 at https://www.samhsa.gov/data/.

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[1] Starting with the 2015 NSDUH, the detailed tables are a combination of the prior detailed tables and the mental health detailed tables. For information on mapping current sections back to pre-2015 sections, refer to the Table Numbering Section of the 2016 detailed tables' introduction at https://www.samhsa.gov/data/.

[2] Starting with the 2016 NSDUH, the detailed tables include measures for past year and past month misuse of opioids (heroin use or pain reliever misuse) and opioid use disorder. For more information on potential measurement issues for pain relievers, see Sections B.4.1 and B.4.2 in Section B of the following reference: Center for Behavioral Health Statistics and Quality. (2017). *2016 National Survey on Drug Use and Health: Methodological summary and definitions.* Retrieved from https://www.samhsa.gov/data/

[3] See the reference in footnote 2.

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Table 4.10A Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, by Gender: Numbers in Thousands, 2015 and 2016

Substance	Total (2015)	Total (2016)	Male (2015)	Male (2016)	Female (2015)	Female (2016)
ILLICIT DRUGS[1]	nr	nr	nr	nr	nr	nr
Marijuana	1,304	1,320	598	595	706	725
Cocaine	161	147	93	70	68	77
Crack	0	6	0	*	*	6
Heroin	12	8	7	4	*	*
Hallucinogens	420	376	244	229	176	148
LSD	243	212	130	134	113	79
PCP	37	16	21	5	16	10
Ecstasy	216	177	129	103	86	74
Inhalants	364[a]	287	144	129	220[a]	158
Methamphetamine	31	16	17	7	14	10
Misuse of Psychotherapeutics[2,3]	nr	nr	nr	nr	nr	nr
Pain Relievers[3]	477	480	244	235	234	245
Tranquilizers	255	304	*	*	*	154
Stimulants	315	304	*	*	164	*
Sedatives	*	*	*	*	*	*
CIGARETTES	907	843	409	451	498[a]	391
Daily Cigarette Use[4]	153	138	78	81	75	57
SMOKELESS TOBACCO[5]	480	402	352	279	127	123
CIGARS	783	687	477	457	307[a]	230
ALCOHOL	2,621	2,583	1,269	1,136	1,352	1,447

* = low precision; -- = not available; da = does not apply; nc = not comparable due to methodological changes; nr = not reported due to measurement issues.

NOTE: Past Year Initiates for a specific substance include those who used that substance (misused in the case of prescription psychotherapeutics) for the first time in the past year. Methodological limitations preclude the estimation of past year initiates for the overall prescription psychotherapeutics category and consequently the overall illicit drugs category.

NOTE: Misuse of prescription psychotherapeutics is defined as use in any way not directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or longer than told; or use in any other way not directed by a doctor. Prescription psychotherapeutics do not include over-the-counter drugs.

[a] The difference between this estimate and the 2016 estimate is statistically significant at the .05 level. Rounding may make the estimates appear identical.

[b] The difference between this estimate and the 2016 estimate is statistically significant at the .01 level. Rounding may make the estimates appear identical.

[1] Illicit Drug Use includes the misuse of prescription psychotherapeutics or the use of marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, or methamphetamine.

[2] Prescription Psychotherapeutics include pain relievers, tranquilizers, stimulants, or sedatives and do not include over-the-counter drugs.

[3] Prescription psychotherapeutic subtypes were revised in 2016; one effect was the comparability of codeine products between 2015 and 2016.

[4] Daily Cigarette Use is defined as ever smoking every day for at least 30 days.

[5] Smokeless Tobacco includes snuff, dip, chewing tobacco, or "snus."

Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2015 and 2016.

U.S. Department of Health & Human Services www.hhs.gov

SURGEON GENERAL

Preventing Tobacco Use Among Youth and Young Adults

Fact Sheet

This is the 31st tobacco-related Surgeon General's report issued since 1964. It describes the epidemic of tobacco use among youth ages 12 through 17 and young adults ages 18 through 25, including the epidemiology, causes, and health effects of this tobacco use and interventions proven to prevent it. Scientific evidence contained in this report supports the following facts:

We have made progress in reducing tobacco use among youth; however, far too many young people are still using tobacco. Today, more than 600,000 middle school students and 3 million high school students smoke cigarettes. Rates of decline for cigarette smoking have slowed in the last decade and rates of decline for smokeless tobacco use have stalled completely.

- Every day, more than 1,200 people in this country die due to smoking. For each of those deaths, at least two youth or young adults become regular smokers each day. Almost 90% of those replacement smokers smoke their first cigarette by age 18.
- There could be 3 million fewer young smokers today if success in reducing youth tobacco use that was made between 1997 and 2003 had been sustained.
- Rates of smokeless tobacco use are no longer declining, and they appear to be increasing among some groups.
- Cigars, especially cigarette-sized cigars, are popular with youth. One out of five high school males smokes cigars, and cigar use appears to be increasing among other groups.
- Use of multiple tobacco products—including cigarettes, cigars, and smokeless tobacco—is common among young people.
- Prevention efforts must focus on young adults ages 18 through 25, too. Almost no one starts smoking after age 25. Nearly 9 out of 10 smokers started smoking by age 18, and 99% started by age 26. Progression from occasional to daily smoking almost always occurs by age 26.

Tobacco use by youth and young adults causes both immediate and long-term damage. One of the most serious health effects is nicotine addiction, which prolongs tobacco use and can lead to severe health consequences. The younger youth are when they start using tobacco, the more likely they'll be addicted.

- Early cardiovascular damage is seen in most young smokers; those most sensitive die very young.
- Smoking reduces lung function and retards lung growth. Teens who smoke are not only short of breath today, they may end up as adults with lungs that will never grow to full capacity. Such damage is permanent and increases the risk of chronic obstructive pulmonary disease.
- Youth are sensitive to nicotine and can feel dependent earlier than adults. Because of nicotine addiction, about three out of four teen smokers end up smoking into adulthood, even if they intend to quit after a few years.
- Among youth who persist in smoking, a third will die prematurely from smoking.

Youth are vulnerable to social and environmental influences to use tobacco; messages and images that make tobacco use appealing to them are everywhere.

- Young people want to fit in with their peers. Images in tobacco marketing make tobacco use look appealing to this age group.
- Youth and young adults see smoking in their social circles, movies they watch, video games they play, websites they visit, and many communities where they live. Smoking is often portrayed as a social norm, and young people exposed to these images are more likely to smoke.
- Youth identify with peers they see as social leaders and may imitate their behavior; those whose friends or siblings smoke are more likely to smoke.
- Youth who are exposed to images of smoking in movies are more likely to smoke. Those who get the most exposure to onscreen smoking are about twice as likely to begin smoking as those who get the least exposure. Images of smoking in movies have declined over the past decade; however, in 2010 nearly a third of top-grossing movies produced for children—those with ratings of G, PG, or PG-13— contained images of smoking.

Tobacco companies spend more than a million dollars an hour in this country alone to market their products. This report concludes that tobacco product advertising and promotions still entice far too many young people to start using tobacco.

- The tobacco industry has stated that its marketing only promotes brand choices among adult smokers. Regardless of intent, this marketing encourages underage youth to smoke. Nearly 9 out of 10 smokers start smoking by age 18, and more than 80% of underage smokers choose brands from among the top three most heavily advertised.
- The more young people are exposed to cigarette advertising and promotional activities, the more likely they are to smoke.
- The report finds that extensive use of price-reducing promotions has led to higher rates of tobacco use among young people than would have occurred in the absence of these promotions.

- Many tobacco products on the market appeal to youth. Some cigarette-sized cigars contain candy and fruit flavoring, such as strawberry and grape.
- Many of the newest smokeless tobacco products do not require users to spit, and others dissolve like mints; these products include snus—a spitless, dry snuff packaged in a small teabag-like sachet—and dissolvable strips and lozenges. Young people find these products appealing in part because they can be used without detection at school or other places where smoking is banned. However, these products cause and sustain nicotine addiction, and most youth who use them also smoke cigarettes.
- Through the use of advertising and promotional activities, packaging, and product design, the tobacco industry encourages the myth that smoking makes you thin. This message is especially appealing to young girls. It is not true—teen smokers are not thinner than nonsmokers.

Comprehensive, sustained, multi-component programs can cut youth tobacco use in half in 6 years.

- Prevention is critical. Successful multi-component programs prevent young people from starting to use tobacco in the first place and more than pay for themselves in lives and health care dollars saved.
- Strategies that comprise successful comprehensive tobacco control programs include mass media campaigns, higher tobacco prices, smoke-free laws and policies, evidence-based school programs, and sustained community-wide efforts.
- Comprehensive tobacco control programs are most effective when funding for them is sustained at levels recommended by the Centers for Disease Control and Prevention.

Was this page helpful?

- ○ Yes
- ○ No

Next

Form Approved OMB# 0920-0379 Exp. Date 9/30/2020

The Health Consequences of Smoking—50 Years of Progress

A Report of the Surgeon General

Executive Summary

2014

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Office of the Surgeon General
Rockville, MD

Suggested Citation

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For more information

For more information about the Surgeon General's report, visit www.surgeongeneral.gov.

To download copies of this document, go to www.cdc.gov/tobacco.

To order copies of this document, go to www.cdc.gov/tobacco and click on Publications Catalog or call 1-800-CDC-INFO (1-800-232-4636); TTY: 1-888-232-6348.

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Overview

For the United States, the epidemic of smoking-caused disease in the twentieth century ranks among the greatest public health catastrophes of the century, while the decline of smoking consequent to tobacco control is surely one of public health's greatest successes. However, the current rate of progress in tobacco control is not fast enough, and much more needs to be done to end the tobacco epidemic. Unacceptably high levels of smoking-attributable disease and death, and the associated costs, will persist for decades without changes in our approach to slowing and even ending the epidemic. If smoking persists at the current rate among young adults in this country, 5.6 million of today's Americans younger than 18 years of age are projected to die prematurely from a smoking-related illness (Chapter 12).

More than 20 million Americans have died as a result of smoking since the first Surgeon General's report on smoking and health was released in 1964 (Table 1) (Chapter 12). Most were adults with a history of smoking, but nearly 2.5 million were nonsmokers who died from heart disease or lung cancer caused by exposure to secondhand smoke. Another 100,000 were babies who died of sudden infant death syndrome (often referred to as SIDS) or complications from prematurity, low birth weight, or other conditions caused by parental smoking, particularly smoking by the mother.

Table 1 Premature deaths caused by smoking and exposure to secondhand smoke, 1965–2014

Cause of death	Total
Smoking-related cancers	6,587,000
Cardiovascular and metabolic diseases	7,787,000
Pulmonary diseases	3,804,000
Conditions related to pregnancy and birth	108,000
Residential fires	86,000
Lung cancers caused by exposure to secondhand smoke	263,000
Coronary heart disease caused by exposure to secondhand smoke	2,194,000
Total	20,830,000

Source: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, unpublished data.

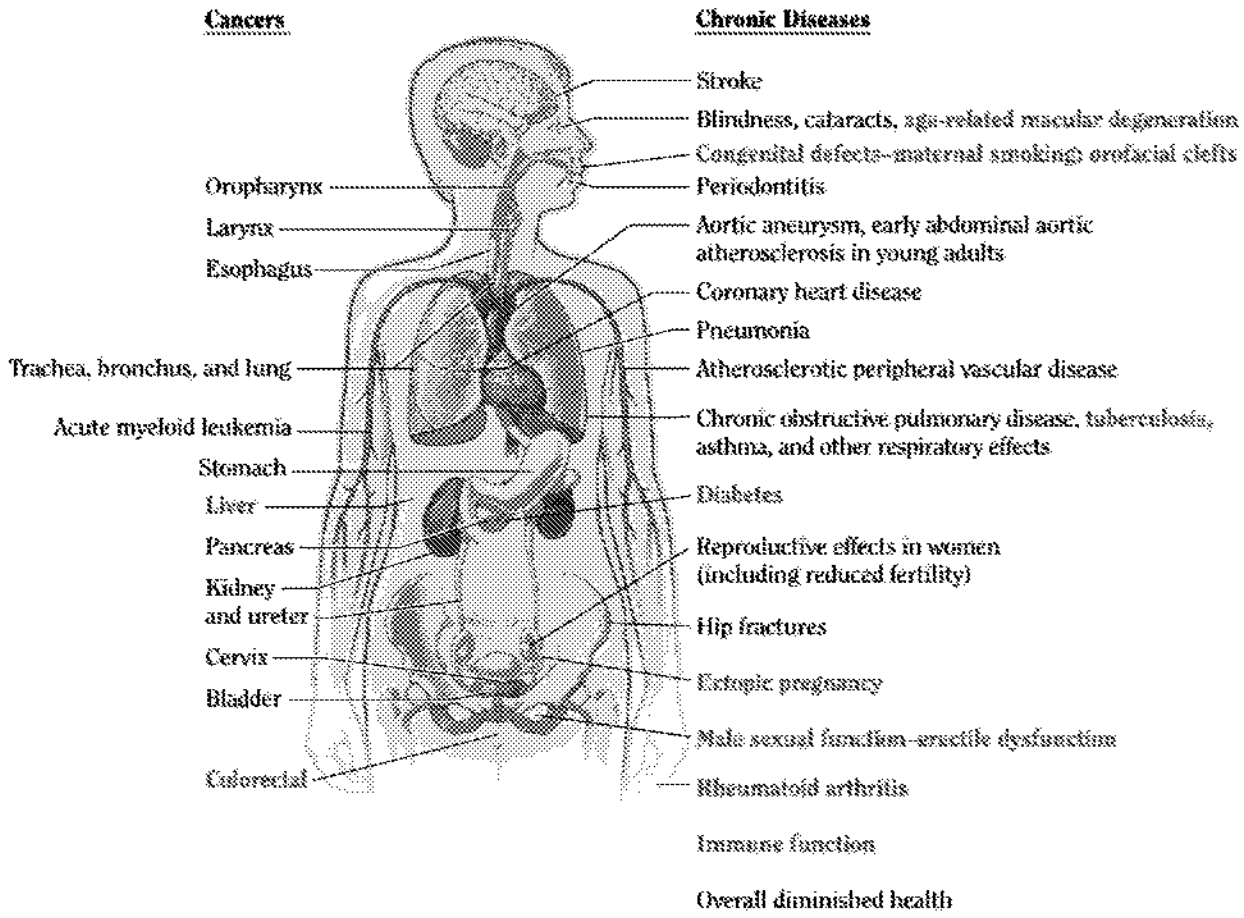
As these figures illustrate, the harms caused by the historic patterns of tobacco use in the United States, and especially by cigarette smoking, are staggering. More than 10 times as many U.S. citizens have died prematurely from cigarette smoking than have died in all the wars fought by the United States during its history. Study after study has confirmed the magnitude of the harm caused to the human body by exposure to toxicants and carcinogens found in tobacco smoke. Since 1964, the 31 previous Surgeon General's reports have chronicled a still growing but already conclusive body of evidence about the adverse impact of tobacco use on human cells and organs and on overall health. Health statistics show that all populations are affected.

Previous Surgeon General's reports have tracked the evolution of cigarettes into the current highly engineered, addictive, and deadly products containing thousands of chemicals that are harmful in themselves, but the burning of tobacco produces the complex chemical mixture of more than 7,000 compounds that cause a wide range of diseases and premature deaths as a result (U.S. Department of Health and Human Services [USDHHS] 2010). Although the prevalence of smoking has declined significantly over the past one-half century, the risks for smoking-related disease and mortality have not. In fact, today's cigarette smokers—both men and women—have a much higher risk for lung cancer and chronic obstructive pulmonary disease (COPD) than smokers in 1964, despite smoking fewer cigarettes (see Chapters 6, 7, and 11, and Figure 12.2 and Figure 13.16).

The 2004 Surgeon General's report showed that smoking impacts nearly every organ of the body (USDHHS 2004). The 2006 report concluded that the scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke (USDHHS 2006). The new evidence in this report provides still more support for these conclusions. Fifty years after the first report in 1964, it is striking that the scientific evidence in this report expands the list of diseases and other adverse health effects caused by smoking and exposure of nonsmokers to tobacco smoke. Figures 1.1A and 1.1B highlight these new findings and show that the disease risks are even greater than presented in previous reports. These new findings include:

- Liver cancer and colorectal cancer are added to the long list of cancers caused by smoking;

Figure 1A The health consequences causally linked to smoking



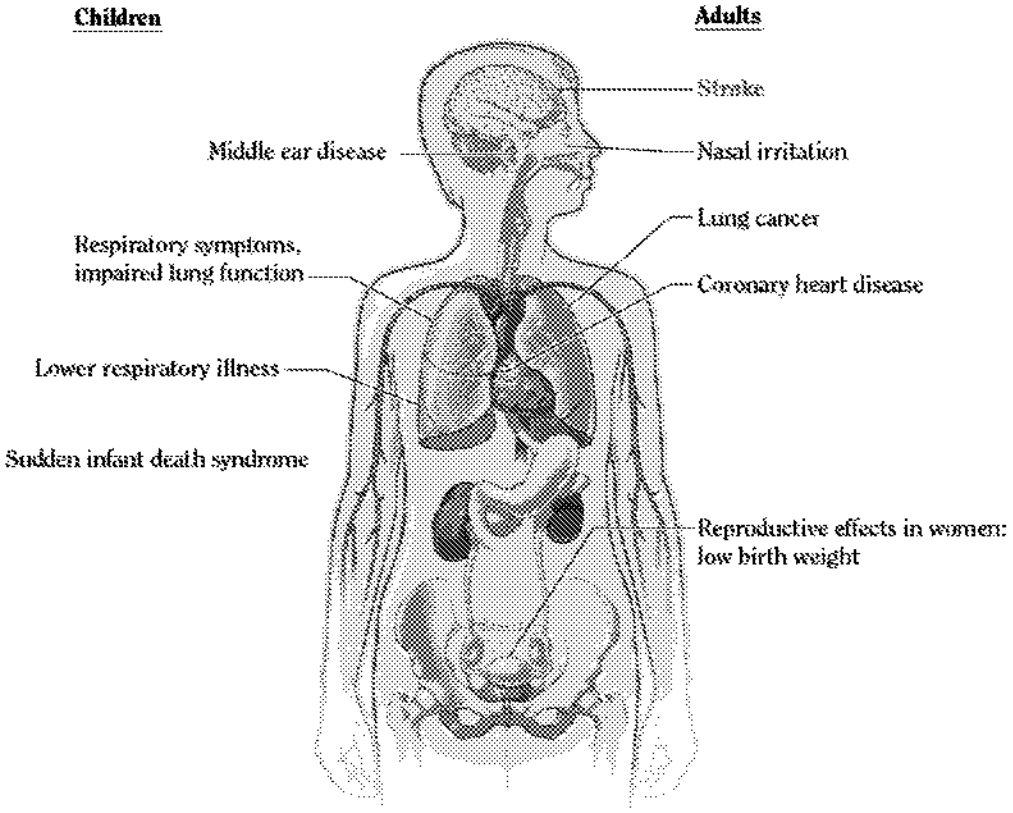
Source: USDHHS 2004, 2006, 2012.
Note: The condition in red is a new disease that has been causally linked to smoking in this report.

- Exposure to secondhand smoke is a cause of stroke;
- Smoking increases the risk of dying from cancer and other diseases in cancer patients and survivors;
- Smoking is a cause of diabetes mellitus; and
- Smoking causes general adverse effects on the body including inflammation and it impairs immune function. Smoking is a cause of rheumatoid arthritis.

Progress has been made in tobacco control. During the 50 years since the 1964 report, approaches have moved from single measures, such as small text-only pack warnings, to implementing comprehensive control programs, including indoor smoking bans, support for cessation, restrictions on advertising and promotion, media campaigns, and tax hikes to raise prices (Chapters 2 and 14). Smoking rates have declined, as have mortality rates for some diseases caused by smoking, such as heart disease and lung cancer for which smoking is the major cause.

Nonetheless, between 2005–2009, smoking was responsible for more than 480,000 premature deaths annually among Americans 35 years of age and older (Chapter 12). More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease were attributable to smoking and exposure to secondhand smoke. Additionally, if current trends continue 5.6 million U.S. youth who are currently younger than 18 years of age will die prematurely during adulthood from their smoking (Chapter 12).

Figure 1B The health consequences causally linked to exposure to secondhand smoke



Source: USDHHS 2004, 2006.
Note: The condition in red is a new disease that has been causally linked to smoking in this report.

Many of the findings in this report have particular relevance to women who are current smokers. For the first time ever, they are as likely as men to die from many diseases caused by smoking (Chapter 12). The relative risk for dying from coronary heart disease among women 35 years of age and older is now higher than for men. Because the risks for women have increased so much in the last decades, women who smoke now have about the same high risk of death from lung cancer as men.

In addition to the impact that smoking has on health and well-being, the nation pays enormous financial costs because of smoking. Productivity losses from premature death alone now exceed $150 billion per year (Chapter 12). Additionally, the value of lost productivity due to premature deaths caused by exposure to secondhand smoke is now estimated to be $5.6 billion per year. The annual costs of direct medical care of adults attributable to smoking are now estimated to be over $130 billion (Chapter 12).

This comprehensive report chronicles the devastating consequences of 50 years of tobacco use in the United States. It updates data on the numerous health effects resulting from smoking and exposure to secondhand smoke, and details public health trends, both favorable and unfavorable, in tobacco use. This report marks the steady progress achieved in reducing the prevalence of smoking and validates tobacco control strategies that have consistently proven to be effective. It also examines strategies with the potential to eradicate the death and disease caused by the tobacco epidemic at long last, and identifies specific measures that should be taken immediately to move smoking off its decades-old number one spot as the largest single cause of preventable death and disease for the citizens of the United States. Finally, the report documents that effective interventions are available and calls for their full implementation.

The Health Consequences of Smoking—50 Years of Progress

A Report of the Surgeon General

2014

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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

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Scientific Basis of the Report

The statements and conclusions throughout this report are documented by the citation of studies published in the scientific literature. For the most part, this report cites peer-reviewed journal articles, including reviews that integrate findings from numerous studies, and books by recognized experts. When a study has been accepted for publication, but the publication has not yet been issued, owing to the delay between acceptance and final publication, the study is referred to as "in press." This report also refers, on occasion, to unpublished research such as a presentation at a professional meeting or a personal communication from the researcher. These personal references are to acknowledge experts whose research is in progress.

Major Conclusions from the Report

1. The century-long epidemic of cigarette smoking has caused an enormous avoidable public health tragedy. Since the first Surgeon General's report in 1964 more than 20 million premature deaths can be attributed to cigarette smoking.

2. 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.

3. Since the 1964 Surgeon General's report, cigarette smoking has been causally linked to diseases of nearly all organs of the body, to diminished health status, and to harm to the fetus. Even 50 years after the first Surgeon General's report, research continues to newly identify diseases caused by smoking, including such common diseases as diabetes mellitus, rheumatoid arthritis, and colorectal cancer.

4. Exposure to secondhand tobacco smoke has been causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children.

5. The disease risks from smoking by women have risen sharply over the last 50 years and are now equal to those for men for lung cancer, chronic obstructive pulmonary disease, and cardiovascular diseases.

6. In addition to causing multiple diseases, cigarette smoking has many other adverse effects on the body, such as causing inflammation and impairing immune function.

7. Although cigarette smoking has declined significantly since 1964, very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country.

8. Since the 1964 Surgeon General's report, 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.

9. The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.

10. For 50 years the Surgeon General's reports on smoking and health have provided a critical scientific foundation for public health action directed at reducing tobacco use and preventing tobacco-related disease and premature death.

Chapter Conclusions

Note: Chapters 2-4 do not have conclusions.

Chapter 5: Nicotine

1. The evidence is sufficient to infer that at high-enough doses nicotine has acute toxicity.

2. The evidence is sufficient to infer that nicotine activates multiple biological pathways through which smoking increases risk for disease.

3. The evidence is sufficient to infer that nicotine exposure during fetal development, a critical window for brain development, has lasting adverse consequences for brain development.

4. The evidence is sufficient to infer that nicotine adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth.

5. The evidence is suggestive that nicotine exposure during adolescence, a critical window for brain development, may have lasting adverse consequences for brain development.

6. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to nicotine and risk for cancer.

Chapter 6: Cancer

Lung Cancer

1. The evidence is sufficient to conclude that the risk of developing adenocarcinoma of the lung from cigarette smoking has increased since the 1960s.

2. The evidence is sufficient to conclude that the increased risk of adenocarcinoma of the lung in smokers results from changes in the design and composition of cigarettes since the 1950s.

3. The evidence is not sufficient to specify which design changes are responsible for the increased risk of adenocarcinoma, but there is suggestive evidence that ventilated filters and increased levels of tobacco-specific nitrosamines have played a role.

4. The evidence shows that the decline of squamous cell carcinoma follows the trend of declining smoking prevalence.

Liver Cancer

1. The evidence is sufficient to infer a causal relationship between smoking and hepatocellular carcinoma.

Colorectal Cancer

1. The evidence is sufficient to infer a causal relationship between smoking and colorectal adenomatous polyps and colorectal cancer.

Prostate Cancer

1. The evidence is suggestive of no causal relationship between smoking and the risk of incident prostate cancer.

2. The evidence is suggestive of a higher risk of death from prostate cancer in smokers than in nonsmokers.

3. In men who have prostate cancer, the evidence is suggestive of a higher risk of advanced-stage disease and less-well-differentiated cancer in smokers than in nonsmokers, and—independent of stage and histologic grade—a higher risk of disease progression.

Breast Cancer

1. The evidence is sufficient to identify mechanisms by which cigarette smoking may cause breast cancer.

2. The evidence is suggestive but not sufficient to infer a causal relationship between tobacco smoke and breast cancer.

3. The evidence is suggestive but not sufficient to infer a causal relationship between active smoking and breast cancer.

4. The evidence is suggestive but not sufficient to infer a causal relationship between exposure to secondhand tobacco smoke and breast cancer.

Adverse Health Outcomes in Cancer Patients and Survivors

1. In cancer patients and survivors, the evidence is sufficient to infer a causal relationship between cigarette smoking and adverse health outcomes. Quitting smoking improves the prognosis of cancer patients.

2. In cancer patients and survivors, the evidence is sufficient to infer a causal relationship between cigarette smoking and increased all-cause mortality and cancer-specific mortality.

3. In cancer patients and survivors, the evidence is sufficient to infer a causal relationship between cigarette smoking and increased risk for second primary cancers known to be caused by cigarette smoking, such as lung cancer.

4. In cancer patients and survivors, the evidence is suggestive but not sufficient to infer a causal relationship between cigarette smoking and (1) the risk of recurrence, (2) poorer response to treatment, and (3) increased treatment-related toxicity.

Chapter 7: Respiratory Diseases

Chronic Obstructive Pulmonary Disease

1. The evidence is sufficient to infer that smoking is the dominant cause of chronic obstructive pulmonary disease (COPD) in men and women in the United States. Smoking causes all elements of the COPD phenotype, including emphysema and damage to the airways of the lung.

2. Chronic obstructive pulmonary disease (COPD) mortality has increased dramatically in men and women since the 1964 Surgeon General's report. The number of women dying from COPD now surpasses the number of men.

3. The evidence is suggestive but not sufficient to infer that women are more susceptible to develop severe chronic obstructive pulmonary disease at younger ages.

4. The evidence is sufficient to infer that severe α1-antitrypsin deficiency and cutis laxa are genetic causes of chronic obstructive pulmonary disease.

Asthma

1. The evidence is suggestive but not sufficient to infer a causal relationship between active smoking and the incidence of asthma in adolescents.

2. The evidence is suggestive but not sufficient to infer a causal relationship between active smoking and exacerbation of asthma among children and adolescents.

3. The evidence is suggestive but not sufficient to infer a causal relationship between active smoking and the incidence of asthma in adults.

4. The evidence is sufficient to infer a causal relationship between active smoking and exacerbation of asthma in adults.

Tuberculosis

1. The evidence is sufficient to infer a causal relationship between smoking and an increased risk of *Mycobacterium tuberculosis* disease.

2. The evidence is sufficient to infer a causal relationship between smoking and mortality due to tuberculosis.

3. The evidence is suggestive of a causal relationship between smoking and the risk of recurrent tuberculosis disease.

4. The evidence is inadequate to infer the presence or absence of a causal relationship between active smoking and the risk of tuberculosis infection.

5. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and the risk of tuberculosis infection.

6. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to secondhand smoke and the risk of tuberculosis disease.

Idiopathic Pulmonary Fibrosis

1. The evidence is suggestive but not sufficient to infer a causal relationship between cigarette smoking and idiopathic pulmonary fibrosis.

Chapter 8: Cardiovascular Disease

1. The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risk of stroke.

2. The estimated increase in risk for stroke from exposure to secondhand smoke is about 20-30%.

3. The evidence is sufficient to infer a causal relationship between the implementation of a smokefree law or policy and a reduction in coronary events among people younger than 65 years of age.

4. The evidence is suggestive but not sufficient to infer a causal relationship between the implementation of a smokefree law or policy and a reduction in cerebrovascular events.

5. The evidence is suggestive but not sufficient to infer a causal relationship between the implementation of a smokefree law or policy and a reduction in other heart disease outcomes, including angina and out-of-hospital sudden coronary death.

Chapter 9: Reproductive Outcomes

Congenital Malformations

1. The evidence is sufficient to infer a causal relationship between maternal smoking in early pregnancy and orofacial clefts.

2. The evidence is suggestive but not sufficient to infer a causal relationship between maternal smoking in early pregnancy and clubfoot, gastroschisis, and atrial septal heart defects.

Neurobehavioral Disorders of Childhood

1. The evidence is suggestive but not sufficient to infer a causal relationship between maternal prenatal smoking and disruptive behavioral disorders, and attention deficit hyperactivity disorder in particular, among children.

2. The evidence is insufficient to infer the presence or absence of a causal relationship between maternal prenatal smoking and anxiety and depression in children.

3. The evidence is insufficient to infer the presence or absence of a causal relationship between maternal prenatal smoking and Tourette syndrome.

4. The evidence is insufficient to infer the presence or absence of a causal relationship between maternal prenatal smoking and schizophrenia in her offspring.

5. The evidence is insufficient to infer the presence or absence of a causal relationship between maternal prenatal smoking and intellectual disability.

Ectopic Pregnancy

1. The evidence is sufficient to infer a causal relationship between maternal active smoking and ectopic pregnancy.

Spontaneous Abortion

1. The evidence is suggestive but not sufficient to infer a causal relationship between maternal active smoking and spontaneous abortion.

Male Sexual Function

1. The evidence is sufficient to infer a causal relationship between smoking and erectile dysfunction.

Chapter 10: Other Specific Outcomes

Eye Disease: Age-Related Macular Degeneration

1. The evidence is sufficient to infer a causal relationship between cigarette smoking and neovascular and atrophic forms of age-related macular degeneration.

2. The evidence is suggestive but not sufficient to infer that smoking cessation reduces the risk of advanced age-related macular degeneration.

Dental Disease

1. The evidence is suggestive but not sufficient to infer a causal relationship between active cigarette smoking and dental caries.

2. The evidence is suggestive but not sufficient to infer a causal relationship between exposure to tobacco smoke and dental caries in children.

3. The evidence is suggestive but not sufficient to infer a causal relationship between cigarette smoking and failure of dental implants.

Diabetes

1. The evidence is sufficient to infer that cigarette smoking is a cause of diabetes.

2. The risk of developing diabetes is 30–40% higher for active smokers than nonsmokers.

3. There is a positive dose-response relationship between the number of cigarettes smoked and the risk of developing diabetes.

Immune Function and Autoimmune Disease

1. The evidence is sufficient to infer that components of cigarette smoke impact components of the immune system. Some of these effects are immune activating and others are immune-suppressive.

2. The evidence is sufficient to infer that cigarette smoking compromises the immune system and that altered immunity is associated with increased risk for pulmonary infections.

3. The evidence is sufficient to infer that cigarette smoke compromises immune homeostasis and that altered immunity is associated with an increased risk for several disorders with an underlying immune diathesis.

Rheumatoid Arthritis

1. The evidence is sufficient to infer a causal relationship between cigarette smoking and rheumatoid arthritis.

2. The evidence is sufficient to infer that cigarette smoking reduces the effectiveness of the tumor necrosis factor-alpha (TNF-α) inhibitors.

Systemic Lupus Erythematosus

1. The evidence is inadequate to infer the presence or absence of a causal relationship between cigarette smoking and systemic lupus erythematosus (SLE), the severity of SLE, or the response to therapy for SLE.

Inflammatory Bowel Disease

1. The evidence is suggestive but not sufficient to infer a causal relationship between cigarette smoking and Crohn's disease.

2. The evidence is suggestive but not sufficient to infer a causal relationship between cigarette smoking and a protective effect for ulcerative colitis.

Chapter 11: General Morbidity and All-Cause Mortality

1. The evidence is sufficient to infer a causal relationship between smoking and diminished overall health. Manifestations of diminished overall health among smokers include self-reported poor health, increased absenteeism from work, and increased health care utilization and cost.

2. The evidence is sufficient to infer that cigarette smoking increases risk for all-cause mortality in men and women.

3. The evidence is sufficient to infer that the relative risk of dying from cigarette smoking has increased over the last 50 years in men and women in the United States.

Chapter 12: Smoking-Attributable Morbidity, Mortality, and Economic Costs

1. Since the first Surgeon General's report on smoking and health in 1964, there have been more than 20 million premature deaths attributable to smoking and exposure to secondhand smoke. Smoking remains the leading preventable cause of premature death in the United States.

2. Despite declines in the prevalence of current smoking, the annual burden of smoking-attributable mortality in the United States has remained above 400,000 for more than a decade and currently is estimated to be about 480,000, with millions more living with smoking-related diseases.

3. Due to the slow decline in the prevalence of current smoking, the annual burden of smoking-attributable mortality can be expected to remain at high levels for decades into the future, with 5.6 million youth currently 0 to 17 years of age projected to die prematurely from a smoking-related illness.

4. Annual smoking-attributable economic costs in the United States estimated for the years 2009–2012 were between $289–332.5 billion, including $132.5–175.9 billion for direct medical care of adults, $151 billion for lost productivity due to premature death estimated from 2005–2009, and $5.6 billion (in 2006) for lost productivity due to exposure to secondhand smoke.

Chapter 13: Patterns of Tobacco Use Among U.S. Youth, Young Adults, and Adults

1. In the United States, the prevalence of current cigarette smoking among adults has declined from 42% in 1965 to 18% in 2012.

2. The prevalence of current cigarette smoking declined first among men (between 1965 and the 1990s), and then among women (since the 1980s). However, declines in the prevalence of smoking among adults (18 years of age and older) have slowed in recent years.

3. Most first use of cigarettes occurs by 18 years of age (87%), with nearly all first use by 26 years of age (98%).

4. Very large disparities in tobacco use remain across racial/ethnic groups and between groups defined by educational level, socioeconomic status, and region.

5. In the United States, there are now more former smokers than there are current smokers. More than half of all ever smokers have quit smoking.

6. The rate of quitting smoking among recent birth cohorts has been increasing, and interest in quitting is high across all segments of society.

7. Patterns of tobacco use are changing, with more intermittent use of cigarettes and an increase in use of other products.

Chapter 14: Current Status of Tobacco Control

1. The evidence is sufficient to conclude that there are diverse tobacco control measures of proven efficacy at the population and individual levels.

2. The evidence is sufficient to conclude that advertising and promotional activities by the tobacco companies cause the onset and continuation of smoking among adolescents and young adults.

3. Tobacco product regulation has the potential to contribute to public health through reductions in tobacco product addictiveness and harmfulness, and by preventing false or misleading claims by the tobacco industry of reduced risk.

4. The evidence is sufficient to conclude that litigation against tobacco companies has reduced tobacco use in the United States by leading to increased product prices, restrictions on marketing methods, and making available industry documents for scientific analysis and strategic awareness.

5. The evidence is sufficient to conclude that increases in the prices of tobacco products, including those resulting from excise tax increases, prevent initiation of tobacco use, promote cessation, and reduce the prevalence and intensity of tobacco use among youth and adults.

6. The evidence is sufficient to conclude that smokefree indoor air policies are effective in reducing exposure to secondhand smoke and lead to less smoking among covered individuals.

7. The evidence is sufficient to conclude that mass media campaigns, comprehensive community programs, and comprehensive statewide tobacco control programs prevent initiation of tobacco use and reduce the prevalence of tobacco use among youth and adults.

8. The evidence is sufficient to conclude that tobacco cessation treatments are effective across a wide population of smokers, including those with significant mental and physical comorbidity.

Chapter 15: The Changing Landscape of Tobacco Control—Current Status and Future Directions

1. Together, experience since 1964 and results from models exploring future scenarios of tobacco control indicate that the decline in tobacco use over coming decades will not be sufficiently rapid to meet targets. The goal of ending the tragic burden of avoidable disease and premature death will not be met quickly enough without additional action.

2. Evidence-based tobacco control interventions that are effective continue to be underutilized and implemented at far below funding levels recommended by the Centers for Disease Control and Prevention. Implementing tobacco control policies and programs as recommended by *Ending the Tobacco Epidemic: A Tobacco Control Strategic Plan* by the U.S. Department of Health and Human Services and the *Ending the Tobacco Problem: A Blueprint for the Nation* by the Institute of Medicine on a sustained basis at high intensity would accelerate the decline of tobacco use in youth and adults, and also accelerate progress toward the goal of ending the tobacco epidemic.

3. New "end game" strategies have been proposed with the goal of eliminating tobacco smoking. Some of these strategies may prove useful for the United States, particularly reduction of the nicotine content of tobacco products and greater restrictions on sales (including bans on entire categories of tobacco products).

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Table 12.2.1 Prevalence of current smoking among adults, 18–30 years of age,[a] and projected number of persons, 0–17 years of age, who will become smokers and die prematurely as adults because of a smoking-related illness, by state—United States, 2012

State	Prevalence (%) of current smoking 18–30 years of age (± 95% CI)	Population, 0–17 years of age[b]	Projected number of smokers 0–17 years of age (± 95% CI)	Projected number of deaths 0–17 years of age
Alabama	29.9 (2.9)	1,124,406	336,200 (303,600–368,800)	108,000
Alaska	23.3 (3.1)	187,100	43,600 (37,800–49,400)	14,000
Arizona	22.2 (3.5)	1,620,894	359,800 (303,100–416,600)	115,000
Arkansas	30.2 (4.0)	710,881	214,700 (186,300–242,400)	69,000
California	14.9 (1.3)	9,240,219	1,376,800 (1,256,700–1,496,900)	441,000
Colorado	23.0 (2.0)	1,231,358	283,200 (258,600–307,800)	91,000
Connecticut	22.1 (2.8)	793,558	175,400 (153,200–197,600)	56,000
Delaware	26.2 (3.4)	205,050	53,700 (46,800–60,700)	17,000
District of Columbia	20.4 (3.7)	109,480	22,300 (18,300–26,400)	7,000
Florida	21.1 (2.6)	4,002,480	844,500 (740,500–944,600)	270,000
Georgia	25.6 (2.7)	2,490,125	637,500 (570,200–704,700)	204,000
Hawaii	22.1 (2.7)	303,011	67,000 (58,800–74,800)	21,000
Idaho	22.1 (3.5)	426,653	94,300 (79,400–108,800)	30,000
Illinois	23.5 (3.3)	3,064,065	720,100 (618,900–818,100)	230,000
Indiana	29.6 (2.5)	1,591,477	471,100 (431,300–509,300)	151,000
Iowa	23.8 (2.5)	722,953	172,100 (154,000–189,400)	55,000
Kansas	26.4 (1.7)	724,304	191,200 (178,900–204,300)	61,000
Kentucky	36.5 (2.8)	1,018,238	371,700 (343,100–401,200)	119,000

Table 12.2.1 Continued

State	Prevalence (%) of current smoking 18–30 years of age (± 95% CI)	Population, 0–17 years of age[b]	Projected number of smokers 0–17 years of age (± 95% CI)	Projected number of deaths 0–17 years of age
Louisiana	27.5 (2.8)	1,117,803	307,400 (276,100–338,700)	98,000
Maine	31.7 (2.5)	265,918	84,300 (77,600–91,200)	27,000
Maryland	21.5 (2.7)	1,343,800	288,900 (252,600–325,200)	92,000
Massachusetts	23.0 (1.8)	1,401,415	322,300 (297,100–349,000)	103,000
Michigan	29.4 (2.5)	2,266,870	666,500 (609,800–723,100)	213,000
Minnesota	25.0 (2.0)	1,276,148	319,000 (293,500–343,300)	102,000
Mississippi	28.7 (2.6)	745,333	213,900 (194,500–234,000)	68,000
Missouri	28.4 (2.9)	1,403,475	398,600 (357,900–440,700)	128,000
Montana	26.6 (2.4)	221,980	59,000 (53,700–64,200)	19,000
Nebraska	25.6 (1.5)	463,405	118,600 (111,700–125,600)	38,000
Nevada	19.4 (2.9)	663,583	128,700 (109,500–147,300)	41,000
New Hampshire	24.7 (3.3)	274,840	67,900 (58,800–77,000)	22,000
New Jersey	22.0 (2.1)	2,026,384	445,800 (403,300–486,300)	143,000
New Mexico	24.2 (2.2)	514,442	124,500 (113,200–135,300)	40,000
New York	20.5 (2.4)	4,263,154	873,900 (771,600–976,300)	280,000
North Carolina	24.6 (2.2)	2,286,528	562,500 (512,200–612,800)	180,000
North Dakota	28.1 (3.1)	154,608	43,400 (38,700–48,200)	14,000
Ohio	30.4 (2.5)	2,663,674	809,800 (743,200–876,300)	259,000
Oklahoma	29.4 (2.6)	937,363	275,600 (251,200–300,900)	88,000

Table 12.2.1 Continued

State	Prevalence (%) of current smoking 18–30 years of age (± 95% CI)	Population, 0–17 years of age[b]	Projected number of smokers 0–17 years of age (± 95% CI)	Projected number of deaths 0–17 years of age
Oregon	24.8 (3.0)	860,624	213,400 (187,600–239,300)	68,000
Pennsylvania	27.8 (2.1)	2,739,386	761,500 (704,000–821,800)	244,000
Rhode Island	22.5 (3.1)	216,474	48,700 (42,000–55,400)	16,000
South Carolina	29.9 (2.3)	1,080,090	322,900 (298,100–347,800)	103,000
South Dakota	32.2 (3.2)	204,169	65,700 (59,200–72,500)	21,000
Tennessee	26.2 (4.1)	1,494,016	391,400 (330,200–452,700)	125,000
Texas	22.3 (2.1)	6,985,639	1,557,800 (1,411,100–1,704,500)	498,000
Utah	13.6 (1.4)	887,972	120,800 (108,300–132,300)	39,000
Vermont	25.4 (3.1)	123,951	31,500 (27,600–35,200)	10,000
Virginia	25.3 (2.8)	1,856,737	469,800 (417,800–521,700)	150,000
Washington	20.5 (1.9)	1,584,967	324,900 (294,800–356,600)	104,000
West Virginia	38.5 (3.4)	384,041	147,900 (134,800–160,500)	47,000
Wisconsin	25.2 (3.2)	1,317,557	332,000 (289,900–374,200)	106,000
Wyoming	27.9 (3.2)	135,490	37,800 (33,500–42,100)	12,000
Total		73,728,088	17,371,900 (15,604,600–19,133,800)	5,557,000

Source: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, unpublished data.
Note: **CI** = confidence interval.
[a]Prevalance data were obtained from the Behavioral Risk Factor Surveillance System.
[b]Population estimates were obtained from the National Center for Health Statistics 2013.

A Vision for Ending the Tobacco Epidemic

This nation must create a society free of tobacco-related death and disease. The leadership of U.S. Department of Health and Human Services (USDHHS) committed to this vision when it published the first ever tobacco control strategic action plan for the United States in 2010—*Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services* (hereafter referred to as the *Strategic Action Plan*) (USDHHS 2010a). This 50th anniversary Surgeon General's report provides the scientific basis for accelerating the implementation of this national action plan. Our work to protect our children's health and improve the public's health is not close to completion; this report finds that if more is not done to combat tobacco use, then 5.6 million of today's youth will die prematurely from a smoking-related illness.

This report provides an historical perspective that reviews and updates evidence on the health consequences of smoking and exposure to tobacco smoke as well as the extensive evidence base on effective tobacco control interventions. The report also presents findings of models of future tobacco use that show the challenge ahead: at the current trajectory of decline of tobacco use, it is not possible to meet the goal of ending the tobacco epidemic quickly enough. Finally, the report discusses different ways to achieve a society free of premature death and disease caused by tobacco.

Historical Perspective

The *Strategic Action Plan* stated "The United States has made historic progress in combating the epidemic of tobacco-caused illness and death since the landmark 1964 Surgeon General's Report on the health effects of cigarette smoking" (USDHHS 2010a, p. 9). The evidence in this Surgeon General's report provides a wealth of findings supporting that statement.

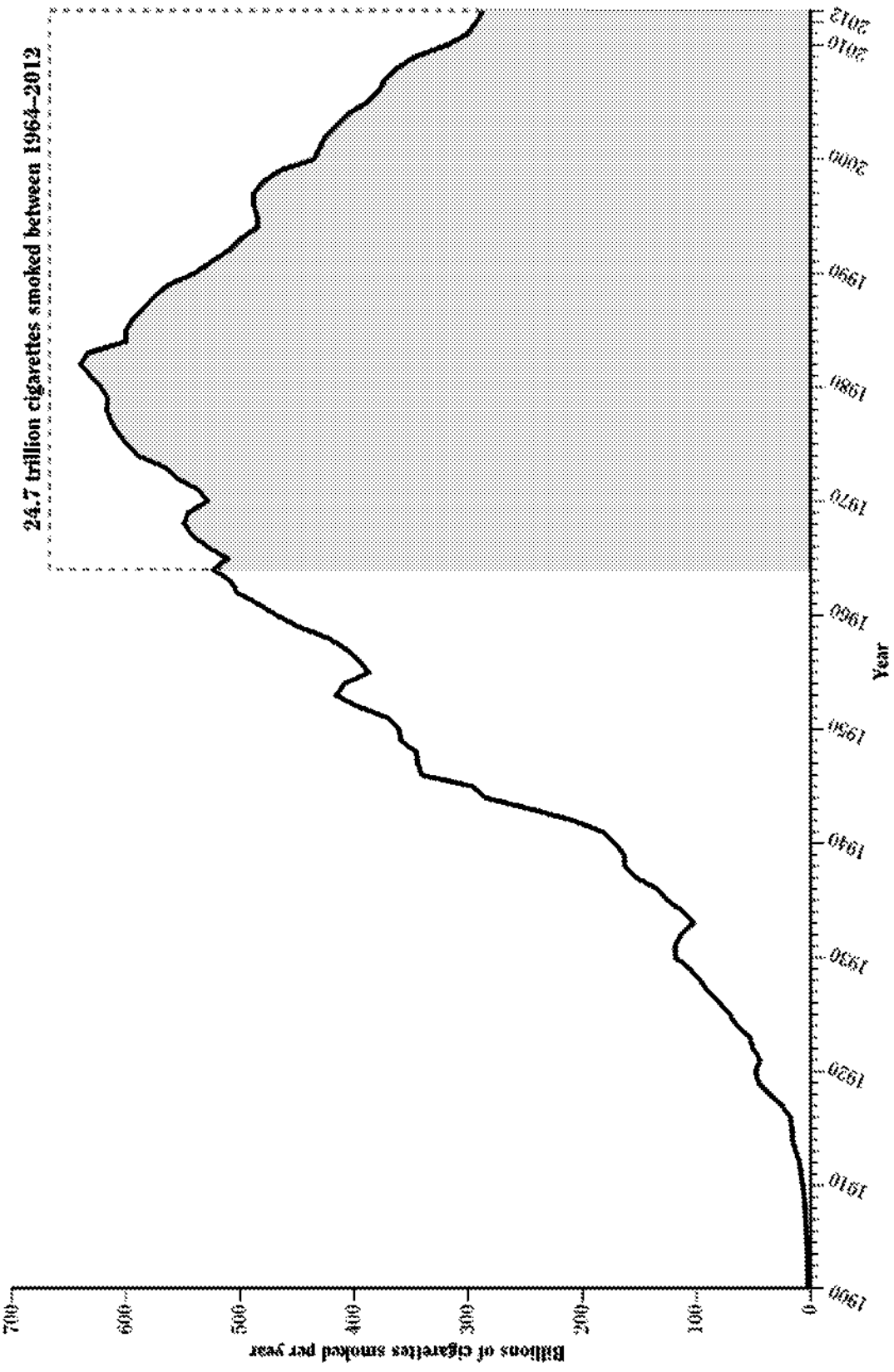
- Per capita cigarette consumption has declined by 72% from 4,345 cigarettes in 1963 to 1,196 in 2012 (see Figure 2.1);
- The prevalence of high school students who currently smoke[1] declined from 36.4% in 1997 to 18.1% in 2011, the lowest level since the start of national surveys (see Chapter 13);
- The prevalence of current smoking[2] among adults has declined from 42.7% in 1965 to 18.1% in 2012 (see Chapter 13).

This progress is considered one of the top public health achievements of the twentieth century (Centers for Disease Control and Prevention [CDC] 1999; Ward and Warren 2007). However, smoking continues to cause unacceptable harm to public health. Several key findings of this report highlight the continuation of the still massive tobacco epidemic in the United States:

- Despite the dramatic decline in per capita cigarette consumption (see Figure 2.1), almost 25 trillion cigarettes have been consumed since 1965 (Figure 16.1).
- More than twenty million Americans have died from smoking-attributable illnesses since 1964 (see Chapter 12).
- Nearly one-half million adults still die prematurely from tobacco use each year (see Chapter 12).
- Approximately 800,000 lung cancer deaths were estimated to have been avoided in the United States during 1975–2000. However, these averted lung cancer deaths are only about 32% of the lung cancer deaths that could have been avoided if tobacco smoking had been completely eliminated after the 1964 Surgeon General's report (Chapter 15).
- The tobacco industry continues to position itself to sustain its sales by recruiting youth and young adults and by maintaining current smokers as consumers of all their nicotine-containing products including cigarettes (see Chapters 13, 14, 15).
- For each smoker who dies from tobacco-related disease, there are two new, younger replacement smokers (USDHHS 2012).

[1]Based on respondents who reported that they smoked cigarettes on at least 1 day during the 30 days before the survey.
[2]Based on adult respondents who reported smoking ≥100 cigarettes in their lifetime and smoking every day or on some days.

Figure 16.1 Total cigarette consumption, United States, 1900–2012



Sources: Miller 1981; U.S. Department of Agriculture, 1987, 1996, 2005, 2007a,b; Centers for Disease Control and Prevention 2012.
Note: Data shown are annual total consumption of cigarettes. This differs from Figure 2.1, which reports the annual adult (18 years of age and older) per capita consumption.

- Disparities in smoking rates persist. Some of the highest prevalence rates are among persons of lower socioeconomic status, some racial/ethnic minority groups, sexual minorities, high school dropouts, and other vulnerable populations including those living with mental illness and substance use disorders.

- Due to the persisting prevalence of smoking among young adults in this country, 5.6 million Americans younger than 18 years of age are projected to die prematurely from a smoking-related illness (see Chapters 12 and 13).

Previous Surgeon General's reports have tracked the evolution of cigarettes into the current highly engineered, addictive, and deadly products containing thousands of chemicals that are themselves harmful. The burning of tobacco produces the complex chemical mixture of over 7,000 compounds that cause a wide range of diseases and premature deaths as a result (USDHHS 2010b). Although the prevalence of smoking has declined significantly over the past half century, risks for smoking-related disease and mortality have not. In fact, today's cigarette smokers—both men and women—have a much higher risk for lung cancer and chronic obstructive pulmonary disease than smokers in 1964, despite smoking fewer cigarettes (see Chapters 6, 7, and 11, and Figures 12.2 and 13.16).

Since 2000, each Surgeon General's report has ended with a call for action. In 2000, Surgeon General Dr. David Satcher clearly stated the challenge that is still applicable today, namely, "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). Knowledge garnered over the subsequent 14 years makes this statement even more cogent today.

In 2007, the Institute of Medicine's report, *Ending the Tobacco Problem: A Blueprint for the Nation*, provided 42 recommendations with the ultimate goal stated as: "... to end the tobacco problem; in other words, to reduce smoking so substantially that it is no longer a significant public health problem for our nation" (Bonnie et al. 2007, p. 1). The 2010 Surgeon General's report (2010b) listed these recommendations along with the detailed recommendations of the President's Cancer Panel for addressing tobacco use prevention and treatment and exposure to secondhand tobacco smoke (Reuben 2007). The 2012 Surgeon General's report built upon recommendations in previous reports in its final chapter: "A Vision for Ending the Tobacco Epidemic" by noting that "we have evidence-based strategies and tools that can rapidly drop youth initiation and prevalence rates down into the single digits" (USDHHS 2012, p. 856).

There is extensive knowledge about what needs to be done—not achieving greater progress results in part from not fully implementing existing knowledge about what works, and in part from the continued efforts of the tobacco industry to promote and market cigarettes and other products. The vision set forth in the *Strategic Action Plan* (USDHHS 2010a) recognizes that dramatic action is needed to change social norms further and to continue to decrease the acceptability of tobacco use (USDHHS 2012), especially smoking.

In recent years, a number of critical legislative steps have been taken to reduce tobacco use, including measures that can reduce the ability of the tobacco industry to promote tobacco use. These legislative measures bring new possibilities for tobacco control.

In February 2009, the *Children's Health Insurance Program Reauthorization Act,* Public Law 111-3, *U.S. Statutes at Large* 8 was signed, which included an unprecedented $0.62 increase in the federal excise tax on cigarettes to $1.01 per pack. This single legislative act—increasing the price of cigarettes—is projected to have reduced the number of middle and high school students who smoke by over 220,000 and the number using smokeless tobacco products by over 135,000 (Huang and Chaloupka 2012).

Raising prices on cigarettes is one of the most effective tobacco control interventions (USDHHS 2012; International Agency for Research on Cancer [IARC] 2011). Even with this tax increase in 2009, the average retail price of cigarettes in this country is still too low in comparison with other countries (World Health Organization [WHO] 2013). Additional price increases would accelerate progress in reducing youth and young adult rates of tobacco use (IARC 2011; USDHHS 2012; WHO 2013). The understanding of price elasticity suggests that the average retail price of cigarettes in the United States across the country would need to be raised to at least $10 a pack, similar to prices in many other countries, in order to have a large and rapid impact (IARC 2011; USDHHS 2012; WHO 2013; Jha and Peto, in press).

In June 2009, the *Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act),* Public Law 111-31, *U.S. Statutes at Large* 123, was signed, thereby granting the U.S. Food and Drug Administration (FDA) the authority to comprehensively regulate thousands of tobacco products for the first time in history. This law gives FDA a number of powerful tools to regulate tobacco products, both existing and new (see Chapter 14). Effective implementation of FDA's tobacco product regulation mandate is needed to reduce the harm caused by tobacco products.

In March 2010, the *Patient Protection and Affordable Care Act (Affordable Care Act),* Public Law 111-148,

U.S. Statutes at Large 124 (2010):119, was signed into law. As part of its emphasis on prevention and health promotion, the law (a) requires private insurance plans and Medicaid expansion plans to cover tobacco cessation treatments, including medications that help people quit smoking; (b) requires state Medicaid programs to cover tobacco cessation medications; (c) expands smoking cessation coverage for pregnant women who receive Medicaid; and (d) provides Medicare beneficiaries with an annual wellness visit that includes personalized prevention plan services with referrals for tobacco cessation services. The *Affordable Care Act* also established the Prevention and Public Health Fund, which represents the most significant investment in U.S. history to scale up and promote effective public health and preventive measures, including programs to prevent and reduce tobacco use. The *Affordable Care Act* strengthens a key element of tobacco use cessation services by making them more available and barrier-free to almost all smokers.

The extensive evidence base supports the conclusion in Chapter 14 that mass media campaigns, comprehensive community programs, and comprehensive statewide tobacco control programs prevent initiation of tobacco use and reduce the prevalence of tobacco use among youth and adults. Although increased application of these and other proven tobacco control strategies would be highly effective, the current levels of implementation of these key strategies are far below the most effective levels according to the evidence base. State funding of tobacco control programs has been declining for years. For example, in 2010 states were only appropriating 2.4% of their tobacco revenues from both tobacco excise taxes and Master Settlement Agreement payments for tobacco control. Reaching CDC's recommended funding level would have required an additional 13% of tobacco revenues, or 3.1 billion of the $24 billion collected (see Chapter 14) (CDC 2012).

Health Consequences

The 2004 Surgeon General's report showed that smoking impacts nearly every organ of the body (USDHHS 2004). The 2006 report concluded that the scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke (USDHHS 2006). The new evidence in this report provides still more support for these conclusions. Fifty years after the first report in 1964, it is striking that the scientific evidence in this report expands the list of diseases and other adverse health effects caused by smoking and exposure to tobacco smoke. Figures 1.1A and 1.1B highlight these new findings and show that the risks for disease are even greater than presented in previous reports. These new findings include:

- Liver cancer and colorectal cancer are now added to the long list of cancers caused by smoking;
- Exposure to secondhand smoke is a cause of stroke;
- Smoking increases the risk of dying from cancer and other diseases in cancer patients and survivors;
- Smoking is a cause of diabetes mellitus; and
- Smoking causes general adverse effects on the body including inflammation and it impairs immune function. Smoking is a cause of rheumatoid arthritis.

This report also updates the estimates of disease, death, and economic costs attributable to smoking and exposure to tobacco smoke. The morbidity burden caused by smoking-attributable diseases is large, and new evidence suggests that over 16 million people alive today live with disease caused by smoking (see Chapter 12). In addition, the risks of death from diseases already on the causal list have increased in recent decades. This is particularly true for lung cancer risk among female smokers and chronic obstructive pulmonary disease risk for both male and female smokers (see Chapters 6 and 7). As the list of diseases caused by smoking has continued to grow, the updated estimate of the annual number of deaths attributable to smoking and exposure to secondhand smoke is now approaching 500,000 (see Chapter 12). This increase has occurred despite decreases in per capita cigarette consumption and prevalence, emphasizing our enhanced understanding of the lethality of cigarettes.

The estimated economic costs attributable to smoking and exposure to tobacco smoke have also increased. The annual indirect costs due to productivity losses are now estimated to be over $150 billion (see Chapter 12). The estimates of direct medical expenditures have also increased as well, now ranging from at least $130 billion annually up to $176 billion or more (see Chapter 12).

Ending the Tobacco Epidemic

The burden of smoking-attributable disease and premature death and its high costs to the nation will continue for decades unless smoking prevalence is reduced more rapidly than the current trajectory. The evidence in this report shows that the nation will fail to achieve the *Healthy People 2020* objective of reducing the prevalence of smoking among adults to 12%. Model estimates sug-

gest that if the status quo in tobacco control in 2008 were maintained, the projected prevalence of smoking among adults in 2050 could still be as high as 15% (see Chapter 15). Trends in smoking rates among youth and adults show progress, but the prevalence of current smoking among youth and adults is only slowly declining and the actual number of youth and young adults starting to smoke has increased since 2002 (see Chapter 13). Additionally, the use of multiple tobacco products is increasingly common, especially among young smokers. Concerns remain that use of these new products may increase initiation rates among youth and young adults, delay quitting, and prolong the smoking epidemic.

As reviewed in this report, the root cause of the smoking epidemic is also evident: the tobacco industry aggressively markets and promotes lethal and addictive products, and continues to recruit youth and young adults as new consumers of these products (see Chapter 14) (USDHHS 2012). As reviewed in Chapter 14, U.S. District Judge Gladys Kessler entered her final opinion and order on August 17, 2006, and found that the tobacco industry defendants violated the *Racketeer Influenced and Corrupt Organizations Act,* Public Law 91-452, *U.S. Statutes at Large* 84 (1970):992, codified at *U.S. Code* 18§§ 1961–68 (1994), by lying, misrepresenting, and deceiving the public "including smokers and the young people they avidly sought as 'replacement smokers,' about the devastating health effects of smoking and environmental tobacco smoke" (*United States v. Philip Morris,* 449 *F. Suppl. 2d1(D.D.C. 2006)*:852). The *Tobacco Control Act* incorporates as congressional findings of fact Judge Kessler's determinations that "the major United States cigarette companies continue to target and market to youth," that the companies sought to "encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998," and that they "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research" (*Tobacco Control Act* 2009, §2(47) – (49)).

Therefore, this report addresses the question: what steps are needed to end the tobacco epidemic? There are different ways to achieve this vision. Should the emphasis be on ending cigarette use; ending the use of the most harmful tobacco products while reducing the harm of remaining products; or ending the use of all tobacco products?

The scientific findings of the 2012 Surgeon General's report (USDHHS 2012) show that there are evidence-based strategies that can rapidly drop initiation and prevalence rates of smoking among youth to single digits. To reach this target, these strategies need to be fully implemented and sustained with sufficient intensity and duration. Without such increased and sustained action, 5.6 million youth younger than 18 years of age in this country today are projected to die prematurely from a smoking-related illness. But millions of these projected deaths could be averted, making tobacco control a highest priority in our overall public health commitment and strategy.

Achieving this goal of rapidly reducing rates of smoking among youth still leaves 42 million current adult smokers who are at risk of dying from a smoking-related disease. The evidence in this and previous reports highlights how deadly inhaling tobacco smoke is, especially from burning cigarettes (USDHHS 2004, 2006, 2010, 2012). Approximately 85% of the tobacco products used since 1964 have been cigarettes (U.S. Department of Agriculture 2008).

The scientific findings of the 2010 Surgeon General's report were definitive on the causation of disease by smoking:

- Major Conclusion #2: "Inhaling the complex chemical mixture of combustion compounds in tobacco smoke causes adverse health outcomes, particularly cancer and cardiovascular and pulmonary diseases, through mechanisms that include DNA damage, inflammation, and oxidative stress."

- Major Conclusion #4: "Sustained use and long-term exposures to tobacco smoke are due to the powerfully addicting effects of tobacco products, which are mediated by diverse actions of nicotine and perhaps other compounds, at multiple types of nicotinic receptors in the brain" (USDHHS 2010b, p. 9).

The scientific evidence is incontrovertible: inhaling the combustion compounds from tobacco smoke, particularly from cigarettes, is deadly. It has been stated that "The cigarette is also a defective product, meaning not just dangerous but *unreasonably* dangerous, killing half its long-term users. And addictive by design" (Proctor 2013, p. i27). The high risks of cigarette smoking and the historic and current patterns of tobacco use in the United States lead to a primary conclusion of this report:

- The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.

Could the use of cigarettes and other combusted tobacco products be rapidly reduced in this country? As noted above, evidence-based strategies that can rapidly drop youth initiation and prevalence rates down to single digits have already been identified and used (USDHHS 2012). Chapter 14 reviews a broad range of well-defined and effective interventions proven to reduce adult smoking rates if implemented and sustained at funding levels consistent with CDC's recommended levels (see Chapter 14). This and previous reports outline effective programs and policies:

- Fully funded comprehensive statewide tobacco control programs funded at levels recommended by CDC;
- A higher average retail price of cigarettes in the United States. Experience from across the globe suggests at least $10 a pack in the United States;
- Complete protection of the entire U.S. population from exposure to tobacco smoke through comprehensive smokefree indoor air policies;
- High-impact media campaigns, such as CDC's Tips from Former Smokers campaign and the proposed U.S. Food and Drug Administration prevention campaigns at a high-frequency level and exposure for 12 months a year for a decade or more; and
- Full access to cessation treatment for nicotine addiction including counseling and medication for all smokers, especially those with mental and physical comorbidities.

However, these five actions are not all that needs to be done. Although more aggressive use of those evidence-based policies and programs reviewed in Chapter 14 is a starting point, the simulation modeling results reviewed (see Chapter 15) suggest that new strategies may be needed to more rapidly reduce rates of smoking. Recently, such tobacco control strategies are beginning to be formulated that might dramatically reduce the use of tobacco products, especially cigarettes. These proposed strategies have been labeled tobacco end game scenarios (see Chapter 15). For the United States, the feasibility and applicability of these various proposals range from possible (reducing the nicotine in cigarettes to nonaddicting levels) to almost certainly infeasible (transferring the tobacco product market to a nonprofit entity). Any application of these end game interventions should come as an integrated national tobacco control strategy that is based on a foundation of enhanced implementation of the proven strategies. Examples of end game options (see Chapter 15), which could complement the proven interventions in accomplishing our overall goal of a society free of tobacco-related death and disease, include but are not limited to: (1) reduce the nicotine content to make cigarettes less addictive (Benowitz and Henningfield 2013), and (2) greater restrictions on sales, particularly at the local level, including bans on entire categories of tobacco products (Berrick 2013; Malone 2013).

In considering options for reducing the health burden caused by smoking, many additional recommended actions have been defined in evidence reviews and guidance documents discussed in this report. For example, selected state experience suggests that all levels of government can enhance revenue collection and minimize tax avoidance and evasion through several policy approaches, such as implementing a high-tech cigarette tax stamp, improving tobacco licensure management, and making the stamps harder to counterfeit (see Chapter 14). These state practices could also be expanded to the national level with a national track and trace system. A track and trace system, in the tobacco control context, is a system that can track goods from manufacture to distribution to sale, identifying points in the supply chain where taxes should be paid and confirm payment. Enforcement enhancements would also be beneficial. Implementing such systems would also simultaneously retain the positive public health effects of taxation and protect product regulation in the market.

In addition to actions taken by the federal government, actions by national and local nongovernmental organizations can have significant impacts on social norms. As reviewed in Chapter 14, the portrayals of tobacco use in U.S. films appear to have rebounded upward in the last 2 years (see Chapter 14, Figures 14.3A and 14.3B). Based on box office attendance data, it has been estimated that youth were exposed to 14.9 million in-theater tobacco-use impressions[3] in youth-rated films in 2012. Youth who are exposed to images of smoking in movies are more likely to smoke; those who experience the most exposure to onscreen smoking are approximately twice as likely to begin smoking as those who receive the least exposure (USDHHS 2012). Actions that would eliminate depiction of tobacco use in movies that are produced and rated as appropriate for children and adolescents could have a sig-

[3]One impression equals one tobacco use incident on screen viewed by one audience member.

nificant benefit in reducing the numbers of youth who become tobacco users. It has been suggested that the movie industry modernize the Motion Picture Association of America voluntary rating system to eliminate smoking from youth-rated films by awarding any film with smoking or other protobacco imagery an R rating (with exceptions for real historical figures who actually smoked or films that actually depict the dangers of smoking or exposure to secondhand smoke) (Glantz and Polansky 2012; Sargent et al. 2012). Further, if such a change in the Motion Picture Association of America rating system would reduce in-theater exposures from a current median of about 275 annual exposures per adolescent from PG-13 movies down to approximately 10 or less, adolescent smoking would be reduced by an estimated 18% (95% confidence interval, 14–21%) (Sargent et al. 2012).

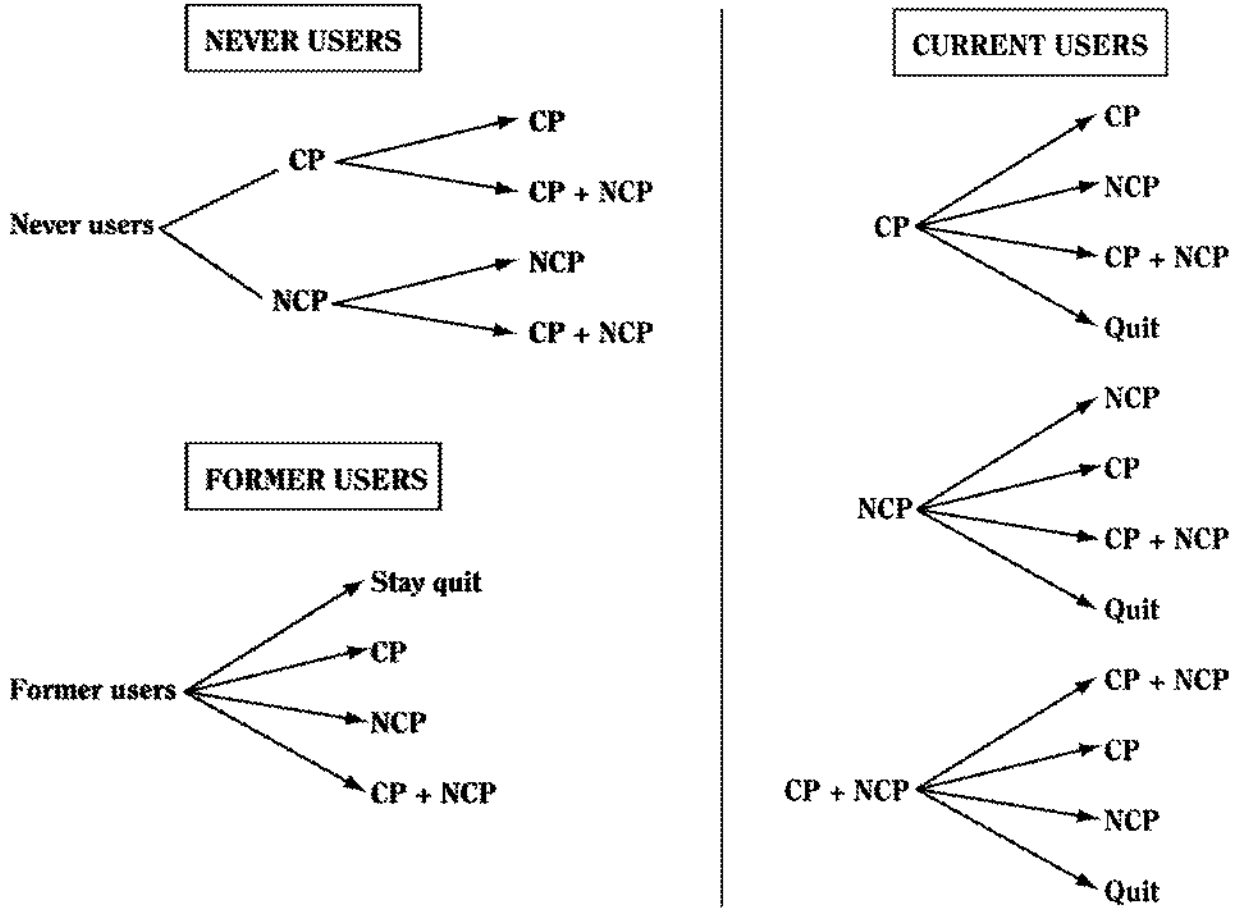
The increasing availability of noncombustible products raises the question of using them to help eliminate the harm caused by tobacco. The *Tobacco Control Act* is governed by a requirement to protect public health, an acknowledgement that the goal of tobacco control is to improve public health overall. A public health standard is critical because strategies that reduce potential harm from toxicant exposure to individual users of tobacco products could adversely affect other individuals and public health by increasing the number of new users of cigarettes and by reducing the number of quitters (Figure 16.2).

This issue of reducing direct *individual* harm in those substituting noncombustibles for cigarettes while minimizing impact on other individuals, who may start or not stop using cigarettes (Figure 16.2), arises in facing the regulatory challenge posed by electronic cigarettes (e-cigarettes or electronic nicotine delivery systems). Although these new products are entering the marketplace rapidly, and will soon be marketed by all three major tobacco manufacturers in the United States, significant questions remain about (1) how to assess the potential toxicity and health effects of the more than 250 electronic cigarette brands; (2) the magnitude of the potential reduced risk from electronic versus continuing use of conventional cigarettes for individual smokers; (3) the need to weigh the potential individual benefits and risks versus population benefits and risks; (4) how the advertising and marketing of these new products should be regulated; and (5) even assuming that electronic cigarettes could be sufficiently safe to users and offer net public health benefits, there are significant questions about the manner in which they should be regulated (Benowitz 2013).

The issue of weighing the relative benefits and risks to individuals and populations is critical when considering the potential role of any noncombustible tobacco products in reducing the occurrence of smoking-caused diseases and morbidity. Currently, there are varying scenarios being discussed. In one scenario, noncombustible tobacco products would be substituted for cigarette smoking among a subset of smokers (people who otherwise would not quit smoking and thus are at high risk for smoking-caused diseases). Proponents claim that such a switch would significantly reduce the burden of death and disease attributable to smoking if smokers completely substituted combustible products with noncombustible products. The perspective rests on the assumption that (a) noncombustible tobacco products, used alone, are far less dangerous to individual users than continued smoking, a conclusion that appears correct based on current understanding (Levy et al. 2004; USDHHS 2010b); (b) with proper marketing, differential taxation, and other carefully calibrated policies, noncombustible products would be adopted as a complete substitute for smoking by significant numbers of current smokers, a thus far unproven assumption; (c) smokers who switched to noncombustible products otherwise would continue to smoke (as opposed to quitting), another area with significant uncertainty; and (d) the net impact on health of all the various outcomes, intended and unintended, would contribute meaningfully to tobacco harm reduction, a proposition that has been explored only once in the literature (Mejia et al. 2010). In that analysis which related only to snus, it was concluded that it would be unlikely that the promotion of the snus form of smokeless tobacco would be associated with substantial health benefits. The probability that the use of snus could delay complete cessation of cigarette smoking among health-concerned smokers would decrease the potential health benefit at the population level.

An alternative scenario regarding noncombustible products as a harm reduction strategy holds that the availability and promotion of noncombustible tobacco products would increase the aggregate damage to health produced by tobacco. Proponents of this position vary on how much they emphasize the inherent dangers of noncombustible tobacco products. Even those who concur that the use of noncombustible tobacco products may not constitute a large direct risk to individual health propose that a strategy based on their use would increase total tobacco-related harm to health. Proponents of this position argue that the availability of noncombustible products can have adverse consequences, especially under current conditions with the widespread marketing and use of cigarettes. These consequences include (a) encouraging children to experiment with tobacco products (with the expectation that a percentage of those who become regular users of noncombustible products will graduate

Figure 16.2 Potential patterns of use of combustible products (CP) and non-combustible products (NCP)



Source: Created by J. Samet for this Surgeon General's Report.

to smoking); (b) helping smokers maintain their addiction by using noncombustible products in environments where they cannot smoke; (c) acting as a non-risk-free substitute for cigarettes for smokers who otherwise would have quit; and (d) giving smokers an alternative means of satisfying their addiction that may lead to higher levels of recidivism to smoking. The evidence indicates that current industry practices raise concerns about all of these potential adverse consequences (USDHHS 2012). One study found that transnational tobacco companies promote less harmful tobacco products in order to maintain and extend the sales of cigarettes and to create alternative forms of tobacco use among young people who are no longer smoking (Peeters and Gilmore 2013). Uncertainties as to the role of noncombustible tobacco products as part of a harm reduction strategy raises issues of promotion of noncombustible tobacco. Further research with attention to their individual and population-level consequences will be helpful to fully address these questions. However, the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced.

Health Effects of Cigarette Smoking

On This Page

Cigarette smoking harms nearly every organ of the body, causes many diseases, and reduces the health of smokers in general.[1,2]

Quitting smoking lowers your risk for smoking-related diseases and can add years to your life.[1,2]

Smoking and Death

Cigarette smoking is the leading preventable cause of death in the United States.[1]

- Cigarette smoking causes more than 480,000 deaths each year in the United States. This is nearly one in five deaths.[1,2,3]
- Smoking causes more deaths each year than the following causes combined:[4]
  - Human immunodeficiency virus (HIV)
  - Illegal drug use
  - Alcohol use
  - Motor vehicle injuries
  - Firearm-related incidents
- More than 10 times as many U.S. citizens have died prematurely from cigarette smoking than have died in all the wars fought by the United States.[1]
- Smoking causes about 90% (or 9 out of 10) of all lung cancer deaths.[1,2] More women die from lung cancer each year than from breast cancer.[5]
- Smoking causes about 80% (or 8 out of 10) of all deaths from chronic obstructive pulmonary disease (COPD).[1]
- Cigarette smoking increases risk for death from all causes in men and women.[1]

- The risk of dying from cigarette smoking has increased over the last 50 years in the U.S.[1]

Smoking and Increased Health Risks

Smokers are more likely than nonsmokers to develop heart disease, stroke, and lung cancer.[1]

- Estimates show smoking increases the risk:
  - For coronary heart disease by 2 to 4 times[1,6]
  - For stroke by 2 to 4 times[1]
  - Of men developing lung cancer by 25 times[1]
  - Of women developing lung cancer by 25.7 times[1]
- Smoking causes diminished overall health, increased absenteeism from work, and increased health care utilization and cost.[1]

Smoking and Cardiovascular Disease

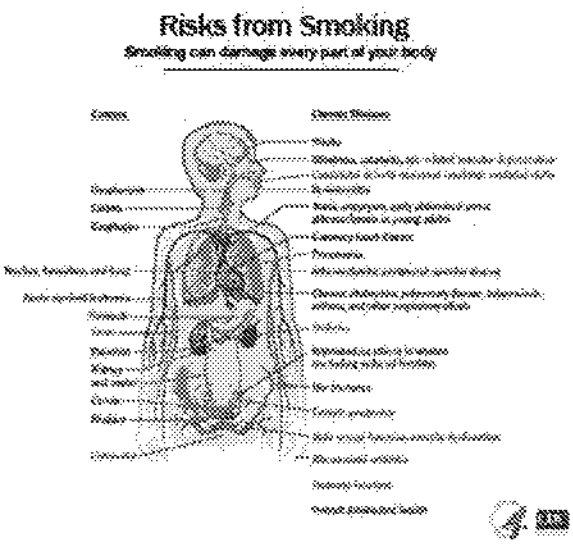
Smokers are at greater risk for diseases that affect the heart and blood vessels (cardiovascular disease).[1,2]

- Smoking causes stroke and coronary heart disease, which are among the leading causes of death in the United States.[1,3]
- Even people who smoke fewer than five cigarettes a day can have early signs of cardiovascular disease.[1]
- Smoking damages blood vessels and can make them thicken and grow narrower. This makes your heart beat faster and your blood pressure go up. Clots can also form.[1,2]
- A stroke occurs when:
  - A clot blocks the blood flow to part of your brain;
  - A blood vessel in or around your brain bursts.[1,2]
- Blockages caused by smoking can also reduce blood flow to your legs and skin.[1,2]

Smoking and Respiratory Disease

Smoking can cause lung disease by damaging your airways and the small air sacs (alveoli) found in your lungs.[1,2]

- Lung diseases caused by smoking include COPD, which includes emphysema and chronic bronchitis.[1,2]
- Cigarette smoking causes most cases of lung cancer.[1,2]
- If you have asthma, tobacco smoke can trigger an attack or make an attack worse.[1,2]
- Smokers are 12 to 13 times more likely to die from COPD than nonsmokers.[1]



Larger infographic

Smoking and Cancer

Smoking can cause cancer almost anywhere in your body:[1,2] (See figure above)

- Bladder
- Blood (acute myeloid leukemia)
- Cervix
- Colon and rectum (colorectal)
- Esophagus
- Kidney and ureter
- Larynx
- Liver
- Oropharynx (includes parts of the throat, tongue, soft palate, and the tonsils)
- Pancreas
- Stomach
- Trachea, bronchus, and lung

Smoking also increases the risk of dying from cancer and other diseases in cancer patients and survivors.[1]

If nobody smoked, one of every three cancer deaths in the United States would not happen.[1,2]

Smoking and Other Health Risks

Smoking harms nearly every organ of the body and affects a person's overall health.[1,2]

- Smoking can make it harder for a woman to become pregnant. It can also affect her baby's health before and after birth. Smoking increases risks for:[1,2,5]
  - Preterm (early) delivery
  - Stillbirth (death of the baby before birth)
  - Low birth weight
  - Sudden infant death syndrome (known as SIDS or crib death)
  - Ectopic pregnancy
  - Orofacial clefts in infants
- Smoking can also affect men's sperm, which can reduce fertility and also increase risks for birth defects and miscarriage.[2]
- Smoking can affect bone health.[1,5]
  - Women past childbearing years who smoke have weaker bones than women who never smoked. They are also at greater risk for broken bones.
- Smoking affects the health of your teeth and gums and can cause tooth loss.[1]
- Smoking can increase your risk for cataracts (clouding of the eye's lens that makes it hard for you to see). It can also cause age-related macular degeneration (AMD). AMD is damage to a small spot near the center of the retina, the part of the eye needed for central vision.[1]
- Smoking is a cause of type 2 diabetes mellitus and can make it harder to control. The risk of developing diabetes is 30–40% higher for active smokers than nonsmokers.[1,2]
- Smoking causes general adverse effects on the body, including inflammation and decreased immune function.[1]
- Smoking is a cause of rheumatoid arthritis.[1]

Quitting and Reduced Risks

- Quitting smoking cuts cardiovascular risks. Just 1 year after quitting smoking, your risk for a heart attack drops sharply.[2]
- Within 2 to 5 years after quitting smoking, your risk for stroke may reduce to about that of a nonsmoker's.[2]
- If you quit smoking, your risks for cancers of the mouth, throat, esophagus, and bladder drop by half within 5 years.[2]
- Ten years after you quit smoking, your risk for lung cancer drops by half.[2]

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For Further Information

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National Center for Chronic Disease Prevention and Health Promotion
Office on Smoking and Health
E-mail: tobaccoinfo@cdc.gov (mailto:tobaccoinfo@cdc.gov)
Phone: 1-800-CDC-INFO

Media Inquiries: Contact CDC's Office on Smoking and Health press line at 770-488-5493.

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Smokeless Tobacco	
Tobacco Marketing and Products	
Youth Tobacco Use	

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Submit (javascript:quicksubscribe();return false;)

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For help with quitting (http://www.smokefree.gov/)

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1-800-784-8669

Related CDC Sites

Tips From Former Smokers®

Division of Cancer Prevention and Control

- Lung Cancer
- National Comprehensive Cancer Control Program

Division of Reproductive Health

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(http://www.youtube.com/playlist?list=PL184B81EA3136E9FE&feature=plcp)

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Quitting Smoking Among Adults — United States, 2000–2015

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Quitting cigarette smoking benefits smokers at any age (*1*). Individual, group, and telephone counseling and seven Food and Drug Administration–approved medications increase quit rates (*1–3*). To assess progress toward the *Healthy People 2020* objectives of increasing the proportion of U.S. adults who attempt to quit smoking cigarettes to ≥80.0% (TU-4.1), and increasing recent smoking cessation success to ≥8.0% (TU-5.1),* CDC assessed national estimates of cessation behaviors among adults aged ≥18 years using data from the 2000, 2005, 2010, and 2015 National Health Interview Surveys (NHIS). During 2015, 68.0% of adult smokers wanted to stop smoking, 55.4% made a past-year quit attempt, 7.4% recently quit smoking, 57.2% had been advised by a health professional to quit, and 31.2% used cessation counseling and/or medication when trying to quit. During 2000–2015, increases occurred in the proportion of smokers who reported a past-year quit attempt, recently quit smoking, were advised to quit by a health professional, and used cessation counseling and/or medication ($p<0.05$). Throughout this period, fewer than one third of persons used evidence-based cessation methods when trying to quit smoking. As of 2015, 59.1% of adults who had ever smoked had quit. To further increase cessation, health care providers can consistently identify smokers, advise them to quit, and offer them cessation treatments (*2–4*). In addition, health insurers can increase cessation by covering and promoting evidence-based cessation treatments and removing barriers to treatment access (*2,4–6*).

NHIS is an annual, nationally representative, in-person survey of the noninstitutionalized U.S. civilian population. The NHIS Sample Adult core questionnaire is administered to a randomly selected adult (referred to as the sample adult) aged ≥18 years in

* Objectives TU-4.1 and TU-5.1. https://www.healthypeople.gov/2020/topics-objectives/topic/tobacco-use/objectives.

INSIDE

Continuing Education examination available at http://www.cdc.gov/mmwr/cme/conted_info.html#weekly.

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each sampled family. NHIS sample sizes and final response rates for sample adults for 2000, 2005, 2010, and 2015 were 32,374 (response rate = 72.1%), 31,428 (69.0%), 27,157 (60.8%), and 33,672 (55.2%), respectively. Current and former smoking were defined according to *Healthy People 2020* measures.[†] Persons attempting to quit included current smokers who stopped smoking for >1 day during the 12 months before the interview because they were trying to quit and former smokers who had quit during the past year. Former smokers who last smoked 6–12 months ago were considered to have achieved recent cessation success. Every 5 years, a supplemental cancer-control questionnaire is administered to NHIS sample adult respondents; the questionnaire contains questions on interest in quitting smoking, receipt of a health professional's advice to quit, and use of cessation counseling and/or medication. Data were adjusted for differences in the probability of selection and nonresponse, and were weighted to provide nationally representative estimates. Logistic regression was conducted to analyze trends during 2000–2015. Both linear and quadratic terms were initially applied to all models. If the quadratic term was not significant, the linear model was used.

[†] To determine smoking status, respondents were asked, "Have you smoked at least 100 cigarettes in your entire life?" Those who answered "yes" were asked, "Do you now smoke cigarettes every day, some days, or not at all?" Current smokers were those who had smoked at least 100 cigarettes during their lifetime and, at the time of the interview, reported smoking every day or some days. Former smokers were those who reported smoking at least 100 cigarettes during their lifetime but currently did not smoke. http://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm.

In 2015, 68.0% of all current smokers reported that they wanted to stop smoking completely. Smaller proportions of smokers aged ≥65 years (53.7%) and 18–24 years (62.3%) were interested in quitting than were smokers aged 25–44 years (72.7%) (Table 1). The prevalence of past-year quit attempts increased during 2000–2015 ($p<0.05$ based on quadratic trend analysis), and was 55.4% in 2015, which was the time point when prevalence was highest (Figure). Past-year quit attempts decreased with increasing age. Higher prevalences of past-year quit attempts were reported by Asians (69.4%) and blacks (63.4%) than by whites (53.3%) (Table 1).

The prevalence of recent cessation increased during 2000–2015 ($p<0.05$ based on linear trend analysis), and was 7.4% in 2015 (Figure). Recent cessation generally increased with increasing level of educational attainment, and smokers with private health insurance (9.4%) reported a higher prevalence of recent cessation than did smokers who were uninsured (5.2%) or enrolled in Medicaid (including persons with dual Medicaid/Medicare eligibility)[§] (5.9%) (Table 1). As of 2015, among adults who had ever smoked, 59.1% (52.8 million) had quit.

During 2000–2015, increases were reported in receipt of advice from a health professional to quit: prevalence was 57.2% in 2015 ($p<0.05$ based on quadratic trend analysis); prevalence was highest in 2005 and 2015, with a decrease observed in 2010

[§] A secondary analysis found that the prevalence of reported cessation behaviors for Medicaid enrollees did not change substantially when persons with dual Medicaid/Medicare eligibility were removed from the Medicaid coverage category.

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TABLE 1. Prevalence of interest in quitting smoking,* past-year quit attempt,† and recent smoking cessation§ among adult smokers aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2015

Characteristic	Interested in quitting % (95% CI)	Past-year quit attempt % (95% CI)	Recent smoking cessation¶ % (95% CI)
Overall	**68.0 (65.9–70.0)**	**55.4 (53.5–57.3)**	**7.4 (6.5–8.3)**
Sex			
Men	66.7 (63.8–69.6)	55.3 (52.7–57.9)	7.2 (6.0–8.5)
Women	69.4 (66.7–72.1)	55.6 (53.0–58.1)	7.6 (6.2–8.9)
Age group (yrs)			
18–24	62.3 (55.7–69.0)	66.7 (61.0–72.4)	9.9 (6.1–13.8)
25–44	72.7 (69.7–75.7)	59.8 (57.3–62.3)	8.9 (7.3–10.5)
45–64	68.7 (65.8–71.6)	49.6 (46.8–52.5)	5.7 (4.6–6.7)
≥65	53.7 (48.4–58.9)	47.2 (42.2–52.3)	5.4 (3.4–7.5)
Race/Ethnicity**			
White, non-Hispanic	67.5 (65.0–70.0)	53.3 (50.8–55.7)	7.1 (6.0–8.2)
Black, non-Hispanic	72.8 (68.2–77.4)	63.4 (59.0–67.9)	4.9 (3.2–6.6)
Hispanic	67.4 (61.9–72.8)	56.2 (51.6–60.9)	8.2 (5.5–10.9)
AI/AN, non-Hispanic	55.6 (35.8–75.4)	52.1 (32.1–72.2)	—††
Asian, non-Hispanic§§	69.6 (59.5–79.8)	69.4 (62.1–76.7)	17.3 (10.1–24.5)
Multiple race, non-Hispanic	59.8 (45.7–73.9)	57.8 (47.2–68.4)	—††
Education¶¶			
≤12 yrs (no high school diploma)	68.0 (63.7–72.2)	50.4 (46.2–54.5)	4.4 (2.7–6.1)
GED certificate	65.7 (58.0–73.4)	48.1 (40.1–56.0)	—††
High school diploma	65.5 (61.9–69.1)	52.2 (48.3–56.2)	6.8 (4.9–8.7)
Some college (no degree)	70.2 (66.1–74.4)	57.8(53.6–61.9)	7.2 (5.4–9.1)
Associate degree	70.6 (65.3–76.0)	57.4 (52.2–62.7)	9.2 (6.3–12.0)
Undergraduate degree	73.3 (67.7–78.8)	57.6 (51.5–63.8)	11.2 (7.4–15.0)
Graduate degree	74.0 (65.1–82.9)	55.8 (46.0–65.6)	10.8 (4.9–16.7)
Poverty status***			
At or above poverty level	68.2 (65.9–70.4)	55.5 (53.3–57.7)	7.9 (6.8–8.9)
Below poverty level	67.3 (63.4–71.1)	55.2 (51.6–58.8)	5.6 (3.8–7.3)
U.S. Census regions†††			
Northeast	74.5 (69.0–80.1)	58.8 (54.6–63.0)	8.6 (5.9–11.3)
Midwest	67.1 (63.1–71.1)	54.0 (49.7–58.4)	6.4 (4.8–8.0)
South	67.2 (64.0–70.4)	54.3 (51.6–57.0)	7.6 (6.1–9.0)
West	65.5 (60.7–70.2)	56.9 (52.5–61.3)	7.6 (5.7–9.6)
Health insurance coverage§§§			
Private	69.0 (66.1–71.8)	57.2 (54.6–59.9)	9.4 (7.9–10.9)
Medicaid and dual eligibles¶¶¶	69.2 (65.3–73.2)	56.3 (52.5–60.1)	5.9 (4.1–7.7)
Medicare-Advantage	40.6 (29.9–51.3)	42.6 (32.2–53.0)	—††
Medicare-only (excluding Advantage)	53.0 (42.5–63.6)	42.0 (32.2–51.8)	—††
Other coverage	63.6 (57.2–69.9)	50.7 (43.9–57.4)	5.5 (2.4–8.7)
Uninsured	69.5 (65.2–73.9)	53.5 (49.7–57.2)	5.2 (3.3–7.0)
Disability/Limitation****			
Yes	66.4 (61.4–71.3)	55.1 (49.6–60.6)	5.8 (3.8–7.7)
No	66.8 (63.5–70.2)	56.3 (53.6–59.0)	7.9 (6.2–9.5)

See table footnotes on page 1460.

(Figure). Smokers aged 45–64 years (65.7%) and ≥65 years (65.7%) reported a higher prevalence of receiving advice to quit than did smokers aged 18–24 years (44.4%) and 25–44 years (49.8%) (Table 2). Lower prevalences of receiving advice to quit were reported by Asian (34.2%), American Indian/Alaska Native (38.1%), and Hispanic (42.2%) smokers than by white smokers (60.2%); and by uninsured smokers (44.1%) than by smokers with any type of insurance (range = 56.8%–69.2%). Smokers reporting a disability/limitation or serious psychological distress reported a higher prevalence of receiving advice to quit than did smokers without these conditions (71.8% and 70.2%, respectively, vs 53.6% and 55.7%).

Use of cessation counseling and/or medication among smokers who were trying to quit increased during 2000–2005 from 21.9% to 29.1%, with no change in 2010 (31.7%) or 2015 (31.2%) ($p<0.05$ based on quadratic trend analysis) (Figure). The prevalence of use of counseling and/or medication increased with age through age 64 years (Table 2). Hispanics and Asians reported a lower prevalence of using counseling and/or medication (19.2% and 20.5%, respectively) than did whites (34.3%), as did uninsured smokers (21.4%) compared with smokers with any type of insurance other than Medicare and Medicare Advantage (range = 32.1%–36.0%). The prevalence of using counseling and/or medication was higher

TABLE 1. (*Continued*) Prevalence of interest in quitting smoking,* past-year quit attempt,† and recent smoking cessation§ among adult smokers aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2015

Characteristic	Interested in quitting % (95% CI)	Past-year quit attempt % (95% CI)	Recent smoking cessation¶ % (95% CI)
Serious Psychological Distress (Kessler Scale)††††			
Yes (Kessler score ≥13)	67.4 (61.3–73.5)	53.0 (46.9–59.1)	—††
No (Kessler score <13)	68.2 (66.0–70.3)	55.5 (53.5–57.5)	8.1 (7.1–9.1)
Sexual orientation¶¶¶¶			
Straight	68.1 (65.9–70.2)	55.4 (53.5–57.3)	7.6 (6.7–8.6)
Gay/Lesbian/Bisexual	66.7 (56.9–76.6)	48.4 (39.4–57.3)	—††

Abbreviations: AI/AN = American Indian/Alaska Native; CI = confidence interval; GED = General Educational Development.

* Current smokers who reported that they wanted to stop smoking completely.

† Current smokers who reported that they stopped smoking for >1 day during the past 12 months because they were trying to quit smoking and former smokers who quit during the past year.

§ Former smokers who quit smoking for ≥6 months during the past year.

¶ Among current smokers who smoked for ≥2 years and former smokers who quit during the past year.

** Excludes 63 respondents of non-Hispanic unknown race. Hispanics can be of any race.

†† Data not reported because sample size is <50 or the relative standard error of the estimate is >30%.

§§ Does not include Native Hawaiians or Other Pacific Islanders.

¶¶ Among persons aged ≥25 years. Excludes 144 persons whose education level was unknown.

*** Family income was reported by the family respondent, who might or might not be the same as the sample adult respondent from whom smoking information was collected. Missing values were imputed. Because the weighted Census poverty thresholds for 2014 were not available when the 2015 National Health Interview Survey (NHIS) instrument was created, the poverty thresholds used in the 2015 NHIS were estimated from several sources: weighted average Census poverty thresholds from 2013; the average Consumer Price Index from 2013; actual Consumer Price Index values for January–July 2014; and projected Consumer Price Index values for August–December 2014.

††† *Northeast:* Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. *Midwest:* Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. *South:* Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. *West:* Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

§§§ Health insurance coverage was from NHIS-recoded data using a hierarchal assignment. Excludes 155 persons whose coverage was unknown.

¶¶¶ A secondary analysis found that the prevalence of reported cessation behaviors for Medicaid enrollees did not change substantially when persons with dual Medicaid/Medicare eligibility were removed from the Medicaid coverage category.

**** Based on proxy or self–reported presence of selected impairments, including vision, hearing, cognition, and movement and limitations in performing activities of daily living and instrumental activities of daily living. Limitations in performing activities of daily living was defined based on response to the question "Does [person] have difficulty dressing or bathing?" and limitations in performing instrumental activities of daily living was defined based on response to the question, "Because of a physical, mental, or emotional condition, does [person] have difficulty doing errands alone, such as visiting a doctor's office or shopping?" Any disability/limitation was defined as a "yes" response pertaining to at least one of the disabilities/limitations listed (i.e., vision, hearing, cognition, movement, activities of daily living, or instrumental activities of daily living). In 2015, the American Community Survey questions were asked of a random half of the respondents from the 2015 Person File. Excludes four persons whose disability status was unknown.

†††† The Kessler Psychological Distress Scale is a series of six questions that asks about feelings of sadness, nervousness, restlessness, worthlessness, hopelessness, and feeling like everything is an effort during the past 30 days. Participants were asked to respond on a Likert Scale ranging between 'None of the Time' (score = 0) and 'All of the time' (score = 4). Responses were summed over the six questions; respondents with a score ≥13 were coded as having serious psychological distress, and respondents with a score <13 were coded as not having serious psychological distress. Excludes 1,416 persons whose psychological distress was unknown. Additional information available at https://www.cdc.gov/nchs/data/databriefs/db203.pdf.

among smokers reporting a disability/limitation (39.0%) or serious psychological distress (41.6%) than among smokers without these conditions (28.5% and 30.1%, respectively). Gay, lesbian, or bisexual smokers reported a lower prevalence of counseling and/or medication use (14.5%) than did straight smokers (31.7%).

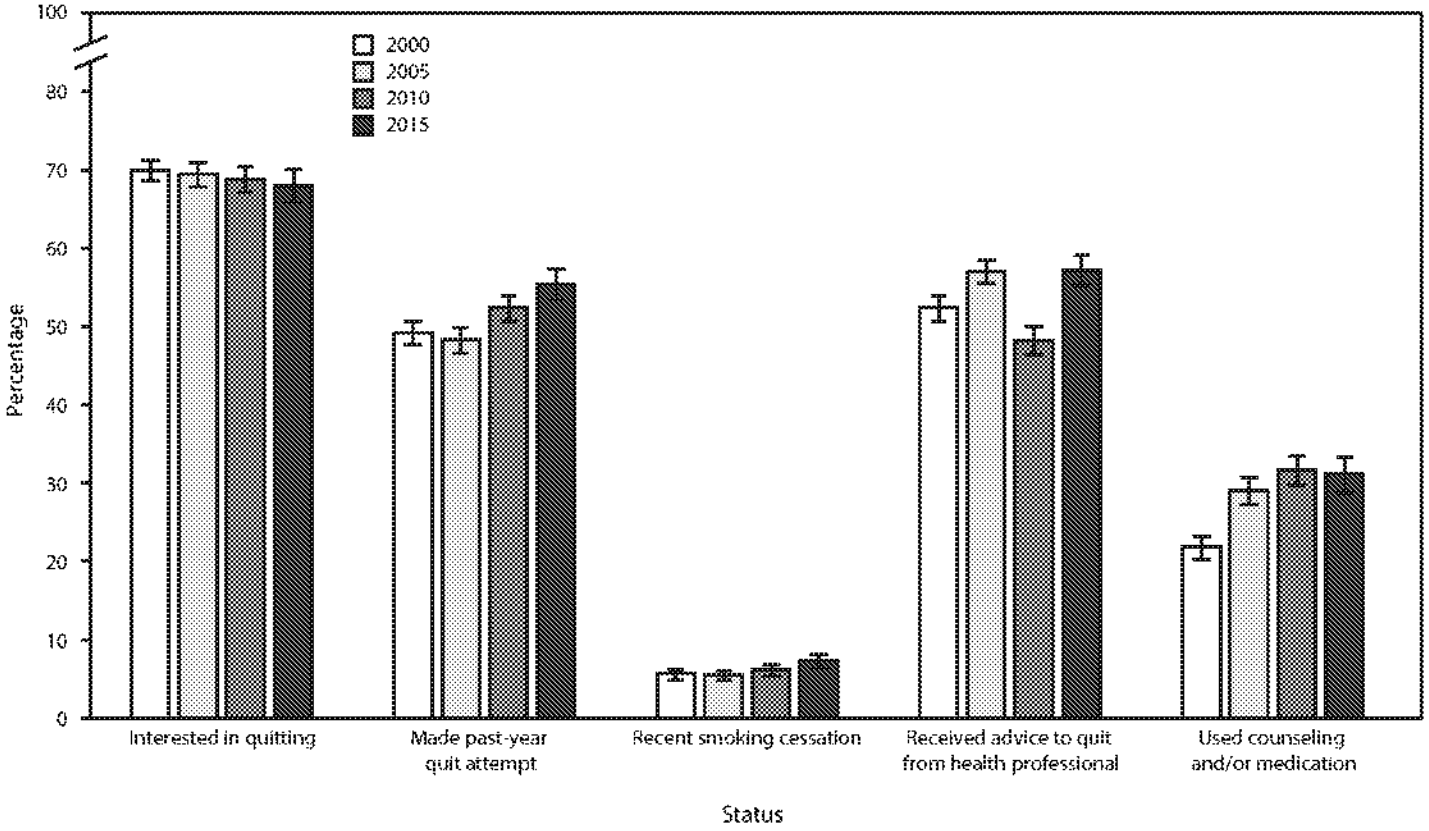
Among smokers who made quit attempts, 6.8% reported using counseling, 29.0% medication, and 4.7% both. Among smokers who used counseling, 4.1% used a telephone quitline, 2.8% used one-on-one counseling, and 2.4% used a stop smoking clinic, class, or support group. Among smokers who used medications, 16.6% used a nicotine patch, 12.5% used nicotine gum or lozenges, 7.9% used varenicline, 2.7% used bupropion, and 2.4% used nicotine spray or inhaler.

Discussion

In 2015, approximately two thirds of cigarette smokers were interested in quitting, and slightly more than half reported receiving advice to quit from a health professional and making a past-year quit attempt. However, fewer than one third of smokers who tried to quit used proven cessation treatments, and fewer than one in 10 smokers overall quit successfully in the past year. Approximately three in five adults who had ever smoked had quit. To enhance cessation rates, it is critical for health care providers to consistently identify smokers, advise them to quit, and offer evidence-based cessation treatments, and for insurers to cover and promote the use of these treatments and remove barriers to accessing them (*2–6*).

During 2000–2015, modest but statistically significant increases occurred in the prevalence of past-year quit attempts

FIGURE. Prevalence of and change* in interest in quitting,† past-year quit attempt,§ recent smoking cessation,¶ receiving a health professional's advice to quit smoking, and use of counseling and/or medication for cessation†† among adult smokers aged ≥18 years — National Health Interview Survey, United States 2000–2015**



* Based on linear and quadratic trend analyses using logistic regression models controlling for sex, race/ethnicity, and age, p <0.05. There was no change for "interested in quitting," a quadratic trend for "made past-year quit attempt," a linear trend for "recent smoking cessation," a quadratic trend for "received advice to quit from health professional," and a quadratic trend for "used counseling and/or medication."

† Current smokers who reported that they wanted to stop smoking completely.

§ Current smokers who reported that they stopped smoking for >1 day in the past 12 months because they were trying to quit smoking and former smokers who quit in the past year.

¶ Former smokers who quit smoking for ≥6 months in the past year, among current smokers who smoked for ≥2 years and former smokers who quit in the past year.

** Received advice from a medical doctor, dentist, or other health professional to quit smoking or to quit using other kinds of tobacco, among current and former cigarette smokers who quit in the past 12 months. The analysis was limited to current and former cigarette smokers who had seen a doctor or other health professional in the past year.

†† For 2010 and 2015, used one-on-one counseling, a stop smoking clinic, class, or support group, and/or a telephone help line or quitline; and/or the nicotine patch, nicotine gum or lozenge, nicotine-containing nasal spray or inhaler, varenicline (U.S. trade name Chantix) and/or bupropion (including trade names Zyban and Wellbutrin) in the past year among current smokers who tried to quit in the past year or used when stopped smoking among former smokers who quit in the past 2 years. For 2005, the list included a nicotine tablet and excluded varenicline, as it was not approved by the Food and Drug Administration until 2006. For 2000, the list included a stop smoking program and excluded a stop smoking class or support group, nicotine lozenge (not approved by the Food and Drug Administration until 2002), and varenicline.

(from 49.2% to 55.4%), recent smoking cessation (5.7% to 7.4%), receipt of health professional advice to quit smoking (52.4% to 57.2%), and use of cessation counseling and/or medication (21.9% to 31.2%). However, recent smoking cessation remains low, and little progress has been made since 2005 toward increasing receipt of advice to quit and use of counseling and/or medication. Use of cessation counseling and medication increases quit rates, especially when they are combined (*2,3,7*): combined behavioral and pharmacotherapy interventions increase cessation by 82%, compared with minimal intervention or usual care (*7*). Use of cessation medications is appropriate for most adult smokers, with the exception of pregnant women, light smokers (i.e., persons who smoke < 5-10 cigarettes daily), and persons with specific medical contraindications (*2,3*). The low prevalence of recent cessation likely is related in part to low use of evidence-based cessation treatments. Because approximately 70% of smokers see a physician annually, and even brief physician advice to quit increases quit rates (*2*), opportunities exist to increase cessation rates through health care system changes and other population-based strategies (*2–4*).

TABLE 2. Prevalence of receiving a health professional's advice to quit smoking,* and use of counseling† and medication§ for cessation among adult smokers aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2015

Characteristic	Received health professional's advice to quit % (95% CI)	Used counseling % (95% CI)	Used medication % (95% CI)	Used counseling and/or medication % (95% CI)
Overall	**57.2 (55.3–59.1)**	**6.8 (5.7–7.9)**	**29.0 (26.8–31.2)**	**31.2 (28.9–33.5)**
Sex				
Men	55.2 (52.5–57.9)	5.8 (4.3–7.4)	27.0 (24.0–30.0)	29.1 (26.0–32.2)
Women	59.3 (56.6–61.9)	7.9 (6.4–9.5)	31.3 (28.2–34.3)	33.6 (30.5–36.6)
Age group (yrs)				
18–24	44.4 (37.1–51.6)	—¶	15.6 (9.5–21.7)	16.8 (10.6–23.0)
25–44	49.8 (46.6–53.0)	6.1 (4.5–7.8)	25.5 (22.2–28.7)	27.4 (24.1–30.8)
45–64	65.7 (62.9–68.4)	8.8 (6.9–11.1)	37.7 (34.0–41.4)	40.2 (36.4–43.9)
≥65	65.7 (61.4–70.0)	9.2 (5.3–13.1)	33.7 (27.7–39.7)	37.0 (31.0–43.1)
Race/Ethnicity**				
White, non-Hispanic	60.2 (58.0–62.4)	6.9 (5.5–8.3)	32.6 (29.8–35.4)	34.3 (31.4–37.2)
Black, non-Hispanic	55.7 (50.2–61.1)	7.6 (4.5–10.8)	25.2 (20.1–30.3)	28.9 (23.5–34.4)
Hispanic	42.2 (37.0–47.5)	5.1 (2.4–7.7)	16.6 (12.4–20.9)	19.2 (14.4–24.0)
AI/AN, non-Hispanic	38.1 (21.4–54.8)	—¶	—¶	—¶
Asian, non-Hispanic††	34.2 (24.2–44.3)	—¶	17.4 (9.4–25.4)	20.5 (12.2–28.8)
Multiple race, non-Hispanic	69.6 (59.2–80.1)	—¶	22.1 (10.5–33.6)	24.6 (12.7–36.4)
Education§§				
≤12 yrs (no high school diploma)	60.8 (56.6–65.1)	5.4 (3.1–7.6)	26.5 (21.8–31.2)	28.7 (23.8–33.6)
GED certificate	61.6 (52.4–70.7)	—¶	30.8 (21.5–40.1)	31.4 (22.0–40.7)
High school diploma	58.1 (53.9–62.3)	7.0 (4.7–9.4)	30.3 (25.5–35.1)	33.1 (28.1–38.1)
Some college (no degree)	59.1 (55.3–63.0)	8.6 (6.0–11.1)	32.5 (28.1–36.9)	34.6 (30.1–39.2)
Associate degree	61.6 (56.4–66.8)	8.6 (5.1–12.2)	33.2 (27.4–39.0)	36.0 (29.8–42.3)
Undergraduate degree	52.6 (46.6–58.5)	7.4 (3.7–11.1)	33.2 (26.5–39.8)	35.1 (28.4–41.7)
Graduate degree	57.7 (48.5–66.8)	—¶	32.8 (22.9–42.6)	35.9 (25.7–46.0)
Poverty status¶¶				
At or above poverty level	57.8 (55.6–60.1)	6.8 (5.6–8.1)	29.5 (27.1–31.8)	31.7 (29.2–34.2)
Below poverty level	54.7 (50.7–58.7)	6.7 (4.6–8.9)	27.0 (21.6–31.6)	29.0 (24.2–33.7)
U.S. Census regions***				
Northeast	65.1 (60.2–70.1)	8.2 (4.9–11.5)	34.7 (27.9–41.5)	37.6 (30.9–44.2)
Midwest	60.0 (56.1–63.9)	4.9 (3.0–6.8)	28.9 (24.9–32.8)	30.2 (26.1–34.4)
South	55.2 (52.2–58.2)	7.2 (5.3–9.0)	27.2 (23.8–30.6)	29.3 (25.7–33.0)
West	50.6 (46.9–54.4)	7.5 (5.1–9.9)	28.0 (23.1–32.8)	30.7 (25.5–35.9)
Health insurance coverage†††				
Private	56.8 (54.0–59.5)	6.8 (5.3–8.3)	29.9 (27.0–32.7)	32.1 (29.1–35.1)
Medicaid and dual eligibles§§§	59.9 (55.7–64.1)	8.0 (5.3–10.7)	32.2 (27.3–37.2)	34.5 (29.3–39.6)
Medicare-Advantage	66.6 (56.5–76.6)	—¶	26.5 (15.5–37.4)	31.6 (19.7–43.4)
Medicare-only (excluding Advantage)	62.0 (51.7–72.3)	—¶	28.5 (15.5–41.5)	35.9 (22.6–49.1)
Other coverage	69.2 (62.8–75.7)	5.2 (2.7–7.7)	34.9 (26.2–43.6)	36.0 (27.3–44.7)
Uninsured	44.1 (38.8–49.3)	4.3 (2.2–6.4)	20.0 (15.6–24.6)	21.4 (17.0–25.8)
Disability/Limitation¶¶¶				
Yes	71.8 (67.4–76.2)	12.6 (8.3–16.9)	35.7 (29.1–42.3)	39.0 (32.1–45.9)
No	53.6 (50.5–56.8)	5.1 (3.8–6.4)	26.3 (22.9–29.6)	28.5 (25.1–31.9)

See table footnotes on page 1463.

Observed disparities were consistent with those reported in previous studies (*8*). In 2015, smokers who were aged <45 years, Hispanic, Asian, with an Associate's or higher degree, lived in the Northeast, had private health insurance, or had no serious psychological distress met the *Healthy People 2020* target for recent cessation (≥8.0%). Disparities in cessation behaviors by race/ethnicity might be partly explained by differences in tobacco use behaviors, health care utilization, access to cessation treatments, and knowledge about these treatments (*1,2,4*). Disparities by insurance status in receipt of advice to quit (44.1% for uninsured smokers versus 56.8% for smokers with private insurance), use of cessation counseling and/or medication (21.4% for uninsured smokers versus 32.1% for smokers with private insurance), and recent cessation (5.2% for uninsured smokers versus 9.4% for smokers with private insurance) are likely attributable, in part, to a lack of access to cessation treatments among the uninsured (*2,4,5*). Higher prevalence of receiving a health professional's advice to quit and use of counseling and/or medication among smokers with serious psychological distress might be related to greater use

TABLE 2. (*Continued*) Prevalence of receiving a health professional's advice to quit smoking,* and use of counseling† and medication§ for cessation among adult smokers aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2015

Characteristic	Received health professional's advice to quit % (95% CI)	Used counseling % (95% CI)	Used medication % (95% CI)	Used counseling and/or medication % (95% CI)
Serious Psychological Distress (Kessler Scale)****				
Yes (Kessler score ≥13)	70.2 (64.5–75.8)	12.4 (6.3–18.4)	40.1 (32.5–47.8)	41.6 (33.7–49.5)
No (Kessler score <13)	55.7 (53.7–57.7)	6.3 (5.3–7.4)	27.9 (25.6–30.1)	30.1 (27.8–32.5)
**Sexual orientation†††† **				
Straight	57.1 (55.1–59.1)	6.9 (5.7–8.0)	29.4 (27.2–31.7)	31.7 (29.3–34.1)
Gay/Lesbian/Bisexual	57.7 (48.5–66.9)	—¶	14.4 (7.8–21.0)	14.5 (7.9–21.1)

Abbreviations: AI/AN = American Indian/Alaska Native; CI = confidence interval; GED = General Educational Development.

* Received advice from a medical doctor, dentist, or other health professional to quit smoking or to quit using other kinds of tobacco, among current and former cigarette smokers who quit in the past 12 months. The analysis was limited to current and former cigarette smokers who had seen a doctor or other health professional in the past year.

† Used one-on-one counseling, a stop smoking clinic, class, or support group, and/or a telephone help line or quitline during the past year among current smokers who tried to quit during the past year or used when stopped smoking among former smokers who quit during the past 2 years.

§ Used nicotine patch, nicotine gum or lozenge, nicotine-containing nasal spray or inhaler, varenicline (U.S. trade name Chantix), and/or bupropion (including trade names Zyban and Wellbutrin) during the past year among current smokers who tried to quit during the past year or used when stopped smoking among former smokers who quit during the past 2 years.

¶ Data not reported because sample size is <50 or the relative standard error of the estimate is >30%.

** Excludes 63 respondents of non-Hispanic unknown race. Hispanics can be of any race.

†† Does not include Native Hawaiians or Other Pacific Islanders.

§§ Among persons aged ≥25 years. Excludes 144 persons whose education level was unknown.

¶¶ Family income was reported by the family respondent, who might or might not be the same as the sample adult respondent from whom smoking information was collected. Missing values were imputed. Because the weighted Census poverty thresholds for 2014 were not available when the 2015 National Health Interview Survey (NHIS) instrument was created, the poverty thresholds used in the 2015 NHIS were estimated from several sources: weighted average Census poverty thresholds from 2013; the average Consumer Price Index from 2013; actual Consumer Price Index values for January–July 2014; and projected Consumer Price Index values for August–December 2014.

*** *Northeast:* Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. *Midwest:* Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. *South:* Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. *West:* Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

††† Health insurance coverage was from NHIS-recoded data using a hierarchal assignment. Excludes 155 persons whose coverage was unknown.

§§§ A secondary analysis found that the prevalence of reported cessation behaviors for Medicaid enrollees did not change substantially when persons with dual Medicaid/Medicare eligibility were removed from the Medicaid coverage category.

¶¶¶ Based on proxy or self–reported presence of selected impairments, including vision, hearing, cognition, and movement and limitations in performing activities of daily living and instrumental activities of daily living. Limitations in performing activities of daily living was defined based on response to the question "Does [person] have difficulty dressing or bathing?," and limitations in performing instrumental activities of daily living was defined based on response to the question, "Because of a physical, mental, or emotional condition, does [person] have difficulty doing errands alone, such as visiting a doctor's office or shopping?" Any disability/limitation was defined as a "yes" response pertaining to at least one of the disabilities/limitations listed (i.e., vision, hearing, cognition, movement, activities of daily living, or instrumental activities of daily living). In 2015, the American Community Survey questions were asked of a random half of the respondents from the 2015 Person File. Excludes four persons whose disability status was unknown.

**** The Kessler Psychological Distress Scale is a series of six questions that asks about feelings of sadness, nervousness, restlessness, worthlessness, hopelessness, and feeling like everything is an effort during the past 30 days. Participants were asked to respond on a Likert Scale ranging between 'None of the Time' (score = 0) and 'All of the time' (score = 4). Responses were summed over the six questions; respondents with a score ≥13 were coded as having serious psychological distress, and respondents with a score <13 were coded as not having serious psychological distress. Excludes 1,416 persons whose psychological distress was unknown. Additional information available at https://www.cdc.gov/nchs/data/databriefs/db203.pdf.

†††† Response options were "straight, that is, not gay" for men, and "straight, that is, not gay or lesbian" for women. Excludes 1,397 persons whose sexual orientation was unknown.

of health care as well as greater tobacco dependence in this population (*1*,*4*).

Changes in the U.S. health care system could have contributed to this report's findings. By increasing the number of adults with health insurance (*9*) and requiring improved cessation coverage by commercial insurance and Medicaid (*5*), the Patient Protection and Affordable Care Act[¶] might have contributed to increases in the number of smokers who attempt to quit, use proven cessation treatments, and successfully quit (*4*,*5*). Improved cessation insurance coverage, together with new health care delivery and payment models and quality measures, might have contributed to increases in health professional advice to quit since 2010 (*4*,*5*).

The findings in this report are subject to at least three limitations. First, cigarette smoking and cessation-related measures were self-reported without validation by biochemical testing, and might be subject to social desirability bias. However, self-reported smoking status correlates with serum cotinine levels (*10*). Second, because NHIS does not include institutionalized populations and persons in the military, results are not generalizable to these groups. Finally, lower NHIS response rates might

[¶] http://housedocs.house.gov/energycommerce/ppacacon.pdf.

Summary

What is already known about this topic?

Quitting cigarette smoking benefits smokers at any age. Cessation counseling and medications each improve smokers' chances of quitting, and have an even greater effect when combined. However, use of counseling and medications remains low.

What is added by this report?

Approximately two thirds of cigarette smokers are interested in quitting, and in 2015, approximately half of smokers reported receiving advice to quit from a health professional and making a quit attempt in the past year. However, fewer than one third of smokers who tried to quit used evidence-based cessation treatments, and fewer than one in 10 smokers overall successfully quit in the past year. As of 2015, approximately three in five adults who had ever smoked had quit.

What are the implications for public health practice?

Health care professionals can help smokers quit by consistently identifying patients who smoke, advising them to quit, and offering them cessation treatments. Health insurers can help smokers quit by covering proven cessation treatments with minimal barriers and promoting their use. States can help smokers quit by implementing population-based policy interventions and anti-tobacco mass media campaigns, and by funding comprehensive state tobacco control programs, including state quitlines, at CDC recommended levels.

result in nonresponse bias. The extent to which nonresponse might have affected the results reported here is unknown.

Funding state tobacco control programs, including state quitlines, at CDC-recommended levels, increasing tobacco prices, implementing comprehensive smoke-free policies, conducting anti-tobacco mass media campaigns, and enhancing access to quitting assistance can increase tobacco cessation and reduce tobacco-related disease and death (*1*,*4*). Opportunities exist for insurers and employers to improve coverage and increase use of cessation treatments and for health systems to integrate cessation interventions into clinical care (*1*,*4*,*5*).

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[1]Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC.

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Best Practices

for Comprehensive Tobacco Control Programs

2014

National Center for Chronic Disease Prevention and Health Promotion
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Section C
Recommended Funding Levels, by State

Kansas

Program Intervention Budgets 2014

Recommended Annual Investment	$27.9 million
Deaths in State Caused by Smoking	
Annual average smoking-attributable deaths	4,400
Youth aged 0-17 projected to die from smoking	61,200
Annual Costs Incurred in State from Smoking	
Total medical	$1,128 million
State Revenue from Tobacco Sales and Settlement	
FY 2012 tobacco tax revenue	$103.9 million
FY 2012 tobacco settlement payment	$58.0 million
Total state revenue from tobacco sales and settlement	$161.9 million
Percent Tobacco Revenue to Fund at Recommended Level	**17%**

	Annual Total (Millions)		Annual Per Capita	
	Minimum	Recommended	Minimum	Recommended
I. State and Community Interventions Multiple social resources working together will have the greatest long-term population impact.	$8.4	$10.5	$2.91	$3.64
II. Mass-Reach Health Communication Interventions Media interventions work to prevent smoking initiation, promote cessation, and shape social norms.	$1.3	$1.9	$0.45	$0.66
III. Cessation Interventions Tobacco use treatment is effective and highly cost-effective.	$7.5	$11.9	$2.60	$4.12
IV. Surveillance and Evaluation Publicly funded programs should be accountable and demonstrate effectiveness.	$1.7	$2.4	$0.60	$0.84
V. Infrastructure, Administration, and Management Complex, integrated programs require experienced staff to provide fiscal management, accountability, and coordination.	$0.9	$1.2	$0.30	$0.42
TOTAL	$19.8	$27.9	$6.86	$9.68

Note: A justification for each program element and the rationale for the budget estimates are provided in Section A. The funding estimates presented are based on adjustments for changes in population and cost-of-living increases since *Best Practices — 2007* was published. The actual funding required for implementing programs will vary depending on state characteristics, such as prevalence of tobacco use, sociodemographic factors, and other factors. See Appendix E for data sources on deaths, costs, revenue, and state-specific factors.

THE TOLL OF TOBACCO IN KANSAS

Tobacco Use in Kansas

- **High school students who smoke: 7.2% [Girls: 5.2% Boys: 9.0%]**
- **High school males who smoke cigars: 10.9%**
- **High school students who use e-cigarettes: 10.6%**
- **Kids (under 18) who try cigarettes for the first time each year: 9,200**
- **Additional Kids (under 18) who become new regular, daily smokers each year: 1,500**
- **Adults in Kansas who smoke: 17.2% [Men: 18.7% Women: 15.7% Pregnant Females: 10.2%]**

Nationwide, youth smoking has declined significantly since the mid-1990s. The 2017 Youth Risk Behavior Survey (YRBS) found that the percentage of high school students reporting that they have smoked cigarettes in the past month decreased to 8.8 percent in 2017, the lowest level since this survey began in 1991. The high school smoking rate has declined by a remarkable 76 percent since peaking at 36.4 percent in 1997. The 2017 National Youth Tobacco Survey, using a different methodology than the YRBS, found that 7.6% of high school students smoke cigarettes. 13.9 percent of U.S. adults currently smoke, significantly less than the 18.9 percent in 2011.

Deaths in Kansas From Smoking

- **Adults who die each year in Kansas from their own smoking: 4,400**
- **Proportion of cancer deaths in Kansas attributable to smoking: 28.6%**
- **Kansas kids who have lost at least one parent to a smoking-caused death: 2,300**
- **Kids alive in state today who will ultimately die from smoking: 61,000 (given current smoking levels)**

Nationally, smoking alone kills more people each year than alcohol, AIDS, car crashes, illegal drugs, murders, and suicides combined. For every person who dies from smoking, at least 30 more are suffering from serious smoking-caused disease and disability.

Tobacco-Related Monetary Costs in Kansas

- **Annual health care expenditures in the State directly caused by tobacco use: $1.12 billion**
  - **State Medicaid program's total health expenditures caused by tobacco use: $237.4 million**
- **Estimated annual health care expenditures in Kansas from secondhand smoke exposure: $60.5 million**
- **Citizens' state/federal taxes to cover smoking-caused gov't costs: $758/household**
- **Smoking-caused productivity losses in Kansas: $1.09 billion**

The above productivity loss is from smoking-death-shortened work lives, alone. Even larger productivity losses come from smoking-caused work absences, on-the-job performance declines, and disability-shortened productive work lives. Other non-health costs caused by tobacco use include direct residential and commercial property losses from smoking-caused fires and smoking-caused cleaning and maintenance costs.

Tobacco Industry Advertising and Other Product Promotion

- **Estimated portion spent in Kansas each year: $76.3 million**

Research has found that kids are three times more sensitive to tobacco advertising than adults and are more likely to be influenced to smoke by cigarette marketing than by peer pressure, with one-third of underage smoking experimentation attributable to tobacco company marketing.

Kansas Government Policies Affecting The Toll of Tobacco in Kansas

- **Annual State tobacco prevention spending from tobacco settlement and tax revenues: $0.8 million [National rank: 39 (with 1 the best), based on percent of CDC recommendation. CDC recommendation: $27.9 million. Percent of CDC recommendation: 3.0%]**
- **State cigarette tax per pack: $1.29 [National rank: 33rd (average state tax is $1.75 per pack)]**

Campaign for Tobacco-Free Kids / August 21, 2018

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Sources

Youth smoking. 2017 Youth Risk Behavior Survey (YRBS). A 2013 YRBS found that 10.2% of high school students smoked. Current smoking = smoked in past month. The 2017 YRBS found that 8.8% of U.S. high school kids smoke. The 2017 National Youth Tobacco Survey (NYTS), using a different methodology than the YRBS, found that 7.6% of U.S. high school kids smoke. ***Male youth cigar smoking.*** 2017 YRBS. The 2017 National YRBS found that 10.5% of US high school males smoke cigars. The 2017 NYTS, using a different methodology than the YRBS, found that 9.0% of high school males smoke cigars. ***Youth e-cigarette use.*** 2017 YRBS. The 2017 National YRBS found that 13.2% of U.S. high school kids use e-cigarettes. The 2017 NYTS, using a different methodology than the YRBS, found that 11.7% of U.S. high school kids use e-cigarettes. ***New youth smokers.*** Estimate based on U.S. Dept of Health & Human Services (HHS), *"Results from the 2016 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables,"* https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf with the state share of the national number estimated proportionally based on the projected number of youth smokers ages 0-17 reported in U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General,* 2014, http://www.surgeongeneral.gov/library/reports/50-years-of-progress/. ***Adult smoking.*** State: CDC, BRFSS 2016 online data: https://www.cdc.gov/brfss/brfssprevalence/index.html. Because of changes in methodology, state-specific adult smoking rates cannot be compared to data prior to 2011. National: CDC, "Early Release of Selected Estimates Based on Data from the 2017 National Health Interview Survey," June 19, 2018, https://www.cdc.gov/nchs/nhis/releases/released201806.htm#8. ***Pregnant Females.*** CDC, "Cigarette Smoking During Pregnancy: United States, 2016." NCHS Data Brief, 305, February 2018, https://www.cdc.gov/nchs/data/databriefs/db305.pdf. ***Adult deaths.*** CDC, *Best Practices for Comprehensive Tobacco Control Programs—2014,* http://www.cdc.gov/tobacco/stateandcommunity/best_practices/. Smoking-related disease and disability from CDC, *Smoking & Tobacco Use,* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#toll. ***Smoking-Attributable Cancer Deaths.*** Lortet-Tieulent, J, et al., "State-Level Cancer Mortality Attributable to Cigarette Smoking in the United States," *JAMA Internal Medicine*, published online October 24, 2016. Includes 12 smoking-related cancers (acute myeloid leukemia and cancers of the oral cavity and pharynx; esophagus; stomach; colorectum; liver; pancreas; larynx; trachea, lung, and bronchus; cervix uteri; kidney and renal pelvis; and urinary bladder. ***Lost Parents.*** Leistikow, B, et al., "Estimates of Smoking-Attributable Deaths at Ages 15-54, Motherless or Fatherless Youths, and Resulting Social Security Costs in the United States in 1994," *Preventive Medicine* 30(5):353-360, May 2000, and state-specific data from author. ***Projected youth smoking deaths.*** HHS, *The Health Consequences of Smoking: 50 Years of Progress, A Report of the Surgeon General,* 2014, http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html.

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Related Campaign for Tobacco-Free Kids Fact Sheets, available at:
http://www.tobaccofreekids.org or https://www.tobaccofreekids.org/us-resources.

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CONTENTS

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TABLE 57. Percentage of high school students who currently smoked cigarettes,* by sex, sexual identity, and sex of sexual contacts — selected U.S. sites, Youth Risk Behavior Surveys, 2017

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI†	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
State surveys																		
Alaska	10.3	(7.0–14.9)	11.1	(8.8–13.9)	10.9	(8.8–13.4)	—§	—	—	—	—	—	—	—	—	—	—	—
Arizona	6.2	(4.4–8.8)	7.5	(5.3–10.6)	7.1	(5.2–9.6)	5.4	(4.0–7.2)	19.4	(12.6–28.7)	8.2	(3.0–20.5)	—	—	—	—	—	—
Arkansas	11.7	(8.6–15.9)	14.8	(11.1–19.6)	13.7	(10.8–17.2)	11.9	(9.0–15.7)	21.5	(12.9–33.6)	20.1	(9.4–37.8)	19.4	(15.0–24.8)	28.1	(12.5–51.7)	2.5	(1.5–4.0)
California	4.6	(2.7–7.6)	6.4	(4.7–8.6)	5.4	(4.3–6.9)	5.5	(4.3–6.9)	5.4	(2.0–13.9)	6.1	(1.9–18.3)	9.5	(6.8–13.3)	13.4	(5.9–27.9)	1.1	(0.7–1.9)
Colorado	7.2	(5.4–9.5)	6.6	(4.0–10.7)	7.0	(5.3–9.2)	5.7	(3.9–8.4)	19.1	(15.2–23.6)	10.0	(5.0–19.0)	—	—	—	—	—	—
Connecticut	5.9	(4.5–7.8)	9.8	(7.1–13.5)	7.9	(6.4–9.7)	5.8	(4.2–7.9)	18.7	(14.0–24.6)	12.3	(6.7–21.5)	9.4	(6.7–13.2)	24.4	(19.4–30.2)	1.8	(1.1–2.9)
Delaware	5.2	(3.8–7.1)	7.2	(5.4–9.6)	6.2	(4.9–7.7)	5.2	(3.9–7.0)	11.0	(7.3–16.3)	11.1	(5.1–22.6)	8.6	(6.5–11.4)	15.7	(9.8–24.2)	1.5	(0.7–3.0)
Florida	4.9	(4.1–5.9)	6.5	(5.3–8.1)	5.7	(4.9–6.7)	4.6	(3.8–5.5)	12.7	(10.5–15.4)	10.1	(7.1–14.2)	8.6	(7.0–10.5)	15.8	(12.8–19.5)	1.3	(0.9–1.8)
Hawaii	5.7	(4.7–6.9)	9.3	(7.7–11.3)	8.1	(6.9–9.5)	6.1	(5.2–7.2)	15.3	(11.2–20.5)	15.5	(10.9–21.5)	11.0	(8.5–14.1)	21.4	(16.7–27.0)	1.7	(1.2–2.3)
Idaho	8.3	(6.4–10.7)	9.8	(7.6–12.6)	9.1	(7.3–11.3)	—	—	—	—	—	—	—	—	—	—	—	—
Illinois	6.5	(5.4–7.9)	8.3	(5.6–12.1)	7.6	(6.0–9.7)	6.6	(5.2–8.3)	13.9	(9.6–19.7)	5.3	(2.7–10.2)	10.8	(8.4–13.9)	21.0	(15.0–28.6)	1.8	(1.0–3.2)
Iowa	11.1	(6.8–17.6)	8.4	(5.8–12.2)	9.9	(7.4–13.2)	7.2	(5.3–9.6)	33.7	(20.7–49.7)	24.2	(10.4–46.6)	14.4	(9.5–21.3)	38.4	(22.9–56.6)	1.7	(0.6–4.5)
Kansas	5.2	(3.6–7.6)	9.0	(7.0–11.6)	7.2	(5.6–9.1)	—	—	—	—	—	—	—	—	—	—	—	—
Kentucky	14.0	(10.7–18.1)	14.3	(10.6–19.1)	14.3	(11.3–17.9)	13.0	(10.1–16.7)	24.3	(17.0–33.4)	14.6	(7.1–27.9)	22.6	(17.7–28.3)	37.8	(30.6–45.6)	4.3	(2.9–6.4)
Louisiana	11.8	(8.3–16.6)	12.4	(8.0–18.5)	12.3	(9.2–16.3)	—	—	—	—	—	—	—	—	—	—	—	—
Maine	7.1	(5.9–8.6)	9.9	(8.8–11.1)	8.7	(7.6–9.9)	7.6	(6.5–8.8)	14.7	(12.3–17.4)	12.2	(8.4–17.5)	12.2	(10.7–13.8)	23.6	(19.4–28.4)	1.8	(1.4–2.1)
Maryland	6.3	(5.8–6.8)	9.3	(8.8–9.9)	8.2	(7.8–8.6)	5.8	(5.4–6.1)	17.2	(15.7–18.7)	11.3	(9.7–13.1)	—	—	—	—	—	—
Massachusetts	3.9	(2.8–5.4)	8.7	(6.5–11.5)	6.4	(5.0–8.0)	6.1	(4.7–7.8)	7.1	(4.3–11.3)	9.4	(4.7–18.1)	10.0	(7.5–13.1)	14.5	(10.0–20.6)	1.5	(0.9–2.5)
Michigan	10.2	(6.8–15.0)	10.4	(5.4–19.2)	10.5	(6.3–16.9)	8.2	(4.6–14.4)	27.0	(14.3–44.9)	16.4	(9.9–26.0)	15.8	(9.2–25.7)	28.8	(19.6–40.1)	2.0	(0.7–5.7)
Missouri	8.1	(6.3–10.3)	10.2	(7.3–14.2)	9.2	(7.3–11.4)	—	—	—	—	—	—	—	—	—	—	—	—
Montana	11.5	(9.9–13.3)	12.3	(10.7–14.2)	12.1	(10.8–13.4)	—	—	—	—	—	—	—	—	—	—	—	—
Nebraska	7.0	(4.7–10.3)	7.4	(5.1–10.4)	7.4	(5.7–9.6)	6.3	(4.6–8.7)	19.7	(12.4–29.6)	7.0	(3.0–15.6)	12.1	(9.0–16.2)	32.0	(19.2–48.1)	1.9	(0.7–5.0)
Nevada	7.0	(4.8–10.2)	6.4	(4.5–8.9)	6.7	(5.1–8.8)	6.3	(4.6–8.5)	9.4	(6.3–13.9)	8.3	(3.1–20.2)	11.0	(7.8–15.3)	13.3	(8.0–21.2)	2.2	(1.1–4.1)
New Hampshire	6.6	(5.8–7.5)	8.7	(7.7–9.7)	7.8	(7.1–8.6)	6.8	(6.1–7.6)	13.2	(11.0–15.8)	13.7	(10.3–18.0)	11.5	(10.5–12.6)	26.6	(22.4–31.3)	1.6	(1.2–2.0)
New Mexico	9.0	(6.8–11.9)	11.9	(9.8–14.2)	10.6	(8.6–12.9)	8.7	(7.3–10.2)	19.2	(14.5–25.0)	21.1	(14.0–30.5)	16.7	(14.2–19.6)	28.0	(21.8–35.2)	2.3	(1.7–3.0)
New York	5.0	(3.7–6.7)	5.4	(4.3–6.6)	5.5	(4.5–6.6)	4.0	(2.9–5.5)	10.9	(8.9–13.3)	10.1	(7.4–13.8)	8.5	(6.2–11.5)	16.7	(12.0–22.6)	1.1	(0.5–2.1)
North Carolina	9.3	(7.8–11.1)	14.6	(11.6–18.2)	12.1	(10.2–14.3)	10.6	(8.9–12.4)	20.1	(15.4–25.7)	20.2	(12.2–31.4)	15.9	(13.6–18.6)	30.1	(21.4–40.5)	3.7	(2.6–5.3)
North Dakota	12.9	(10.3–16.1)	12.3	(9.6–15.6)	12.6	(10.5–15.1)	11.4	(9.3–14.0)	26.4	(20.5–33.2)	6.2	(2.6–14.2)	—	—	—	—	—	—
Oklahoma	11.9	(9.0–15.6)	13.1	(10.1–16.9)	12.5	(10.0–15.4)	11.7	(9.2–14.8)	20.3	(13.2–29.9)	14.1	(5.1–33.4)	20.0	(16.1–24.4)	26.4	(18.3–36.5)	2.9	(1.7–5.0)
Pennsylvania	7.7	(6.1–9.7)	9.5	(7.8–11.7)	8.7	(7.5–10.2)	7.8	(6.6–9.2)	19.9	(14.7–26.5)	4.5	(1.7–11.1)	13.1	(10.9–15.7)	27.2	(20.0–35.7)	2.0	(1.4–2.9)
Rhode Island	4.7	(3.0–7.4)	6.6	(3.9–10.9)	6.1	(4.3–8.7)	4.4	(2.5–7.7)	15.3	(7.4–29.2)	14.1	(8.6–22.4)	8.4	(4.7–14.4)	18.4	(10.0–31.6)	0.8	(0.3–2.0)
South Carolina	9.5	(6.9–13.2)	10.2	(7.8–13.3)	10.0	(8.7–11.6)	8.4	(6.8–10.3)	23.2	(15.2–33.7)	7.2	(1.8–24.8)	13.7	(11.2–16.6)	33.7	(21.7–48.2)	2.6	(1.5–4.5)
Tennessee	8.5	(6.2–11.7)	9.9	(7.6–12.9)	9.4	(7.2–12.1)	—	—	—	—	—	—	—	—	—	—	—	—
Texas	5.5	(3.7–7.9)	8.9	(7.4–10.5)	7.4	(6.2–8.7)	6.7	(5.6–8.1)	11.2	(7.0–17.4)	6.3	(3.5–10.9)	11.8	(9.6–14.5)	20.3	(13.0–30.5)	0.9	(0.5–1.6)
Utah	3.0	(1.9–4.7)	4.3	(3.0–6.1)	3.8	(2.8–5.1)	—	—	—	—	—	—	—	—	—	—	—	—
Vermont	7.8	(7.3–8.3)	10.5	(9.9–11.1)	9.3	(8.9–9.7)	8.2	(7.8–8.6)	17.4	(15.8–19.1)	11.3	(9.3–13.5)	13.0	(12.4–13.7)	30.2	(27.6–32.8)	1.3	(1.1–1.6)
Virginia	5.5	(4.4–6.8)	7.3	(6.0–9.0)	6.5	(5.6–7.5)	—	—	—	—	—	—	—	—	—	—	—	—
West Virginia	10.3	(8.0–13.2)	17.7	(13.8–22.5)	14.4	(11.4–18.0)	12.1	(9.2–15.7)	34.7	(27.1–43.1)	16.0	(7.5–30.8)	19.4	(15.4–24.2)	38.4	(27.0–51.4)	3.4	(2.1–5.6)
Wisconsin	6.4	(4.8–8.6)	9.1	(7.4–11.1)	7.8	(6.6–9.3)	6.8	(5.5–8.3)	15.8	(12.2–20.2)	6.7	(2.8–15.1)	10.7	(8.7–13.1)	27.6	(18.6–39.0)	2.5	(1.5–4.1)
Median	***7.1***		***9.3***		***8.2***		***6.8***		***18.1***		***11.2***		***12.0***		***26.5***		***1.8***	
Range	***3.0–14.0***		***4.3–17.7***		***3.8–14.4***		***4.0–13.0***		***5.4–34.7***		***4.5–24.2***		***8.4–22.6***		***13.3–38.4***		***0.8–4.3***	

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI†	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
Large urban school district surveys																		
Baltimore, MD	1.3	(0.6–2.9)	6.2	(3.6–10.5)	3.8	(2.4–6.1)	2.8	(1.5–5.1)	5.5	(2.3–12.9)	6.3	(1.5–23.2)	4.0	(2.1–7.6)	9.5	(3.2–24.6)	0.0	—
Boston, MA	2.2	(1.4–3.4)	3.9	(2.6–5.7)	3.1	(2.3–4.1)	2.8	(2.0–3.9)	3.4	(1.2–9.3)	7.9	(3.4–17.6)	3.7	(2.3–5.9)	10.2	(5.5–17.9)	0.6	(0.2–1.8)
Broward County, FL	5.3	(2.5–10.7)	5.9	(3.2–10.5)	5.7	(3.6–8.7)	5.2	(2.9–9.1)	10.7	(4.7–22.3)	3.0	(0.7–12.3)	7.1	(3.7–13.3)	19.4	(9.8–34.7)	0.3	(0.0–2.6)
Chicago, IL	6.6	(4.6–9.4)	5.0	(3.1–8.1)	6.0	(4.3–8.5)	4.5	(3.1–6.6)	11.7	(7.0–18.8)	9.5	(3.8–21.9)	6.4	(3.7–10.8)	19.9	(13.7–27.8)	1.6	(0.7–3.3)
Cleveland, OH	5.7	(4.1–7.8)	7.0	(5.1–9.7)	6.7	(5.3–8.4)	5.0	(3.8–6.5)	15.0	(10.0–22.0)	12.5	(5.7–25.3)	5.4	(3.9–7.5)	16.0	(10.5–23.5)	0.9	(0.4–2.0)
DeKalb County, GA	2.2	(1.3–3.8)	5.4	(4.1–7.1)	3.8	(2.9–5.0)	2.9	(2.1–3.9)	6.2	(3.4–10.9)	5.2	(2.2–11.5)	4.5	(3.2–6.2)	13.4	(8.3–21.0)	0.7	(0.3–1.6)
Detroit, MI	1.7	(0.9–3.1)	5.1	(3.0–8.7)	3.4	(2.3–5.2)	2.0	(1.1–3.7)	9.9	(5.4–17.6)	3.3	(0.6–17.3)	3.5	(1.8–6.7)	10.6	(6.2–17.4)	0.1	(0.0–0.6)
District of Columbia	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Duval County, FL	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Ft. Worth, TX	4.5	(3.4–5.9)	6.3	(4.9–8.0)	5.5	(4.5–6.7)	4.4	(3.5–5.4)	14.5	(10.6–19.6)	5.9	(2.6–12.9)	8.7	(6.9–10.9)	20.4	(14.4–28.1)	1.2	(0.8–1.9)
Houston, TX	5.5	(4.5–6.9)	6.7	(5.2–8.6)	6.2	(5.2–7.3)	5.0	(4.1–6.2)	11.5	(8.7–15.1)	13.2	(7.8–21.5)	8.9	(7.2–11.0)	23.3	(17.6–30.1)	1.2	(0.7–2.0)
Los Angeles, CA	1.7	(1.0–2.9)	3.3	(2.7–4.1)	2.7	(2.1–3.4)	2.1	(1.7–2.6)	9.7	(3.6–23.5)	3.6	(0.7–15.3)	3.6	(2.3–5.6)	10.9	(3.8–27.4)	0.9	(0.4–2.0)
Miami-Dade County, FL	3.5	(2.6–4.8)	4.8	(3.2–7.1)	4.5	(3.5–5.8)	3.3	(2.3–4.6)	8.7	(5.8–13.1)	13.4	(6.5–25.6)	5.6	(4.2–7.4)	13.2	(8.4–20.2)	0.9	(0.3–2.5)
New York City, NY	3.4	(2.7–4.3)	6.1	(4.8–7.9)	5.0	(4.1–6.1)	3.4	(2.5–4.6)	10.3	(8.1–13.2)	8.5	(7.3–9.9)	7.1	(5.1–10.0)	16.0	(12.5–20.3)	1.0	(0.6–1.7)
Oakland, CA	2.8	(1.7–4.5)	5.6	(3.8–8.2)	4.4	(3.2–5.9)	4.1	(2.9–5.8)	7.0	(4.0–11.8)	4.4	(1.4–12.8)	6.7	(4.6–9.6)	9.3	(5.2–16.1)	1.1	(0.5–2.6)
Orange County, FL	2.0	(1.1–3.6)	5.3	(3.5–8.1)	3.9	(2.6–5.7)	3.2	(2.1–4.9)	3.9	(1.6–9.1)	14.5	(7.0–27.5)	5.5	(3.7–8.3)	9.2	(4.0–19.5)	1.1	(0.5–2.8)
Palm Beach County, FL	2.9	(1.8–4.4)	4.5	(3.2–6.3)	3.8	(2.8–5.0)	2.6	(1.8–3.8)	10.2	(6.3–16.0)	9.8	(4.8–19.0)	5.6	(4.0–7.9)	14.0	(8.8–21.5)	0.2	(0.1–0.9)
Philadelphia, PA	2.9	(1.8–4.7)	4.1	(2.1–7.9)	3.5	(2.3–5.3)	2.8	(2.0–4.0)	5.1	(2.1–11.7)	15.0	(4.4–40.6)	3.4	(2.2–5.1)	14.3	(5.5–32.1)	1.0	(0.4–2.4)
San Diego, CA	4.0	(3.1–5.2)	4.4	(3.1–6.1)	4.2	(3.4–5.2)	4.1	(3.3–5.1)	6.1	(3.7–9.8)	1.8	(0.3–9.0)	6.9	(5.5–8.6)	8.1	(4.5–14.3)	0.9	(0.4–1.8)
San Francisco, CA	3.9	(2.9–5.2)	5.2	(4.0–6.7)	4.7	(3.8–5.9)	4.0	(3.2–5.1)	11.0	(6.8–17.3)	6.8	(3.7–12.3)	7.4	(5.7–9.6)	18.1	(10.9–28.4)	1.5	(1.0–2.4)
Shelby County, TN	2.4	(1.5–3.8)	4.1	(2.8–6.1)	3.4	(2.4–4.8)	2.2	(1.4–3.4)	8.8	(4.9–15.2)	11.2	(5.0–23.3)	3.7	(2.4–5.6)	8.6	(4.5–15.8)	0.9	(0.4–2.1)
Median	***2.9***		***5.2***		***4.2***		***3.3***		***9.7***		***7.9***		***5.6***		***13.4***		***0.9***	
Range	***1.3–6.6***		***3.3–7.0***		***2.7–6.7***		***2.0–5.2***		***3.4–15.0***		***1.8–15.0***		***3.4–8.9***		***8.1–23.3***		***0.0–1.6***	

* On at least 1 day during the 30 days before the survey.
† 95% confidence interval.
§ Not available.

TABLE 67. Percentage of high school students who currently used an electronic vapor product,* by sex, sexual identity, and sex of sexual contacts — selected U.S. sites, Youth Risk Behavior Surveys, 2017

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI†	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
State surveys																		
Alaska	16.4	(13.5–19.7)	15.1	(12.3–18.2)	15.7	(13.6–18.1)	—§	—	—	—	—	—	—	—	—	—	—	—
Arizona	13.1	(10.0–16.9)	18.9	(13.6–25.6)	16.1	(12.2–20.9)	14.3	(10.5–19.1)	30.8	(21.9–41.4)	7.6	(2.7–19.9)	—	—	—	—	—	—
Arkansas	10.2	(7.0–14.7)	17.2	(13.5–21.7)	13.9	(11.1–17.2)	12.5	(9.3–16.7)	24.4	(17.6–32.7)	13.7	(4.5–35.1)	20.3	(14.8–27.3)	26.6	(15.1–42.4)	2.9	(1.4–5.7)
California	15.2	(11.6–19.7)	19.1	(16.1–22.5)	17.3	(15.0–19.9)	17.3	(14.6–20.4)	20.0	(13.6–28.4)	10.1	(4.1–22.7)	28.9	(24.1–34.1)	28.2	(17.7–41.7)	7.1	(4.8–10.5)
Colorado	26.0	(20.6–32.1)	26.1	(20.4–32.7)	26.2	(21.0–32.1)	27.2	(21.5–33.7)	29.6	(21.6–39.1)	21.3	(14.8–29.7)	—	—	—	—	—	—
Connecticut	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Delaware	12.6	(10.3–15.3)	14.8	(12.5–17.5)	13.6	(12.0–15.4)	13.1	(11.2–15.3)	17.5	(11.9–25.0)	14.0	(7.3–25.2)	19.8	(17.0–22.9)	23.2	(15.4–33.3)	5.3	(3.6–7.7)
Florida	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Hawaii	22.0	(20.2–23.9)	28.2	(25.1–31.5)	25.5	(23.5–27.5)	23.7	(21.6–25.8)	34.8	(30.2–39.6)	21.2	(15.2–28.8)	39.6	(36.2–43.0)	46.9	(39.4–54.6)	11.9	(9.9–14.2)
Idaho	12.6	(10.0–15.6)	16.0	(12.8–19.9)	14.3	(11.7–17.3)	—	—	—	—	—	—	—	—	—	—	—	—
Illinois	11.9	(8.6–16.2)	14.1	(10.3–19.0)	13.2	(10.0–17.4)	12.4	(9.1–16.6)	22.8	(17.2–29.5)	6.1	(2.9–12.6)	20.0	(15.1–26.0)	34.9	(26.9–43.8)	4.4	(2.4–8.0)
Iowa	8.2	(4.1–15.9)	9.4	(5.6–15.4)	9.0	(5.5–14.5)	8.2	(4.5–14.3)	19.9	(10.1–35.5)	5.3	(1.1–22.7)	12.0	(5.9–22.9)	30.4	(22.1–40.1)	3.5	(1.7–7.1)
Kansas	7.5	(5.9–9.4)	13.6	(10.5–17.3)	10.6	(8.7–12.9)	—	—	—	—	—	—	—	—	—	—	—	—
Kentucky	11.3	(8.9–14.4)	16.4	(13.0–20.5)	14.1	(11.7–16.8)	13.2	(11.2–15.6)	23.2	(14.6–34.8)	9.9	(3.5–25.2)	22.3	(18.8–26.1)	32.0	(22.8–42.7)	4.3	(2.9–6.4)
Louisiana	9.7	(7.4–12.5)	14.1	(10.8–18.4)	12.2	(9.9–15.0)	—	—	—	—	—	—	—	—	—	—	—	—
Maine	13.1	(11.6–14.8)	18.2	(16.3–20.2)	15.8	(14.4–17.4)	15.5	(14.0–17.2)	17.6	(15.3–20.1)	16.5	(12.8–21.0)	24.9	(22.7–27.1)	29.0	(25.5–32.7)	4.1	(3.5–4.8)
Maryland	12.1	(11.5–12.8)	14.0	(13.3–14.7)	13.3	(12.7–13.9)	11.5	(11.0–12.0)	22.0	(20.1–24.0)	13.2	(11.4–15.1)	—	—	—	—	—	—
Massachusetts	18.4	(15.7–21.5)	21.9	(18.3–25.9)	20.1	(17.4–23.1)	19.9	(17.1–23.0)	22.9	(18.6–27.8)	19.9	(11.7–31.7)	31.2	(26.6–36.3)	37.9	(31.9–44.3)	7.3	(5.9–9.0)
Michigan	13.1	(8.7–19.4)	16.3	(11.3–22.9)	14.8	(10.6–20.4)	13.5	(9.2–19.5)	24.2	(14.5–37.6)	15.1	(7.5–28.1)	23.8	(16.4–33.1)	33.6	(21.3–48.5)	4.4	(2.5–7.7)
Missouri	7.9	(5.4–11.5)	13.6	(11.4–16.2)	10.9	(8.7–13.6)	—	—	—	—	—	—	—	—	—	—	—	—
Montana	20.7	(17.7–24.1)	24.0	(21.7–26.5)	22.5	(20.2–24.9)	—	—	—	—	—	—	—	—	—	—	—	—
Nebraska	7.1	(5.1–9.7)	11.3	(8.6–14.8)	9.4	(7.4–11.7)	8.6	(6.7–11.0)	17.5	(10.4–28.0)	8.7	(3.5–19.7)	17.0	(13.1–21.7)	20.6	(12.3–32.5)	3.7	(2.5–5.4)
Nevada	14.8	(11.4–19.0)	15.8	(12.5–19.8)	15.5	(12.5–19.1)	14.8	(11.9–18.2)	19.0	(14.0–25.4)	17.3	(8.3–32.6)	25.6	(21.3–30.5)	26.1	(16.7–38.3)	5.9	(3.7–9.3)
New Hampshire	20.4	(18.9–21.9)	26.9	(24.9–28.9)	23.8	(22.4–25.2)	23.8	(22.3–25.4)	26.3	(22.9–30.1)	18.5	(14.4–23.4)	35.5	(33.4–37.8)	45.0	(40.1–49.9)	9.0	(7.9–10.4)
New Mexico	22.4	(20.2–24.9)	26.9	(23.5–30.4)	24.7	(22.2–27.4)	24.1	(21.9–26.5)	30.3	(23.9–37.6)	19.3	(14.0–25.9)	36.9	(34.0–39.9)	42.8	(37.8–48.0)	11.1	(9.5–12.9)
New York	13.7	(11.9–15.7)	14.5	(12.0–17.5)	14.5	(12.5–16.8)	12.8	(10.4–15.6)	22.2	(17.6–27.6)	19.2	(17.0–21.5)	24.2	(20.1–28.9)	36.5	(30.8–42.6)	4.7	(3.7–6.1)
North Carolina	19.8	(16.3–23.9)	24.2	(19.3–29.8)	22.1	(18.1–26.6)	21.6	(17.2–26.8)	28.9	(24.0–34.4)	14.0	(9.6–20.0)	32.2	(26.3–38.8)	39.5	(32.0–47.6)	9.0	(6.3–12.6)
North Dakota	19.0	(16.1–22.2)	22.0	(18.5–26.0)	20.6	(17.8–23.7)	20.0	(17.2–23.2)	28.7	(21.7–36.8)	11.6	(5.9–21.7)	—	—	—	—	—	—
Oklahoma	13.8	(10.5–18.0)	18.9	(14.7–23.9)	16.4	(13.2–20.0)	15.3	(12.1–19.1)	29.9	(20.5–41.3)	15.1	(5.8–34.2)	27.4	(21.4–34.4)	41.1	(29.2–54.2)	2.8	(1.7–4.6)
Pennsylvania	9.8	(8.2–11.8)	12.7	(9.8–16.3)	11.3	(9.3–13.7)	11.0	(8.7–13.7)	16.8	(12.1–22.8)	6.0	(2.6–13.3)	19.3	(15.3–24.0)	25.5	(18.2–34.6)	2.7	(1.9–4.0)
Rhode Island	17.0	(14.0–20.6)	22.3	(18.3–26.9)	20.1	(16.9–23.7)	20.1	(16.8–24.0)	21.1	(11.7–35.0)	17.7	(9.1–31.8)	29.9	(22.4–38.7)	35.6	(25.8–46.8)	9.2	(7.4–11.3)
South Carolina	9.4	(7.0–12.6)	14.0	(11.1–17.6)	11.9	(9.7–14.4)	10.3	(8.0–13.2)	21.6	(13.5–32.7)	14.7	(8.1–25.0)	17.5	(14.0–21.6)	32.7	(19.5–49.3)	3.3	(1.7–6.3)
Tennessee	8.6	(6.0–12.1)	13.8	(11.4–16.7)	11.5	(9.3–14.1)	—	—	—	—	—	—	—	—	—	—	—	—
Texas	7.0	(4.7–10.5)	13.1	(10.1–16.8)	10.3	(7.8–13.4)	9.7	(7.1–12.9)	15.3	(9.5–23.8)	4.7	(1.2–16.0)	16.7	(12.1–22.6)	22.1	(12.0–37.0)	2.4	(1.6–3.6)
Utah	7.0	(5.0–9.7)	8.1	(5.2–12.4)	7.6	(5.5–10.4)	—	—	—	—	—	—	—	—	—	—	—	—
Vermont	9.2	(8.6–9.8)	14.4	(13.7–15.1)	12.0	(11.6–12.5)	11.7	(11.2–12.2)	15.2	(13.6–16.9)	11.0	(9.1–13.3)	18.8	(18.0–19.7)	29.7	(27.0–32.4)	1.9	(1.6–2.2)
Virginia	10.8	(9.1–12.9)	12.6	(10.0–15.9)	11.8	(9.8–14.0)	—	—	—	—	—	—	—	—	—	—	—	—
West Virginia	8.9	(6.6–11.8)	19.1	(15.8–22.9)	14.3	(11.7–17.3)	13.3	(10.8–16.2)	20.6	(12.6–32.0)	12.1	(5.0–26.8)	20.5	(17.2–24.2)	29.8	(20.8–40.6)	2.8	(1.6–4.9)
Wisconsin	8.8	(6.7–11.4)	14.0	(10.8–18.1)	11.6	(9.3–14.4)	11.2	(8.9–14.1)	14.3	(9.5–20.8)	12.2	(7.0–20.5)	18.8	(15.0–23.3)	28.4	(18.3–41.2)	3.5	(2.1–5.7)
Median	***12.6***		***15.8***		***14.3***		***13.4***		***22.1***		***13.9***		***23.0***		***31.2***		***4.4***	
Range	***7.0–26.0***		***8.1–28.2***		***7.6–26.2***		***8.2–27.2***		***14.3–34.8***		***4.7–21.3***		***12.0–39.6***		***20.6–46.9***		***1.9–11.9***	

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI[†]	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
Large urban school district surveys																		
Baltimore, MD	3.7	(2.1–6.5)	5.8	(3.3–9.9)	4.8	(3.3–6.9)	3.5	(2.0–6.1)	5.6	(2.0–14.5)	1.7	(0.2–12.8)	4.5	(2.3–8.6)	9.0	(2.9–24.5)	0.9	(0.2–3.9)
Boston, MA	5.9	(4.3–8.2)	5.2	(3.5–7.5)	5.7	(4.5–7.3)	4.5	(3.4–6.0)	15.7	(9.8–24.4)	3.6	(1.0–12.8)	7.3	(5.4–9.8)	11.5	(6.3–20.0)	1.6	(0.8–3.1)
Broward County, FL	6.5	(3.6–11.3)	9.7	(6.3–14.6)	8.1	(5.8–11.3)	8.4	(6.1–11.4)	6.9	(3.2–14.1)	0.4	(0.0–3.3)	12.2	(8.5–17.3)	15.7	(7.1–31.1)	2.6	(1.0–6.2)
Chicago, IL	6.0	(3.6–9.8)	6.2	(3.9–9.6)	6.6	(4.5–9.7)	5.1	(3.2–8.0)	12.5	(7.6–20.0)	7.3	(3.2–15.6)	7.4	(4.3–12.5)	19.4	(13.4–27.3)	1.8	(0.8–4.2)
Cleveland, OH	7.8	(5.8–10.6)	8.8	(6.6–11.6)	8.5	(7.0–10.2)	7.3	(5.7–9.2)	13.9	(8.4–22.1)	9.4	(3.3–24.1)	8.6	(6.4–11.5)	16.6	(10.4–25.4)	3.1	(1.6–5.8)
DeKalb County, GA	3.1	(2.1–4.5)	9.0	(7.1–11.4)	6.1	(5.0–7.5)	4.8	(3.6–6.2)	9.5	(6.0–14.9)	13.2	(6.9–23.8)	8.2	(6.2–10.9)	14.4	(9.3–21.5)	2.3	(1.3–4.1)
Detroit, MI	4.1	(2.7–6.4)	4.9	(3.0–7.9)	4.7	(3.4–6.5)	3.1	(1.9–4.8)	13.3	(8.4–20.6)	4.3	(1.4–12.6)	4.9	(3.1–7.7)	11.5	(6.6–19.2)	2.1	(1.0–4.3)
District of Columbia	9.2	(8.2–10.2)	11.8	(10.7–13.0)	10.9	(10.2–11.7)	9.3	(8.5–10.1)	17.9	(15.5–20.5)	13.2	(10.0–17.3)	11.9	(10.7–13.3)	21.3	(18.4–24.5)	3.1	(2.5–3.9)
Duval County, FL	7.5	(6.3–9.1)	7.8	(6.4–9.6)	7.9	(6.8–9.1)	5.0	(4.2–6.1)	17.7	(13.7–22.6)	12.6	(8.1–19.2)	9.4	(7.6–11.5)	19.5	(15.3–24.6)	0.9	(0.4–1.8)
Ft. Worth, TX	5.5	(4.4–7.0)	9.0	(7.4–10.8)	7.4	(6.3–8.6)	6.3	(5.2–7.5)	18.2	(13.4–24.3)	2.6	(0.7–9.0)	11.2	(9.2–13.5)	21.1	(14.7–29.3)	2.3	(1.6–3.4)
Houston, TX	6.0	(4.9–7.3)	7.0	(5.5–8.9)	6.6	(5.5–7.9)	5.5	(4.6–6.7)	10.0	(6.6–14.8)	10.4	(4.7–21.3)	10.8	(8.7–13.3)	19.0	(13.4–26.3)	1.6	(1.0–2.4)
Los Angeles, CA	3.4	(1.8–6.3)	6.1	(5.0–7.4)	4.9	(3.6–6.6)	4.4	(3.2–6.0)	13.2	(5.6–28.1)	2.0	(0.2–15.9)	7.3	(5.2–10.0)	13.7	(6.0–28.6)	2.0	(1.0–3.9)
Miami-Dade County, FL	5.7	(4.3–7.6)	8.6	(6.8–10.9)	7.4	(6.2–8.8)	5.9	(4.7–7.4)	13.7	(9.7–18.9)	14.3	(7.1–26.9)	9.9	(7.9–12.4)	21.9	(16.1–29.2)	1.3	(0.7–2.3)
New York City, NY	15.5	(13.8–17.3)	18.3	(16.5–20.2)	17.3	(15.8–18.9)	15.4	(13.9–17.1)	28.6	(24.5–33.1)	18.7	(16.3–21.3)	26.0	(23.0–29.3)	34.7	(30.2–39.4)	8.9	(7.9–10.0)
Oakland, CA	10.5	(8.5–12.9)	11.7	(9.5–14.2)	11.2	(9.6–13.1)	10.4	(8.8–12.3)	19.0	(13.3–26.5)	10.7	(5.3–20.5)	15.9	(12.9–19.4)	22.3	(14.6–32.3)	5.0	(3.5–7.0)
Orange County, FL	6.8	(4.8–9.5)	12.0	(9.2–15.5)	9.6	(7.7–12.0)	8.4	(6.5–10.8)	11.5	(6.7–19.0)	17.6	(8.6–32.9)	15.3	(11.9–19.4)	22.8	(14.5–34.0)	3.2	(1.8–5.6)
Palm Beach County, FL	8.9	(6.7–11.7)	10.9	(8.8–13.3)	10.0	(8.5–11.7)	8.8	(7.2–10.7)	15.0	(10.0–21.7)	14.5	(7.6–26.0)	17.5	(14.4–21.0)	26.6	(18.6–36.4)	1.8	(1.1–2.9)
Philadelphia, PA	5.4	(3.3–8.5)	4.6	(2.4–8.8)	5.0	(3.1–8.1)	3.8	(2.2–6.3)	11.0	(5.8–20.1)	8.2	(2.0–28.6)	5.7	(3.5–9.1)	16.8	(7.2–34.5)	1.3	(0.7–2.6)
San Diego, CA	6.8	(5.2–8.8)	8.5	(6.8–10.6)	7.7	(6.5–9.0)	7.7	(6.4–9.3)	9.5	(5.9–14.9)	3.9	(1.4–10.4)	13.8	(11.1–17.1)	17.5	(11.7–25.3)	1.5	(0.9–2.3)
San Francisco, CA	6.8	(5.5–8.4)	7.1	(5.4–9.4)	7.1	(5.8–8.6)	6.7	(5.4–8.2)	11.1	(7.3–16.6)	5.0	(2.1–11.4)	13.2	(10.2–17.0)	22.2	(15.4–30.9)	2.6	(1.8–3.7)
Shelby County, TN	4.9	(3.4–7.1)	7.2	(5.4–9.6)	6.3	(4.8–8.2)	4.6	(3.4–6.1)	11.3	(7.3–16.9)	15.1	(8.0–26.7)	7.3	(5.4–9.7)	11.0	(6.4–18.2)	1.5	(0.7–3.2)
Median	***6.0***		***8.5***		***7.4***		***5.9***		***13.2***		***9.4***		***9.9***		***19.0***		***2.0***	
Range	***3.1–15.5***		***4.6–18.3***		***4.7–17.3***		***3.1–15.4***		***5.6–28.6***		***0.4–18.7***		***4.5–26.0***		***9.0–34.7***		***0.9–8.9***	

* Including e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens, on at least 1 day during the 30 days before the survey.
† 95% confidence interval.
§ Not available.

TABLE 75. Percentage of high school students who currently used smokeless tobacco,* by sex, sexual identity, and sex of sexual contacts — selected U.S. sites, Youth Risk Behavior Surveys, 2017

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI†	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
State surveys																		
Alaska	5.9	(3.5–9.8)	11.7	(8.0–16.8)	9.0	(6.1–12.9)	—§	—	—	—	—	—	—	—	—	—	—	—
Arizona	2.1	(1.3–3.6)	6.9	(4.6–10.2)	4.6	(3.2–6.6)	4.0	(2.4–6.4)	7.3	(3.8–13.8)	6.3	(1.4–23.9)	—	—	—	—	—	—
Arkansas	6.1	(3.0–11.9)	17.9	(13.9–22.6)	12.7	(10.1–15.8)	10.3	(8.2–12.8)	18.9	(8.8–36.1)	21.3	(9.0–42.4)	16.7	(12.9–21.3)	13.2	(8.0–21.2)	2.6	(1.4–4.8)
California	0.9	(0.3–3.0)	3.9	(2.8–5.4)	2.8	(1.9–4.2)	2.6	(1.8–3.6)	3.4	(1.3–8.4)	4.1	(0.8–17.5)	3.0	(2.0–4.6)	7.4	(3.2–16.5)	0.6	(0.1–4.4)
Colorado	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Connecticut	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Delaware	1.4	(0.8–2.5)	5.5	(4.1–7.2)	3.5	(2.7–4.4)	3.4	(2.5–4.6)	2.8	(1.2–6.1)	10.1	(4.9–19.7)	5.0	(3.6–6.8)	8.2	(4.0–16.2)	0.7	(0.2–2.2)
Florida	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Hawaii	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Idaho	2.1	(1.1–3.9)	7.3	(5.4–9.7)	4.7	(3.4–6.5)	—	—	—	—	—	—	—	—	—	—	—	—
Illinois	3.0	(2.2–4.1)	7.6	(5.2–11.0)	5.6	(3.9–7.9)	4.4	(3.1–6.1)	10.6	(7.6–14.6)	7.8	(3.5–16.8)	7.0	(4.9–10.1)	16.9	(12.1–23.1)	1.0	(0.5–2.0)
Iowa	2.9	(1.7–4.9)	9.1	(5.8–14.2)	6.2	(4.2–9.3)	5.7	(3.4–9.4)	11.2	(5.3–22.0)	6.0	(1.1–27.0)	7.8	(4.5–13.3)	13.4	(4.2–35.3)	2.7	(1.2–6.2)
Kansas	1.3	(0.7–2.4)	9.1	(7.3–11.1)	5.3	(4.3–6.4)	—	—	—	—	—	—	—	—	—	—	—	—
Kentucky	3.1	(1.8–5.3)	17.2	(14.0–20.9)	10.6	(8.9–12.6)	10.9	(9.0–13.1)	8.3	(4.5–14.6)	8.8	(3.7–19.6)	16.7	(13.6–20.4)	8.6	(4.8–15.0)	3.4	(2.2–5.3)
Louisiana	5.0	(2.9–8.6)	15.8	(11.6–21.1)	10.7	(8.1–14.2)	—	—	—	—	—	—	—	—	—	—	—	—
Maine	1.8	(1.4–2.3)	7.7	(6.7–8.8)	5.0	(4.3–5.7)	4.6	(4.0–5.4)	4.9	(3.6–6.5)	10.1	(7.4–13.7)	6.8	(5.9–7.8)	10.8	(8.7–13.4)	0.8	(0.5–1.2)
Maryland	3.2	(2.9–3.5)	8.3	(7.8–8.9)	6.2	(5.8–6.6)	4.2	(3.9–4.5)	12.7	(11.3–14.1)	10.1	(8.5–12.0)	—	—	—	—	—	—
Massachusetts	2.2	(1.6–3.1)	7.3	(5.7–9.3)	4.8	(3.9–5.8)	4.6	(3.8–5.7)	3.4	(1.7–6.7)	6.7	(2.7–15.5)	8.0	(6.3–10.2)	6.8	(3.5–12.8)	0.9	(0.5–1.6)
Michigan	1.9	(1.2–2.9)	10.4	(7.5–14.4)	6.3	(4.7–8.5)	5.7	(4.0–8.0)	9.0	(4.0–18.8)	11.4	(4.3–26.8)	9.3	(6.2–13.6)	15.8	(8.7–27.1)	1.6	(0.8–3.2)
Missouri	3.7	(2.4–5.8)	8.1	(5.9–10.9)	6.1	(4.5–8.1)	—	—	—	—	—	—	—	—	—	—	—	—
Montana	5.3	(3.9–7.2)	13.8	(12.1–15.6)	9.8	(8.5–11.2)	—	—	—	—	—	—	—	—	—	—	—	—
Nebraska	1.6	(1.0–2.7)	8.3	(6.1–11.1)	5.3	(4.0–7.0)	5.0	(3.6–6.8)	7.3	(3.4–14.9)	5.4	(1.7–15.8)	9.0	(6.5–12.3)	7.8	(3.3–17.5)	1.8	(0.9–3.3)
Nevada	1.6	(0.8–3.3)	3.8	(2.3–6.1)	3.0	(1.9–4.5)	2.1	(1.3–3.4)	4.9	(2.2–10.5)	8.3	(2.5–24.4)	4.3	(2.5–7.2)	6.2	(3.0–12.2)	0.5	(0.1–1.8)
New Hampshire	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
New Mexico	4.4	(3.3–5.7)	11.8	(9.8–14.1)	8.2	(7.1–9.4)	6.6	(5.5–7.9)	14.3	(10.1–19.9)	20.3	(14.5–27.8)	10.9	(9.1–13.1)	26.9	(21.4–33.3)	2.1	(1.4–3.2)
New York	2.5	(1.8–3.6)	5.9	(4.4–7.8)	4.6	(3.6–6.0)	2.7	(2.0–3.7)	11.9	(8.4–16.5)	10.8	(7.9–14.7)	6.6	(4.6–9.5)	16.6	(10.9–24.5)	0.4	(0.2–0.7)
North Carolina	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
North Dakota	2.7	(1.9–3.9)	12.8	(10.7–15.3)	8.0	(6.8–9.5)	8.3	(7.0–9.8)	6.6	(4.7–9.3)	6.6	(2.6–15.8)	—	—	—	—	—	—
Oklahoma	2.7	(1.5–5.0)	15.2	(12.3–18.6)	9.2	(7.6–11.1)	9.0	(7.3–11.1)	12.9	(6.7–23.5)	7.9	(2.0–27.1)	14.3	(11.7–17.5)	15.7	(7.6–29.9)	2.5	(1.5–4.2)
Pennsylvania	2.0	(1.4–2.8)	9.7	(7.4–12.5)	6.0	(4.8–7.5)	6.1	(4.7–7.8)	5.8	(3.5–9.7)	3.9	(1.6–9.1)	9.2	(6.9–12.1)	9.5	(5.8–15.4)	1.9	(1.1–3.1)
Rhode Island	1.1	(0.4–2.9)	8.0	(5.2–12.3)	5.0	(3.4–7.4)	3.7	(2.2–6.1)	6.0	(2.1–16.3)	21.2	(10.8–37.5)	7.1	(4.1–12.2)	10.6	(5.6–19.2)	0.2	(0.0–1.5)
South Carolina	2.3	(1.1–4.8)	13.7	(10.8–17.2)	8.4	(6.4–10.8)	7.4	(5.3–10.4)	10.3	(6.6–15.6)	7.5	(4.3–12.8)	11.5	(7.9–16.5)	9.7	(5.4–16.5)	1.9	(0.9–4.2)
Tennessee	2.4	(1.7–3.5)	11.6	(8.9–15.0)	7.3	(5.8–9.2)	—	—	—	—	—	—	—	—	—	—	—	—
Texas	2.4	(1.5–3.7)	7.9	(6.0–10.2)	5.4	(4.3–6.6)	5.2	(4.1–6.6)	5.0	(2.3–10.9)	3.8	(1.0–13.2)	8.1	(6.1–10.6)	7.4	(3.7–14.5)	1.2	(0.6–2.6)
Utah	1.0	(0.5–2.2)	4.5	(2.6–7.6)	3.0	(1.8–5.0)	—	—	—	—	—	—	—	—	—	—	—	—
Vermont	1.7	(1.4–2.0)	8.3	(7.8–8.9)	5.2	(4.9–5.5)	5.2	(4.9–5.5)	4.2	(3.4–5.2)	7.5	(5.9–9.5)	7.9	(7.4–8.5)	9.2	(7.7–11.0)	0.8	(0.7–1.0)
Virginia	1.1	(0.7–1.7)	7.0	(5.7–8.6)	4.2	(3.6–4.9)	—	—	—	—	—	—	—	—	—	—	—	—
West Virginia	2.8	(1.9–3.9)	19.3	(15.4–23.8)	11.5	(9.2–14.3)	11.3	(8.9–14.3)	9.6	(4.5–19.4)	15.1	(6.4–31.5)	18.7	(15.2–22.8)	11.6	(6.4–20.0)	1.7	(0.9–3.1)
Wisconsin	1.8	(0.8–3.9)	9.8	(7.2–13.4)	5.9	(4.2–8.3)	5.4	(3.8–7.7)	7.1	(3.4–14.1)	8.4	(3.8–17.6)	8.6	(5.7–12.7)	12.8	(6.1–24.6)	2.0	(1.1–3.4)
Median	***2.3***		***8.3***		***5.9***		***5.2***		***7.3***		***8.1***		***8.1***		***10.6***		***1.6***	
Range	***0.9–6.1***		***3.8–19.3***		***2.8–12.7***		***2.1–11.3***		***2.8–18.9***		***3.8–21.3***		***3.0–18.7***		***6.2–26.9***		***0.2–3.4***	

	Sex						Sexual Identity						Sex of sexual contacts					
	Female		Male		Total		Heterosexual (straight)		Gay, lesbian, or bisexual		Not sure		Opposite sex only		Same sex only or both sexes		No sexual contact	
Site	%	CI[†]	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI	%	CI
Large urban school district surveys																		
Baltimore, MD	3.7	(2.2–6.2)	7.5	(4.5–12.4)	5.8	(3.8–8.5)	2.8	(1.8–4.3)	12.5	(7.1–21.1)	6.0	(1.5–20.8)	3.7	(1.9–7.2)	17.4	(8.5–32.4)	0.1	(0.0–0.6)
Boston, MA	0.9	(0.4–2.0)	3.7	(2.3–5.7)	2.4	(1.6–3.5)	2.2	(1.4–3.4)	3.8	(1.3–10.6)	2.1	(0.5–8.2)	2.6	(1.4–4.7)	6.2	(3.1–11.8)	0.2	(0.0–1.4)
Broward County, FL	1.1	(0.4–3.5)	6.4	(3.5–11.5)	3.9	(2.3–6.5)	3.1	(1.7–5.6)	8.8	(3.0–22.8)	2.8	(0.6–11.9)	3.6	(1.5–8.0)	12.0	(4.9–26.6)	0.5	(0.1–2.3)
Chicago, IL	2.6	(1.1–5.8)	5.7	(3.8–8.4)	4.5	(2.8–7.1)	2.3	(1.6–3.4)	10.6	(5.1–20.8)	10.0	(4.5–21.0)	3.1	(1.9–5.0)	15.8	(10.4–23.2)	0.4	(0.1–1.6)
Cleveland, OH	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
DeKalb County, GA	1.3	(0.6–2.7)	5.3	(3.8–7.3)	3.4	(2.6–4.3)	2.2	(1.5–3.2)	6.9	(3.7–12.4)	8.3	(3.8–17.1)	3.5	(2.3–5.3)	9.7	(5.5–16.6)	0.9	(0.3–2.5)
Detroit, MI	2.0	(1.3–3.1)	4.7	(2.6–8.3)	3.4	(2.3–5.2)	1.9	(1.1–3.4)	8.2	(4.8–13.8)	2.6	(0.4–14.2)	2.4	(1.4–4.2)	8.2	(4.9–13.5)	0.6	(0.2–1.8)
District of Columbia	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Duval County, FL	3.2	(2.3–4.4)	7.5	(6.0–9.3)	5.9	(4.8–7.1)	2.3	(1.8–3.0)	13.0	(9.2–18.0)	16.0	(10.4–23.8)	4.9	(3.8–6.3)	10.4	(7.4–14.4)	0.1	(0.0–0.5)
Ft. Worth, TX	1.6	(1.0–2.4)	4.3	(3.2–5.6)	3.2	(2.5–4.0)	2.4	(1.8–3.1)	7.2	(4.6–11.1)	5.4	(2.6–11.1)	4.2	(3.2–5.6)	6.9	(3.7–12.6)	0.4	(0.2–0.9)
Houston, TX	2.9	(2.2–3.9)	4.5	(3.4–5.8)	3.9	(3.1–4.9)	2.6	(1.9–3.5)	8.2	(5.6–11.9)	9.2	(5.4–15.2)	4.4	(3.2–5.9)	12.9	(8.6–19.0)	0.7	(0.4–1.4)
Los Angeles, CA	2.0	(1.2–3.4)	1.6	(0.7–3.6)	1.9	(1.1–3.3)	1.6	(0.9–2.9)	5.7	(1.7–17.0)	1.7	(0.2–13.3)	2.1	(0.9–5.2)	10.8	(5.5–20.3)	0.6	(0.2–1.5)
Miami-Dade County, FL	2.0	(1.3–3.0)	4.4	(3.0–6.5)	3.6	(2.6–4.9)	2.2	(1.6–2.9)	9.2	(5.5–14.9)	16.1	(8.7–27.7)	3.3	(2.1–5.3)	10.0	(5.2–18.3)	0.8	(0.4–1.8)
New York City, NY	2.4	(1.9–3.1)	4.9	(3.9–6.0)	4.0	(3.4–4.8)	2.3	(1.9–2.8)	9.9	(7.2–13.3)	7.9	(6.4–9.7)	4.3	(3.5–5.3)	14.7	(11.2–19.1)	0.5	(0.3–0.8)
Oakland, CA	2.8	(1.9–4.1)	4.8	(3.4–6.8)	4.0	(3.1–5.3)	3.8	(2.8–5.0)	5.3	(2.1–12.9)	2.8	(0.9–8.6)	4.5	(3.0–6.7)	10.8	(6.4–17.7)	1.0	(0.4–2.2)
Orange County, FL	1.2	(0.6–2.4)	4.2	(2.7–6.5)	2.9	(2.0–4.4)	1.8	(1.1–3.0)	6.3	(2.6–14.2)	8.1	(2.9–20.3)	3.6	(2.1–6.1)	8.1	(3.8–16.4)	0.6	(0.2–2.0)
Palm Beach County, FL	2.5	(1.7–3.7)	5.5	(3.9–7.6)	4.3	(3.3–5.5)	2.1	(1.4–3.1)	13.8	(9.5–19.5)	16.4	(10.2–25.4)	4.1	(2.7–6.3)	16.3	(11.6–22.4)	0.7	(0.3–1.6)
Philadelphia, PA	0.9	(0.3–2.4)	3.7	(2.1–6.5)	2.3	(1.2–4.2)	1.2	(0.5–2.8)	7.3	(3.6–14.2)	5.0	(1.1–20.1)	1.5	(0.6–3.5)	11.5	(5.5–22.7)	0.0	—
San Diego, CA	1.5	(1.0–2.3)	2.5	(1.7–3.8)	2.1	(1.6–2.8)	1.9	(1.3–2.7)	2.9	(1.4–5.9)	3.4	(1.6–7.3)	3.3	(2.2–4.8)	4.7	(1.8–11.6)	0.3	(0.1–0.8)
San Francisco, CA	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Shelby County, TN	2.4	(1.6–3.4)	5.7	(4.2–7.7)	4.7	(3.6–6.0)	2.4	(1.7–3.4)	10.7	(7.3–15.4)	15.9	(8.9–26.8)	3.2	(2.2–4.6)	11.3	(7.2–17.3)	0.2	(0.1–0.7)
Median	***2.0***		***4.7***		***3.7***		***2.3***		***8.2***		***7.0***		***3.5***		***10.8***		***0.5***	
Range	***0.9–3.7***		***1.6–7.5***		***1.9–5.9***		***1.2–3.8***		***2.9–13.8***		***1.7–16.4***		***1.5–4.9***		***4.7–17.4***		***0.0–1.0***	

* Chewing tobacco, snuff, dip, snus, or dissolvable tobacco products (e.g., Red Man, Levi Garrett, Beech-Nut, Skoal and Skoal Bandits, Copenhagen, Camel Snus, Marlboro Snus, General Snus, Ariva and Stonewall, or Camel Orbs), not counting any electronic vapor products, on at least 1 day during the 30 days before the survey.
† 95% confidence interval.
§ Not available.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1132

[Docket No. FDA–2016–N–2527]

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products. FDA is taking this action because NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco use. Because products with higher NNN levels pose higher risks of cancer, FDA finds that establishing a NNN limit in finished smokeless tobacco products is appropriate for the protection of the public health.

DATES: Submit either electronic or written comments on the proposed rule by April 10, 2017. In accordance with 21 CFR 10.40(c), in finalizing this rulemaking FDA will review and consider all comments submitted before the time for comment on this proposed regulation has expired. If your comment is submitted after the expiration of the comment period, it will not be reviewed and considered by FDA unless you apply for, and receive, an extension of the comment period pursuant to 21 CFR 10.40(b)(3). Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by February 22, 2017, (see the "Paperwork Reduction Act of 1995" section). See section VII of this document for the proposed effective date of a final ruled based on this document.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–2527 for "Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, Tobacco Product Standard: NNN Level in Finished Smokeless Tobacco Products.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Colleen Lee, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

In Sweden, all snus manufacturers must adhere to the requirements of the Swedish Food Act. In addition, a smokeless tobacco manufacturer developed the GothiaTek voluntary standard, which establishes limits for the tobacco (*e.g.,* low-nitrosamine raw tobacco that has been air-cured or sun-cured) and other ingredients as well as the manufacturing process (Refs. 11, 4). The current GothiaTek standard for NNN and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (combined) in snus is 0.95 µg/g wet weight[2] tobacco, which would be about 2 µg/g (combined NNN and NNK) dry weight tobacco (Refs. 13, 16). Swedish snus that is made using the GothiaTek standard tends to have lower levels of toxicants, including NNN, than other smokeless tobacco products in other countries (Ref. 4).

Swedish snus is usually refrigerated by retailers to maintain its quality and taste but refrigeration is not generally required to maintain stability because modern Swedish snus production techniques achieve very low levels of microbial activity and yield no new nitrosamine formation even when held at room temperature (Ref. 11). One of the methods used to limit microbial activity is pasteurization. In this process, the leaf tobacco is ground and subjected to heat treatment. The heating is achieved by combining the tobacco with water and salt, placed in closed process blenders, and using steam to achieve temperatures up to 80 to 100 °C for several hours (Ref. 11).

In recent years, some U.S. tobacco manufacturers began introducing snus products (*e.g.,* Marlboro Snus and Camel Snus) in the United States (Ref. 17). Some of the early marketing of these tobacco products emphasized the Swedish origins of snus but there is limited data available on whether the chemical composition or manufacturing processes of these products are equivalent to Swedish snus (Refs. 4, 18, 19). Studies indicate that early versions of these snus products would not comply with the current GothiaTek standard for NNN and NNK (*i.e.,* 0.95 µg/g per wet weight combined) (Ref. 13). From the limited information available, snus manufactured in the United States appears to consist of tobacco that has been air-cured or sun-cured and is pasteurized or heat treated (Refs. 20, 21). It may contain up to 34 percent moisture and may contain some flavoring, flavoring strip, and/or sweeteners (Ref. 4, 56). It is generally sold portioned in sachets or small pouches (Ref. 4).

Unlike the relatively higher moisture content of moist snuff, dry snuff usually has a moisture content of less than 10 percent (Ref. 1). Dry snuff is a powdered tobacco product that may be used orally or nasally, although nasal use is rare in the United States (Ref. 4). Typically dry snuff is made with tobacco that has been fire-cured, fermented, and finely ground or pulverized into a powder (Refs. 1, 4). A pinch or dip of dry snuff is typically held between the cheek and gum (Ref. 1).

Chewing tobacco is sold as loose leaf, plug, or twist. It is typically fire-cured or air-cured tobacco that has been fermented or aged (Refs. 4, 1). It may be flavored and sweetened and then processed into a plug, twist, or loose leaf (Refs. 4, 1). Chewing tobacco may be chewed or held in the mouth (*i.e.,* dipped) (Ref. 5).

Dissolvable tobacco products that are smokeless tobacco products are generally made of finely ground tobacco and sold as small lozenges, sticks (toothpick), or strips (Refs. 4, 5). Such dissolvable tobacco products may be flavored and may have a moisture content ranging from 1 to 20 percent, depending on the product (Refs. 9, 22, 56). As the name suggests, a dissolvable tobacco product is placed in the mouth until it dissolves.

B. Current Prevalence and Initiation Rates

In the United States, smokeless tobacco products are predominately used by men and high school age boys. According to the 2014 National Survey on Drug Use and Health, an estimated 8.7 million (3.3 percent) Americans aged 12 and over were current (any use in the past month) smokeless tobacco users (chewing tobacco or snuff) in 2014, which is generally similar to the percentage of smokeless tobacco users estimated by this study for most years from 2002 to 2013 (Ref. 23). An estimated 6.4 percent of males over the age of 12 were current smokeless tobacco users, while only 0.3 percent of females were current users (Ref. 24 at tables 2.9B, 2.10B). Among adults, the highest prevalence of current use of smokeless tobacco was observed among young adults aged 18 to 25 at 5.6 percent (Ref. 24 at 18). According to the National Youth Tobacco Survey, in 2015, there were an estimated 1.1 million middle and high school students that reported current (past 30 day) use of chewing tobacco, snuff or dip, snus, or dissolvable tobacco products (Ref. 25). The overall level of current smokeless tobacco product usage was 6 percent among high school students, and 1.8 percent among middle school students (Ref. 25). Among youth, the prevalence of smokeless tobacco use varies by sex and race. In 2015, 10 percent of male high school students reported current use of smokeless tobacco, including snus and dissolvables, compared with 1.8 percent of female high school students (Ref. 25). Among high school students, the prevalence of current use of smokeless tobacco, including snus and dissolvables, was highest among non-Hispanic White students (7.8 percent), followed by Hispanic students (4.8 percent), and non-Hispanic Black students (1.9 percent) (Ref. 25).

An estimated 1.0 million Americans aged 12 or older used smokeless tobacco for the first time in 2014 (Ref. 24 at table 4.5B). Nearly 75 percent of these new initiates were male and about 42 percent were under age 18 when they first used a smokeless tobacco product (Ref. 24 at tables 4.6B, 4.9A). The average age at first use of smokeless tobacco among recent initiates in 2014 was 19.0 years, which was similar to the 2013 estimate (Refs. 26, 24 at table 4.13B).

IV. Rationale for Developing a Standard for NNN

A. Smokeless Tobacco is Carcinogenic

The scientific evidence demonstrates that smokeless tobacco products cause certain types of cancer, and that cancer rates are higher in regions of the world where smokeless tobacco products have higher levels of NNN. In 1986, the Surgeon General of the United States released a report finding that "users of smokeless tobacco products face a strongly increased risk of oral cancer" (Ref. 27). In 2007, IARC classified smokeless tobacco as carcinogenic to humans (Group 1), concluding that sufficient evidence in humans demonstrate that smokeless tobacco causes cancers of the oral cavity and pancreas (Ref. 1). IARC confirmed these findings of the carcinogenicity of smokeless tobacco in a 2012 review, concluding that there is sufficient evidence in both humans and experimental animal studies that smokeless tobacco causes oral, esophageal, and pancreatic cancer (Ref. 2). The Scientific Committee on Emerging and Newly Identified Health Risks (Ref. 3) was tasked by the European Commission to evaluate the cancer risks of smokeless tobacco products, with particular attention to moist snuff, which, in the European Union is available only in Sweden, in the form of snus. It concluded in its

[2] The term "wet weight" refers to the weight of tobacco as used by the consumer, while the term "dry weight" refers to the weight of tobacco after the removal of water.

2008 review that smokeless tobacco products cause esophageal and pancreatic cancer in humans and that studies in the United States demonstrate an increased risk of oral cancer among smokeless tobacco users, however, the evidence for "users of Swedish moist snuff (snus) is less clear" (Ref. 3). More recently, the National Cancer Institute (NCI), National Institutes of Health, in coordination with the Centers for Disease Control and Prevention (CDC) published a report on smokeless tobacco use and health effects in 2014, concluding that smokeless tobacco use causes oral, esophageal, and pancreatic cancer (Ref. 4).

TABLE 1—CONCLUSIONS OF AUTHORITATIVE REVIEWS ON SMOKELESS TOBACCO AND CANCER RISK

Authoritative body	Year	Conclusions
Surgeon General of the United States.	1986	"In summary, users of smokeless tobacco products face a strongly increased risk of oral cancer, particularly for the tissues that come in contact with the tobacco."
International Agency for Research on Cancer (IARC).	2007	"There is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas."
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).	2008	"STP [smokeless tobacco products] are carcinogenic to humans and the pancreas has been identified as a main target organ. All STP cause localised oral lesions and a high risk for development of oral cancer has been shown for various STP but the evidence for oral cancer in users of Swedish moist snuff (snus) is less clear."
International Agency for Research on Cancer (IARC).	2012	"There is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity, oesophagus and pancreas."
National Cancer Institute (NCI)	2014	"There is sufficient evidence that ST [smokeless tobacco] products cause addiction, precancerous oral lesions, and cancer of the oral cavity, esophagus, and pancreas, and adverse reproductive and developmental effects including stillbirth, preterm birth, and low birth weight."

B. NNN in Smokeless Tobacco Products is Carcinogenic

Smokeless tobacco products contain thousands of chemical constituents, including carcinogens such as TSNAs (Refs. 2, 1, 4). TSNAs are formed from nitrosation, a chemical reaction between tobacco alkaloids (nicotine, nornicotine, anatabine, and anabasine) and nitrosating agents such as nitrite (Refs. 28, 2). Because TSNAs are formed from tobacco alkaloids, they are only found in tobacco products (Ref. 28).

In smokeless tobacco, TSNAs are present at a level capable of causing cancer (Ref. 4). Of the five TSNAs identified in tobacco products, NNN and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) have been classified by IARC as carcinogenic to humans (Group 1) (Refs. 2, 4).[3]

The relatively high level of these carcinogens has led the World Health Organization (WHO) to call for limits on these constituents in tobacco products (Ref. 78). Tobacco science researchers have also called for the reduction of TSNAs in smokeless tobacco products due to their potential impact on the increased cancer risk associated with smokeless tobacco use (Refs. 175, 176).

1. Evidence for NNN Carcinogenicity in Animals

There is sufficient evidence to indicate NNN may act as both a local and systemic carcinogen in experimental animals. Studies have shown that NNN given by various routes of administration consistently causes oral and esophageal tumors in rats, as well as nasal cavity and tracheal tumors across multiple species, with noted route- and species-specific differences (Refs. 7, 178, 148, 59, 94, 149 through 160). Rats are more likely to develop tumors in the esophagus, oral and nasal cavity following oral or subcutaneous exposure to NNN (Refs. 7, 59, 94, 95, 148, 149) whereas mice develop tumors in lung, forestomach, and to a limited extent liver (Refs. 155, 156, 160). In hamsters, tracheal tumors and nasal cavity tumors are observed following oral or intraperitoneal exposure to NNN (Refs. 59, 151), with tracheal tumors also observed following subcutaneous exposure (Ref. 152). Studies in experimental animals also demonstrate that NNN can induce tumor formation in a dose-dependent manner. For example, in rats, a dose-dependent formation of nasal cavity tumors has been observed following subcutaneous or oral exposure (via gastric instillation) to NNN (Refs. 149, 161). In hamsters, NNN stimulates tumors of the nasal cavity, trachea and liver in a dose-dependent manner following subcutaneous exposure (Ref. 151).

Although a dose-dependent relationship between oral and esophageal tumor formation following exposure to NNN has not been extensively studied, chronic oral exposure to NNN via drinking water clearly identifies oral cavity and esophageal tissues as the major targets of tumorigenesis in animals (Refs. 7, 95). As indicated previously, sites of tumor formation following exposure to NNN are not limited to oral and esophageal tissues. Studies in experimental animals demonstrate oral exposure to NNN stimulates tumor formation in other tissues, such as nasal cavity, stomach, lung and liver (Refs. 151, 155, 156, 161, 178, 179). However, the number of tumors observed in oral and esophageal tissues are often greater than the number of tumors observed in other, non-target tissues. For example, a greater number of rats were reported to develop tumors in the esophagus compared with the lung following exposure to NNN in liquid diet (Ref. 94). Another study reported a similar trend, with esophageal and oral tumors observed in 35 and 18 percent of rats exposed to NNN via oral gavage, respectively, whereas only 5 percent of exposed animals developed lung tumors (Ref. 178). A more recent study by Balbo et al. (Ref. 7) found that 100 percent of rats treated orally with NNN in their drinking water developed malignant oral tumors. A high incidence of esophageal tumors has been consistently observed in rats following oral exposure to NNN across studies, with 83 percent of animals developing esophageal tumors following exposure via liquid diet (Ref. 94) and 60 to 100 percent of animals developing esophageal tumors following exposure via drinking water (Refs. 148, 95, 59, 7).

The high incidence of tumor formation in esophageal and oral tissue observed in experimental animal studies is consistent with what is known regarding the metabolism of NNN and subsequent DNA adduct formation in target tissues. NNN is a genotoxic carcinogen, it reacts with DNA and is assumed to exhibit proportional

[3] Section IV.D.3 explains why FDA is not proposing a product standard for NNK levels in smokeless tobacco at this time.

responses at low doses (Refs. 168, 169). The general understanding of the mechanism of action (MOA) of NNN-induced carcinogenicity centers around its metabolic activation. The metabolic activation of NNN leads to the formation of DNA and hemoglobin adducts and subsequent mutagenicity, ultimately resulting in cancer. NNN can be metabolized by 2′-hydroxylation and 5′-hydroxylation, with the 2′-hydroxylation the more predominant metabolic pathway (Ref. 8). The noted DNA adducts formed from NNN are POB–DNA via the 2′-hydroxylation pathway (Refs. 172, 173, 177) and py-py-dI via the 5′-hydroxylation pathway (Ref. 169). NNN has a chiral center at the 2′-position and exists in 2 enantiomeric forms, (*R*)–NNN and (*S*)–NNN, with (*S*)–NNN being the predominant enantiomer in smokeless tobacco products (Refs. 180, 181).

The MOA for NNN-induced carcinogenicity is supported by the pattern of mutagenesis and DNA adduct formation in target tissues following oral exposure to NNN in experimental animals. For example, NNN was found to be mutagenic in tongue, oral and esophageal tissue in mice following oral exposure via drinking water (Ref. 174). Both POB–DNA and py-py-dI adducts have been detected in the oral cavity, esophageal mucosa, nasal cavity, liver and lung of rats following exposure to NNN via drinking water (Refs. 169 through 173). Additionally, dose-dependent formation of POB–DNA adducts has been observed in oral, esophageal and nasal mucosa following oral exposure to NNN (Ref. 170), as has py-py-dI (Ref. 169). A greater number of DNA adduct formation has been also been observed in oral and esophageal tissues compared with other sites, consistent with previous findings of increased tumor formation in oral and esophageal tissues compared with other sites (Refs. 94, 178). For example, POB-adduct formation was greater in oral cavity and esophageal mucosa compared with lung or liver in rats following oral exposure to (*S*)-NNN via drinking water (Refs. 171, 172). These findings are consistent with previous reports of increased oral and esophageal tumor formation as compared with other tissues (Refs. 94, 178) and the reported high incidence of oral and esophageal tumors following oral exposure to NNN in rats (Refs. 7, 95).

Recent evidence has demonstrated target organ specificity for the carcinogenic effects of NNN and NNK in animals and in humans. As previously discussed, NNN's carcinogenic effects have been documented in the esophagus, nasal, and oral cavities when administered orally to animals (Refs. 7, 59, 95, 148), which provides some degree of concordance with effects observed at these sites in epidemiological studies (Refs. 77, 96). In contrast, NNK is known for being a powerful systemic lung carcinogen. NNK causes lung tumors in animals, including mice, rats, and hamsters, independent of the route of administration (Refs. 8, 149, 162 through 167). Even when animals are given NNK orally, a dose-dependent formation of lung tumors is observed (Refs. 164, 165, 166). Indeed, a recent study found 100 percent of animals receiving NNK via oral exposure developed lung tumors (Ref. 167). However, no oral cavity or esophageal tumors have been reported in animals exposed only to NNK (Ref. 8).

2. Evidence for NNN Carcinogenicity in Humans

Although the data on NNN exposure in humans is more limited, two recent epidemiological studies have found strong associations between NNN and cancer risk among cigarette smokers, providing evidence that increased exposure to NNN through use of certain tobacco products is associated with greater risk of head, neck, and esophageal cancer in tobacco users. In one nested case-control study among Chinese men, urinary levels of NNN in smokers were significantly associated with increased risk of developing esophageal cancer, but not lung cancer, after controlling urinary total NNAL (used to measure NNK exposure), smoking intensity and duration, alcohol consumption, and urinary cotinine (nicotine metabolite used to measure nicotine exposure) (Ref. 77). In the same cohort, total urinary NNAL was independently and significantly associated with increased risk of developing lung cancer (Ref. 183), whereas no association was observed between urinary total NNAL and esophageal cancer risk (Ref 77). In a second case-control study, mean levels of NNN were significantly higher in cases diagnosed with head and neck squamous cell carcinoma compared to matched controls, although no adjustment was made for potential confounding factors (Ref. 96). Although these studies were conducted among smokers, they support the significant role of NNN in cancer development in humans and are highly relevant to smokeless tobacco users, who have comparable levels of exposure to NNN and NNK as those of cigarette users (Refs. 97, 72, 98, 99). Moreover, these epidemiological findings support the target organ specificity and cancer risk associated with exposure to NNN (oral and esophageal) versus NNK (lung) that are observed in experimental animals (see section IV.B.1).

3. Geographic Differences in Cancer Risks From Smokeless Tobacco Use

Although there is some heterogeneity among particular study estimates, research on the association between smokeless tobacco use and oral cancer risk generally has found significant differences in risk by geographic region. For the United States, Boffetta et al. analyzed nine oral cancer risk estimates from seven independent studies that either adjusted for smoking or were restricted to never smokers and found a summary relative risk for smokeless tobacco use of 2.6 (Ref. 100). Lee and Hamling published a separate analysis that generated an overall relative risk estimate of 2.16 from all available U.S. studies (Ref. 114). The authors also generated estimates of never smoker oral cancer relative risks (a relative risk of 3.33) for 5 studies and smoking-adjusted oral cancer relative risks (a relative risk of 1.65) for 12 studies for U.S. smokeless tobacco users. Toombak, a smokeless tobacco product commonly used in Sudan, has been found to have a relative risk for oral cancer of 3.9 (Refs. 104, 4), while in India and Pakistan use of smokeless tobacco products, including pattiwala, naswar, khaini, and zarda, was associated with relative risks for oral cancer as high as 14 (Ref. 1 at table 71). In Scandinavia, increased oral cancer risks were observed in some but not all studies (Refs. 92, 188, 189, 191, 192).

The geographic variations in oral cancer risks are believed to be due to differences in product toxicant content (Ref. 100). TSNA concentrations in smokeless tobacco products vary by product and region; NNN levels are generally lowest in snus manufactured in Sweden, while NNN levels in smokeless tobacco products sold in the United States are typically higher (Refs. 11, 13, 5, 10). Many smokeless tobacco products sold elsewhere in the world, including in India and Sudan, contain even higher levels of NNN and other carcinogens than those in the United States (Refs. 206, 105). These analyses, in addition to the toxicological evidence demonstrating that NNN is a potent oral cavity and esophageal carcinogen, provide strong support for a relationship between smokeless tobacco use, NNN levels in these products, and oral cancer risk by geographic region. Thus, FDA believes that reducing NNN levels in smokeless tobacco products would reduce cancer risk.

Tobacco Product Use Among Middle and High School Students — United States, 2011–2017

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Tobacco use is the leading cause of preventable disease and death in the United States, and nearly all tobacco use begins during youth and young adulthood (*1*,*2*). CDC and the Food and Drug Administration (FDA) analyzed data from the 2011–2017 National Youth Tobacco Surveys (NYTS)* to determine patterns of current (past 30-day) use of seven tobacco product types among U.S. middle school (grades 6–8) and high school (grades 9–12) students and estimate use nationwide. Among high school students, current use of any tobacco product decreased from 24.2% (estimated 3.69 million users) in 2011 to 19.6% (2.95 million) in 2017. Among middle school students, current use of any tobacco product decreased from 7.5% (0.87 million) in 2011 to 5.6% (0.67 million) in 2017. In 2017, electronic cigarettes (e-cigarettes) were the most commonly used tobacco product among high (11.7%; 1.73 million) and middle (3.3%; 0.39 million) school students. During 2016–2017, decreases in current use of hookah and pipe tobacco occurred among high school students, while decreases in current use of any tobacco product, e-cigarettes, and hookah occurred among middle school students. Current use of any combustible tobacco product, ≥2 tobacco products, cigarettes, cigars, smokeless tobacco, and bidis did not change among middle or high school students during 2016–2017. Comprehensive and sustained strategies can help prevent and reduce the use of all forms of tobacco products among U.S. youths (*1*,*2*).

NYTS is a cross-sectional, voluntary, school-based, self-administered, pencil-and-paper questionnaire survey of U.S. middle and high school students. A three-stage cluster sampling procedure is used to generate a nationally representative sample of U.S. students attending public and private schools in grades 6–12. Briefly, primary sampling units are selected at the first stage, schools are selected at the second stage, and students are selected from intact classrooms at each grade level at the third stage. This report used data from seven NYTS waves (2011–2017). Sample sizes and response rates were 18,766, 72.7% (2011); 24,658, 73.6% (2012); 18,406, 67.8% (2013); 22,007, 73.3% (2014); 17,711, 63.4% (2015); 20,675, 71.6% (2016); and 17,872, 68.1% (2017).

Participants were asked about current (past 30-day) use of cigarettes, cigars, smokeless tobacco,† e-cigarettes,§ hookah,¶ pipe tobacco,** and bidis (small imported cigarettes wrapped in a leaf). Current use for each product was defined as use on ≥1 day during the past 30 days. "Any tobacco product use" was defined as use of one or more tobacco products in the past 30 days, and "≥2 tobacco product use" was defined as use of two or more tobacco products in the past 30 days. "Any combustible tobacco product use" was defined as use of cigarettes, cigars, hookah, pipe tobacco, and/or bidis in the past 30 days.

Data were weighted to account for the complex survey design and adjusted for nonresponse. National prevalence estimates with 95% confidence intervals and population estimates rounded down to the nearest 10,000 were computed. Current use estimates for 2017 were determined for any tobacco product, ≥2 tobacco products, any combustible tobacco product, and each tobacco product individually, overall and by selected demographics for each school level (high and middle). The

* https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm.

† Beginning in 2015, the definition of smokeless tobacco included chewing tobacco/snuff/dip, snus, and dissolvable tobacco to better reflect this class of tobacco products. Thus, estimates for individual smokeless tobacco products (chewing tobacco/snuff/dip, snus, and dissolvable tobacco) are not reported.

§ During 2011–2013, e-cigarette use was assessed by the question "In the past 30 days, which of the following products have you used on at least one day?" and the response option, "Electronic cigarettes or e-cigarettes such as Ruyan or NJOY." In 2014, current use of e-cigarettes was assessed by the question "During the past 30 days, on how many days did you use e-cigarettes such as Blu, 21st Century Smoke, or NJOY?" During 2015–2017, e-cigarette questions were preceded by an introductory paragraph defining the product. In 2015, current use of e-cigarettes was assessed by the question "During the past 30 days, on how many days did you use electronic cigarettes or e-cigarettes?" In 2016 and 2017, current use of e-cigarettes was assessed by the question "During the past 30 days, on how many days did you use e-cigarettes?"

¶ During 2011–2015, current hookah smoking was assessed by the question "In the past 30 days, which of the following products have you used on at least one day?" Hookah was the fourth or fifth response option during 2011–2013, the first option in 2014, and the fourth option in 2015. During 2016–2017, hookah questions were preceded by an introductory paragraph defining the product; current hookah smoking was assessed by the question "In the past 30 days, on how many days did you smoke tobacco in a hookah or waterpipe?"

** During 2011–2013, pipe tobacco use was assessed by the question "During the past 30 days, on how many days did you smoke tobacco in a pipe?" During 2014–2017, current use of pipe tobacco was assessed by the question "In the past 30 days, which of the following products have you used on at least one day?" and the response option "Pipes filled with tobacco (not waterpipe)." Pipe tobacco was the second response option available in 2014, the fifth option in 2015, and the second option during 2016–2017.

presence of linear and quadratic trends during 2011–2017 were assessed, adjusting for race/ethnicity, sex, and grade.[††] T-tests were performed to examine differences between 2016 and 2017. For all analyses, p-values <0.05 were considered statistically significant.

[††] A test for linear trend was significant if an overall statistically significant decrease or increase occurred during the study period. Data also were assessed for the presence of quadratic trends. A significant quadratic trend indicated that the rate of change accelerated or decelerated across the study period.

In 2017, 19.6% of high school students (estimated 2.95 million users) reported current use of any tobacco product, including 9.2% (1.38 million; 46.8% of current tobacco product users) who currently used ≥2 tobacco products, and 12.9% (1.94 million; 65.8% of current tobacco product users) who currently used any combustible tobacco product (Table). E-cigarettes were the most commonly used tobacco product among high school students (11.7%), followed by cigars (7.7%), cigarettes (7.6%), smokeless tobacco (5.5%), hookah (3.3%), pipe tobacco (0.8%), and bidis (0.7%). Smokeless

TABLE. Estimated prevalence of tobacco use among high school and middle school students in the past 30 days, by product,* school level, sex, and race/ethnicity† — National Youth Tobacco Survey, United States, 2017

	Sex		Race/Ethnicity				Total	
Tobacco product	Female % (95% CI)	Male % (95% CI)	White† % (95% CI)	Black† % (95% CI)	Hispanic % (95% CI)	Other† % (95% CI)	% (95% CI)	Estimated no. users§
High school students								
E-cigarettes	9.9 (8.0–12.1)	13.3 (11.1–15.9)	14.2 (12.2–16.5)	4.9 (3.5–6.8)	10.1 (7.0–14.4)	5.5 (3.1–9.5)	**11.7 (9.7–13.9)**	**1,730,000**
Cigarettes	7.5 (6.1–9.2)	7.6 (6.4–9.0)	9.5 (8.0–11.3)	2.8 (1.7–4.4)	6.2 (4.6–8.3)	3.8 (2.2–6.2)	**7.6 (6.5–8.9)**	**1,120,000**
Cigars	6.3 (5.0–7.8)	9.0 (7.6–10.7)	8.4 (6.9–10.0)	7.8 (5.8–10.4)	6.7 (5.1–8.6)	4.1 (2.6–6.3)	**7.7 (6.5–9.0)**	**1,130,000**
Smokeless tobacco	3.0 (2.3–4.0)	7.7 (5.9–10.0)	7.2 (5.6–9.4)	1.8 (1.2–2.8)	3.7 (2.6–5.3)	—¶	**5.5 (4.2–7.0)**	**810,000**
Hookah	3.2 (2.5–4.1)	3.3 (2.5–4.3)	2.8 (2.1–3.7)	3.1 (2.3–4.3)	4.6 (3.4–6.3)	3.3 (2.1–5.1)	**3.3 (2.7–4.0)**	**480,000**
Pipe tobacco	0.5 (0.4–0.8)	1.0 (0.8–1.4)	0.7 (0.5–1.1)	—	1.3 (0.8–2.0)	—	**0.8 (0.6–1.0)**	**120,000**
Bidis	0.6 (0.4–0.9)	0.7 (0.4–1.1)	0.5 (0.3–0.8)	—	1.1 (0.7–1.7)	—	**0.7 (0.5–1.0)**	**100,000**
Any tobacco product**	17.5 (15.2–20.1)	21.5 (18.7–24.6)	22.7 (20.3–25.4)	14.2 (11.6–17.3)	16.7 (12.9–21.4)	10.7 (7.0–16.2)	**19.6 (17.2–22.3)**	**2,950,000**
≥2 tobacco products††	7.6 (6.2–9.4)	10.7 (9.0–12.6)	11.3 (9.6–13.2)	4.4 (3.1–6.2)	8.2 (5.9–11.3)	4.0 (2.6–6.2)	**9.2 (7.8–10.9)**	**1,380,000**
Any combustible tobacco product§§	12.2 (10.4–14.2)	13.5 (11.6–15.6)	14.4 (12.4–16.5)	10.9 (8.7–13.6)	11.8 (9.2–15.1)	6.8 (4.4–10.3)	**12.9 (11.2–14.8)**	**1,940,000**
Middle school students								
E-cigarettes	2.9 (2.3–3.7)	3.7 (3.0–4.5)	3.4 (2.6–4.5)	2.2 (1.3–3.6)	4.0 (2.9–5.5)	—	**3.3 (2.8–3.9)**	**390,000**
Cigarettes	2.2 (1.7–2.9)	2.0 (1.5–2.8)	1.7 (1.3–2.4)	2.1 (1.2–3.6)	3.5 (2.6–4.7)	—	**2.1 (1.8–2.6)**	**250,000**
Cigars	1.4 (1.0–2.0)	1.6 (1.1–2.2)	1.1 (0.7–1.7)	1.9 (1.1–3.1)	2.4 (1.6–3.4)	—	**1.5 (1.2–2.0)**	**170,000**
Smokeless tobacco	1.2 (0.9–1.7)	2.4 (1.8–3.2)	1.6 (1.0–2.3)	—	3.2 (2.4–4.2)	—	**1.9 (1.5–2.4)**	**210,000**
Hookah	1.1 (0.7–1.5)	1.6 (1.1–2.4)	0.6 (0.3–1.1)	1.8 (1.1–3.1)	2.7 (1.9–3.9)	—	**1.4 (1.0–1.8)**	**150,000**
Pipe tobacco	—	—	—	—	—	—	**0.4 (0.3–0.7)**	**40,000**
Bidis	—	—	—	—	—	—	**0.3 (0.2–0.5)**	**30,000**
Any tobacco product**	4.8 (4.0–5.8)	6.4 (5.4–7.4)	5.1 (4.0–6.4)	4.9 (3.6–6.5)	7.7 (6.3–9.4)	—	**5.6 (5.0–6.4)**	**670,000**
≥2 tobacco products††	2.0 (1.6–2.6)	2.7 (2.0–3.7)	1.9 (1.4–2.7)	2.5 (1.6–3.8)	3.7 (2.7–5.0)	—	**2.4 (2.0–2.9)**	**280,000**
Any combustible tobacco product§§	3.2 (2.5–4.0)	3.5 (2.7–4.4)	2.4 (1.8–3.1)	3.9 (2.7–5.7)	5.3 (4.2–6.6)	—	**3.4 (2.8–4.0)**	**390,000**

Abbreviation: CI = confidence interval; E-cigarettes = electronic cigarettes.

* Past 30-day use of e-cigarettes was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?" Past 30-day use of cigarettes was determined by asking, "During the past 30 days, on how many days did you smoke cigarettes?" Past 30-day use of cigars was determined by asking, "During the past 30 days, on how many days did you smoke cigars, cigarillos, or little cigars?" Past 30-day use of hookah was determined by asking, "During the past 30 days, on how many days did you smoke tobacco in a hookah or waterpipe?" Smokeless tobacco was defined as use of chewing tobacco, snuff, dip, snus, and/or dissolvable tobacco products. Past 30-day use of smokeless tobacco was determined by asking the following question for use of chewing tobacco, snuff, and dip: "During the past 30-days, on how many days did you use chewing tobacco, snuff, or dip?," and the following question for use of snus and dissolvable tobacco products: "In the past 30 days, which of the following products did you use on at least one day?" Responses from these questions were combined to derive overall smokeless tobacco use. Past 30-day use of pipe tobacco (not hookah) and bidis were determined by asking, "In the past 30 days, which of the following products have you used on at least one day?"

† Blacks, whites, and others are non-Hispanic; Hispanic persons could be of any race.

§ Estimated total number of users was rounded down to the nearest 10,000 persons.

¶ Data are statistically unreliable because samples size was <50 or relative standard error was >0.3.

** Any tobacco product use was defined as use of any tobacco product (e-cigarettes, cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis) on at least one day in the past 30 days.

†† ≥2 tobacco products use was defined as use of two or more tobacco products (e-cigarettes, cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis) on at least one day in the past 30 days.

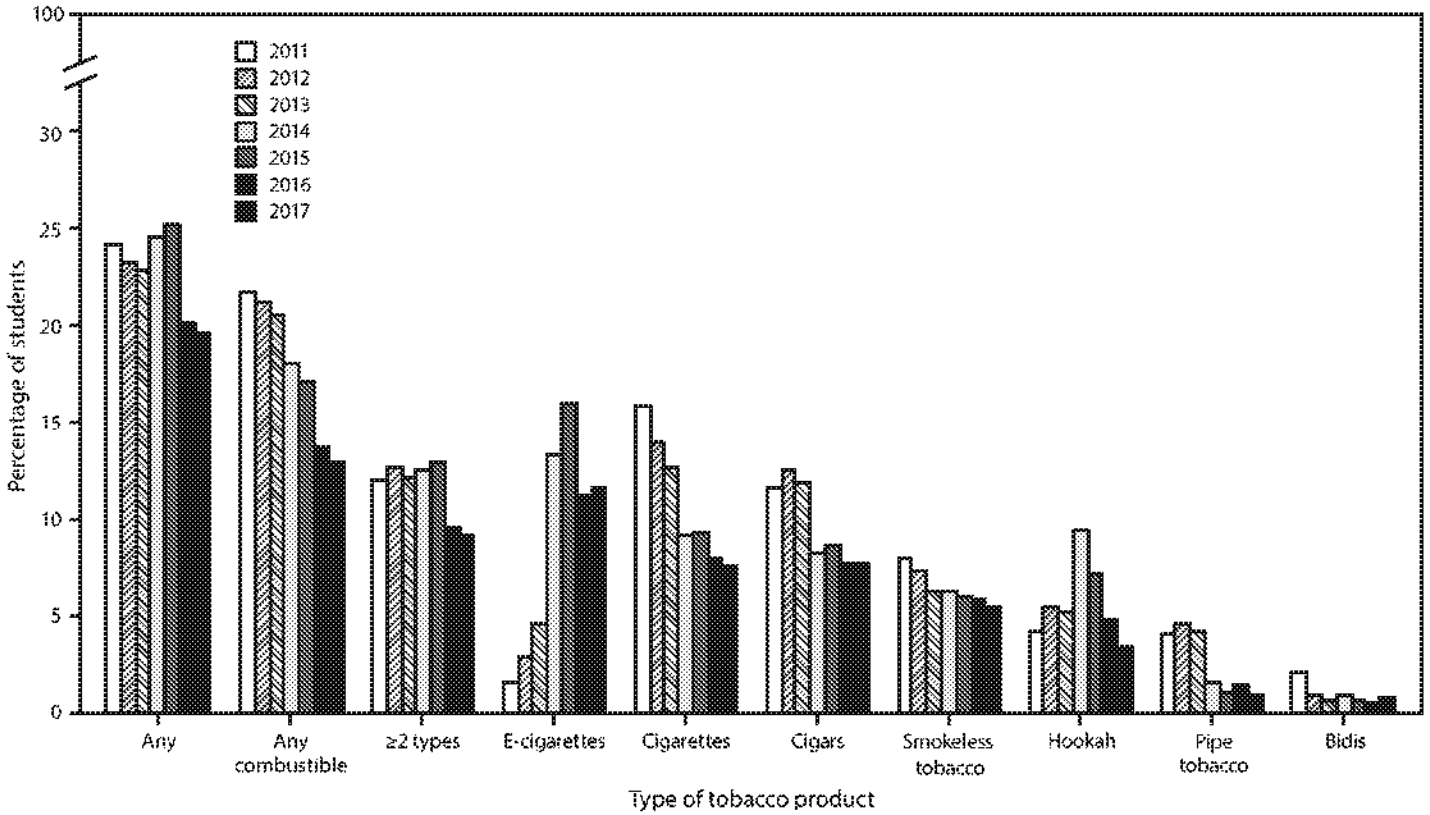
§§ Any combustible tobacco product use was defined as use of cigarettes, cigars, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

tobacco use was higher among males than among females. E-cigarettes were the most commonly used tobacco product among non-Hispanic white (white) (14.2%) and Hispanic (10.1%) high school students, whereas cigars were the most commonly used tobacco product among non-Hispanic black (black) high school students (7.8%).

Among middle school students, 5.6% (0.67 million) currently used any tobacco product, including 2.4% (0.28 million; 41.8% of current tobacco product users) who currently used ≥2 tobacco products, and 3.4% (0.39 million; 58.2% of current tobacco product users) who currently used any combustible tobacco product (Table). The most commonly used tobacco product among middle school students was e-cigarettes (3.3%), followed by cigarettes (2.1%), smokeless tobacco (1.9%), cigars (1.5%), hookah (1.4%), pipe tobacco (0.4%), and bidis (0.3%). Any tobacco product use was 6.4% among males and 4.8% among females. E-cigarettes were the most commonly used product among Hispanic (4.0%), white (3.4%), and black (2.2%) middle school students.

Among high school students, a nonlinear decrease occurred in the current use of any tobacco product from 2011 (24.2%) to 2017 (19.6%). Nonlinear decreases also occurred in the current use of ≥2 tobacco products (12.0% to 9.2%) and any combustible tobacco product (21.8% to 12.9%). By product, linear decreases occurred for cigarettes (15.8% to 7.6%), cigars (11.6% to 7.7%), and smokeless tobacco (7.9% to 5.5%); nonlinear decreases occurred for pipe tobacco (4.0% to 0.8%) and bidis (2.0% to 0.7%) (Figure 1). E-cigarette use among

FIGURE 1. Estimated percentage of high school students who currently use any tobacco product,* any combustible tobacco product,† ≥2 tobacco products,§ and selected tobacco products — National Youth Tobacco Survey, United States, 2011–2017¶,,††**



* Use of any tobacco product was defined as use of electronic cigarettes (e-cigarettes), cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

† Use of any combustible tobacco product was defined as use of cigarettes, cigars, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

§ Use of ≥2 tobacco products was defined as use of two or more of the following tobacco products: e-cigarettes, cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

¶ During 2016–2017, current use of hookah and pipe tobacco decreased significantly ($p<0.05$).

** During 2011–2017, current use of cigarettes, cigars, and smokeless tobacco exhibited linear decreases ($p<0.05$). Current use of any tobacco product, any combustible tobacco product, ≥2 types of tobacco products, pipe tobacco, and bidis exhibited nonlinear decreases ($p<0.05$). Current use of e-cigarettes exhibited a nonlinear increase ($p<0.05$). Current use of hookah exhibited a nonlinear change ($p<0.05$).

†† Beginning in 2015, the definition of smokeless tobacco included chewing tobacco/snuff/dip, snus, and dissolvable tobacco to better reflect this class of tobacco products. Thus, estimates for individual smokeless tobacco products (chewing tobacco/snuff/dip, snus, and dissolvable tobacco) are not reported. This definition was applied across all years (2011–2017) for comparability purposes.

high school students increased nonlinearly during 2011–2017 (1.5% to 11.7%).

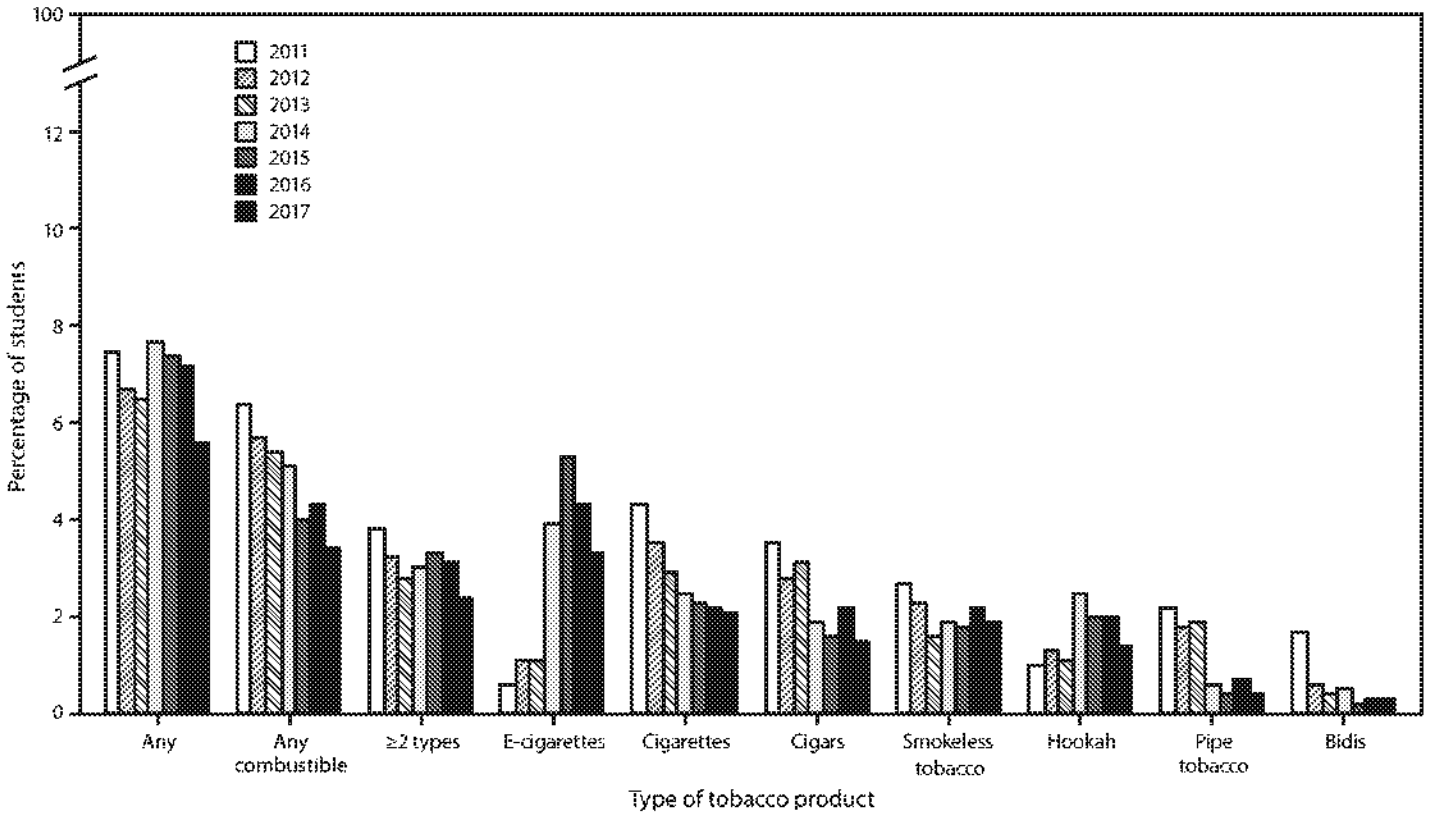
Among middle school students, linear decreases occurred in current use of any tobacco product (7.5% to 5.6%), ≥2 tobacco products (3.8% to 2.4%), and any combustible tobacco product (6.4% to 3.4%). By product, linear decreases occurred for cigars (3.5% to 1.5%), smokeless tobacco (2.7% to 1.9%), and pipe tobacco (2.2% to 0.4%); nonlinear decreases occurred for cigarettes (4.3% to 2.1%) and bidis (1.7% to 0.3%). Nonlinear increases occurred in use of e-cigarettes (0.6% in 2011 to 3.3% in 2017) and hookah (1.0% to 1.4%) among middle school students (Figure 2).

During 2016–2017, among high school students, decreases occurred in current use of hookah (4.8% to 3.3%) and pipe tobacco (1.4% to 0.8%). Among middle school students, decreases occurred in current use of any tobacco product (7.2% to 5.6%), e-cigarettes (4.3% to 3.3%), and hookah (2.0% to 1.4%).

Discussion

Among U.S. middle and high school students, the current use of any tobacco product decreased during 2011–2017. However, in 2017, approximately one in five high school students (2.95 million) and one in 18 middle school students (0.67 million) currently used a tobacco product. Since 2014, e-cigarettes have been the most commonly used tobacco product among both middle and high school students. Furthermore, approximately one in two high school students who used a

FIGURE 2. Estimated percentage of middle school students who currently use any tobacco product,* any combustible tobacco product,† ≥2 tobacco products,§ and selected tobacco products — National Youth Tobacco Survey, United States, 2011–2017¶,,††**



* Use of any tobacco product was defined as use of electronic cigarettes (e-cigarettes), cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

† Use of any combustible tobacco product was defined as use of cigarettes, cigars, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

§ Use of ≥2 tobacco products was defined as use of two or more of the following tobacco products: e-cigarettes, cigarettes, cigars, smokeless tobacco, hookah, pipe tobacco, and/or bidis on at least one day in the past 30 days.

¶ During 2016–2017, current use of any tobacco product, e-cigarettes, and hookah decreased significantly ($p<0.05$).

** During 2011–2017, current use of any tobacco product, any combustible tobacco product, ≥2 tobacco products, cigars, smokeless tobacco, and pipe tobacco exhibited significant linear decreases ($p<0.05$). Cigarettes and bidis exhibited significant nonlinear decreases ($p<0.05$). E-cigarettes and hookah exhibited significant nonlinear increases ($p<0.05$).

†† Beginning in 2015, the definition of smokeless tobacco included chewing tobacco/snuff/dip, snus, and dissolvable tobacco to better reflect this class of tobacco products. Thus, estimates for individual smokeless tobacco products (chewing tobacco/snuff/dip, snus, and dissolvable tobacco) are not reported. This definition was applied across all years (2011–2017) for comparability purposes.

Summary

What is already known about this topic?

Tobacco use is the leading cause of preventable disease and death in the United States; nearly all tobacco use begins during youth and young adulthood.

What is added by this report?

During 2011–2017, prevalence of current use of any tobacco product decreased from 24.2% to 19.6% among high school students and from 7.5% to 5.6% among middle school students. Electronic cigarettes were the most commonly used tobacco product among high school (11.7%) and middle school students (3.3%) in 2017.

What are the implications for public health practice?

Sustained implementation of population-based strategies, in coordination with Food and Drug Administration regulation of tobacco products, are critical to reducing tobacco product use and initiation among U.S. youths.

tobacco product and two in five middle school students who used a tobacco product reported using ≥2 tobacco products. Among youths, symptoms of nicotine dependence are increased in multiple tobacco product–users compared with those in single product–users (*3*).

Tobacco prevention and control strategies at the national, state, and local levels might have contributed to the reduction in any tobacco product use in recent years, including tobacco product price increases, comprehensive smoke-free policies, media campaigns warning about the risks for youth tobacco product use, and youth access restrictions (*1*,*2*,*4*). However, several factors continue to promote and influence tobacco product use among youths, including exposure to tobacco product advertising and imagery through various media, as well as the availability of flavored tobacco products (*2*,*5*,*6*). Sustained and targeted interventions to address these factors could help prevent and reduce all forms of tobacco use among U.S. youths (*1*,*2*,*4*). In March 2018, the Food and Drug Administration issued an advance notice of proposed rulemaking to obtain information related to the role that flavors play in tobacco product use (*7*).

The findings in this report are subject to at least four limitations. First, findings might not be generalizable to all youths; those who are home-schooled, have dropped out of school, or are in detention centers are not included in this survey. Second, data were self-reported and might be subject to recall and response bias. Third, changes in the wording and placement of survey questions for certain tobacco products during 2011–2017 might limit comparability of responses between years. Finally, data on some tobacco products were unavailable for certain years (e.g., roll-your-own cigarettes), which might result in underestimation of overall tobacco product use.

The sustained implementation of population-based strategies, in coordination with the regulation of tobacco products by FDA (*8*), are critical to reducing all forms of tobacco product use and initiation among U.S. youths (*1*,*2*,*4*). Strategies to reduce youth tobacco product use include increasing the price of tobacco products, implementing comprehensive smoke-free policies, implementing advertising and promotion restrictions and national public education media campaigns, and raising the minimum age of purchase for tobacco products to 21 years (*1*,*4*,*9*).

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule

VIII. Regulation of Electronic Nicotine Delivery Systems (Including E-Cigarettes) and the Continuum of Nicotine-Delivering Products

In the preamble to the NPRM, FDA noted that there are distinctions in the health risks presented by various nicotine-delivering products. FDA requested comment as to how e-cigarettes should be regulated based on this continuum of risk. We explained that some studies have revealed the existence of toxicants in both the e-cigarette liquid and the exhaled aerosol of some e-cigarettes but that we do not have sufficient data to determine what effects e-cigarettes have on public health at the population level. We also noted that some individuals report using e-cigarettes to successfully quit smoking, but we expressed concerns about dual use of e-cigarettes and combusted tobacco products and the possibility that flavored e-liquids are leading children to initiate tobacco use with e-cigarettes.

In this final rule, FDA clarifies that although there are many types of ENDS (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), all are subject to FDA's chapter IX authorities with this final deeming rule. Comments regarding e-cigarettes, including comments on how the products should be regulated in light of this continuum, and FDA's responses are discussed in the following sections.

A. Terminology

(Comment 113) Some comments expressed confusion as to what is encompassed by the term "e-cigarette." Other comments stated that the "electronic smoking devices" covered under this deeming rule should include e-cigarettes, e-cigars, e-hookah, and vape pens.

(Response) FDA agrees that electronic nicotine delivery systems or ENDS are sold under several different names including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. These products all meet the definition of "tobacco product" and, therefore, under this rule, all are subject to FDA's tobacco control authorities, regardless of a novel name or heating source. In addition, the definition of tobacco product includes components and parts (the objects intended or reasonably expected to be used with or for the human consumption of a tobacco product that are not accessories) (*e.g.*, e-liquids, tanks, cartridges, pods, wicks, atomizers), which, under this rule, have also been deemed to be subject to FDA's authority under chapter IX of the FD&C Act.

B. Prevalence

In the NPRM, FDA expressed concern about the increase in prevalence of the newly deemed products, particularly the alarming rise in e-cigarette use by middle school and high school students. The comments included peer-review studies, focus group results, and data regarding the prevalence of ENDS use.

(Comment 114) Some comments noted that it was difficult to fully ascertain prevalence of use of these products because they are sold under many different names. However, they generally agreed that the prevalence of e-cigarette use has increased in recent years, citing peer-reviewed studies and data from state or regional surveys (*e.g.*, Ref. 108). For example, comments cited the 2013 North Carolina Youth Tobacco Survey (NCYTS) and expressed concern that, while the current cigarette smoking rates among North Carolina high school students decreased in recent years, the overall current use of tobacco products increased from 22.5 percent in 2011 to 24.5 percent in 2013. In particular, the rate of e-cigarette use increased from 1.7 percent in 2011 to 7.7 percent in 2013, and 2.7 percent of high school students who had never tried a cigarette indicated that they were considering using e-cigarettes in the next year.

However, some of these comments believed that the data showing an increase in e-cigarette use among youth and young adults only reflects their experimentation (and not long-term use) and that there are no data showing that this experimentation leads to long-term use or dual use with combusted tobacco products. Others stated that although e-cigarette use may be increasing among youth and young adults, this increase is due to the fact that young adult smokers are switching to e-cigarettes, as are adult smokers.

(Response) FDA agrees with comments stating that the prevalence of use of the newly deemed tobacco products has been increasing, which further substantiates the need for this final rule. FDA remains concerned about the rise in use of newly deemed products by youth and young adults, particularly the increase in use of ENDS. As we stated in the NPRM and throughout this document, long-term studies are not yet available to determine whether these youth and young adults are only experimenting with tobacco use, becoming established ENDS users or dual users, or transitioning to combusted products. In addition, there is not sufficient evidence to conclude that youth and young adults are using ENDS as a means to quit smoking.

(Comment 115) Many comments contended that the great majority of e-cigarette users consist of former smokers and those trying to quit smoking, rather than those who are initiating tobacco use with e-cigarettes (*e.g.*, Ref. 109). The comments included data from regional surveys indicating that even where there has been a significant increase in youth and young adult e-cigarette use, the increase is seen in experimenters and not daily users. For example, a few comments referred to a report commissioned by Public Health England which referred to a study that found that only 1 percent of 16 to 18-year-old never smokers have experimented with e-cigarettes and few, if any, progress to sustained use (Ref. 110).

(Response) Data reported by the CDC's National Center for Health Statistics (NCHS), which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicate that current cigarette smokers and recent former smokers (*i.e.*, those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.*, those individuals who quit smoking more than one year ago) and adults who had never smoked (Ref. 24). In addition, the CDC states that current cigarette smokers who had tried to quit smoking in the past year were more likely to use e-cigarettes than those who had not tried to quit (id.). It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would have ceased smoking cigarettes regardless of e-cigarette use; and (2) whether the e-cigarette use preceded or followed smoking cessation. Similar patterns have been observed in Europe, where researchers found that "e-cigarette use was more likely among smokers who had made a past year quit attempt" when compared to smokers who had not (Ref. 111). As discussed in further detail in response to Comment 144, a meta-analysis of 15 cohort studies, 3 cross-sectional studies, and two clinical trials (one RCT, one non-RCT) found that cigarette smokers who also used e-cigarettes had statistically significantly worse quit rates than those cigarette smokers who did not use e-cigarettes (Ref. 112).

However, FDA also remains concerned about the dramatic rise in ENDS use among youth; between 2011 and 2014, past 30 day e-cigarette use among high school students increased nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014 (Ref. 22),

and between 2011 and 2013, the number of never-smoking youth who had reported ever using an e-cigarette increased 3-fold, from 79,000 to more than 263,000 youth (Ref. 113). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9), and ENDS may deliver as much nicotine as other tobacco products (Ref. 114).

FDA is investing in long-term, population-level research, such as the PATH Study, to help assess the likelihood that previous nonusers of tobacco who experiment with ENDS will initiate regular tobacco use over time. Such longitudinal studies can further assess the factors associated with potential smoking cessation among e-cigarette users.

(Comment 116) The comments generally agreed that youth are increasingly using e-cigarettes, but disagreed as to the product's impact on nicotine addiction. As FDA noted in the proposal and as discussed by many comments, the CDC found that ever use of e-cigarettes by middle and high school students in the United States increased from 3.3 percent in 2011 to 6.8 percent in 2012 (Ref. 108). While the majority of comments recognized an increase in dual use, some suggested that this was not an issue because youth are using e-cigarettes to quit smoking, resulting in some dual use until they can completely abstain from conventional cigarettes (Ref. 115).

(Response) FDA remains concerned about the rise in ENDS use among youth and young adults as well as the trends in dual use of ENDS and combusted products in both youth and adults (Ref. 116). In addition, as stated in the NPRM and throughout this final rule, all tobacco products are potentially addictive and some ENDS may deliver as much nicotine as other tobacco products (Ref. 20). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9). FDA believes that this final deeming rule, along with the minimum age restrictions and health warning requirements, is an important step toward combatting this rise in tobacco product use among youth and young adults.

A recently published paper by Friedman (Ref. 42) looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors and concluded, based on state-level data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Given the various issues with this study (see previous discussion regarding this publication in response to comment 33), FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but emphasizes that further research will be needed to explore the effects of this rule on product switching and dual usage.

C. Toxicity and Nicotine in E-Liquid and Aerosol

Although FDA noted in the NPRM that we do not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the public health, we identified concerns regarding the toxicants in e-liquid and the exhaled aerosol and the nicotine delivery from e-cigarettes. Comments were divided on the safety and toxicity of e-liquids, e-cigarettes, and the exhaled aerosol.

(Comment 117) The comments expressed concerns that e-cigarette users subject themselves to dangerous constituents, including formaldehyde and other toxicants. One comment stated that the release of formaldehyde occurs only when the voltage on e-cigarettes is set to 4.8 volts or higher (Ref. 67). Some comments also submitted studies showing the existence of other e-liquid constituents, including prescription weight loss and erectile dysfunction drugs (Ref. 117).

(Response) Studies show that e-liquid tobacco products contain nicotine, propylene glycol, glycerin, tobacco specific nitrosamines, tobacco alkaloids, carbonyls, ethylene glycol, diacetyl, and acetyl propionyl (Refs. 19, 118, 119). Chemicals such as nicotine, carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds have been identified in e-cigarette aerosols (Refs. 19, 118, 119, 120, 121, 122).

In addition, several studies substantiated the data included with comments, finding that flavored e-liquids contain chemicals that could be dangerous to consumers when inhaled. For example, researchers in one study tested 159 e-liquids with sweet flavors, such as toffee, chocolate, and caramel, and found that almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl (Ref. 123), both of which pose known inhalation risks (*e.g.*, Ref. 124). Among those that tested positive, nearly half of the e-liquids in the study could expose users to levels that exceed recommended workplace limits for breathing these chemicals (Ref. 123). An additional recent study analyzed 51 types of flavored e-cigarettes for total mass of diacetyl, 2,3-pentanedione, and acetoin (Ref. 125). Researchers detected diacetyl above the laboratory limit of detection 39 of the 51 flavors tested, ranging from limit of qualification (LOQ) to 239 µg/e-cigarette. 2,3-pentanedione and acetoin were also detected in 23 and 46 of the 51 flavors tested at concentrations up to 64 and 529 µg/e-cigarette (id.). It is noted that the study involved a convenience sample of 51 types of flavored e-cigarettes and may not be representative of the types of e-liquids currently available to users. Absent a regulatory standard, FDA acknowledges that it may not be possible to account for the wide variability of concentrations of constituents in the flavors of current ENDS products. Another study analyzed 30 e-cigarette liquids and found that many flavors, including cotton candy and bubble gum, contained aldehydes, a class of chemicals that can cause respiratory irritation, airway constriction, and other effects (Ref. 126). Specifically, researchers noted that two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde (id.). Similarly, researchers found that several cinnamon-flavored e-liquids contained a chemical, cinnamaldehyde, which researchers stated was highly toxic to human cells in laboratory tests (Ref. 127).

Some studies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke (Ref. 122). FDA recognizes that specific product design parameters, such as voltage, can affect toxicant deliveries (Ref. 67). For example, some ENDS devices and some power levels of operating ENDS devices have been reported to deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129) and can affect the public health. In addition, a 2010 study conducted by the Virginia Commonwealth University determined that in a controlled evaluation of smokers naïve to the use of e-cigarettes and using a particular model of e-cigarette, acute effects of using the product did not result in measurable levels of nicotine or carbon monoxide, although e-cigarettes did suppress nicotine/tobacco abstinence symptom ratings (Ref. 130). Moreover, a recent evaluation of the relative health risks of ENDS products conducted by Public Health England has drawn attention to scientific reviews concluding that ENDS

are "likely to be much less, if at all, harmful to users or bystanders" and a prior paper that reported the findings from an international expert panel of academics. Employing an analysis model that quantifies the relative health harms of 12 tobacco products using a series of 14 harm criteria, the expert panel determined that while cigarettes scored 100 percent in their assessment of maximum relative harm, ENDS products were rated to have only 4 percent maximum relative harm, which contributed to Public Health England's assessment that ENDS are around 95 percent safer than smoking combusted cigarettes (Ref. 131; see Refs. 76, 132).

The recent evaluation's use of the prior paper has several limitations, and the prior paper itself observed that it was reporting outcomes based on the decision-conferencing process from a group of experts who were selected without any "formal criterion," though "care was taken to have raters from many different disciplines" and primarily based on geographic location "to ensure a diversity of expertise and perspective" (Ref. 76). In addition, the authors acknowledge that there is a "lack of hard evidence for the harms of most products on most of the criteria" (Refs. 76, 133, 134). The authors did not explain what scientific information was available to the experts upon which they should base their ratings. The authors did not explain the derivation of the quantitative assessment of each harm criterion. It is unclear if the authors carried out or referenced a quantitative risk analysis, a standard practice when assessing relative risk, nor did the authors indicate that they used mean levels of exposure to HPHCs in users or other quantitative evidence as an approximation of risk. In addition, population effects appear to be largely outside the scope of this analysis since the manuscript did not address the likelihood that the characteristics of the products would make them more or less likely to appeal to new users, be used in conjunction with other tobacco products or discourage quitting. They did not describe an assessment of population effects such as a quantitative assessment of youth use prevalence. FDA does not find the beliefs reported in the prior paper (Ref. 76) to be sufficiently conclusive on the relative risks of using different tobacco products.[14] However, previous studies detected the presence of aldehydes, especially formaldehyde, in the vapor from some ENDS to exist at levels much lower than in cigarette smoke (Ref. 132). Moreover, across several Japanese brands evaluated by another researcher in a self-published Web site, under some use conditions, ENDS released 1/50th of the level of formaldehyde released by cigarettes (Ref. 135). The highest level detected was six times lower than the level in cigarette smoke (id.). A clinical investigation comparing the levels of toxicants and carcinogen metabolites in the urine of e-cigarette users and combusted cigarette users found that e-cigarette users had significantly lower levels of all evaluated toxicants, which included acrolein and crotonaldehyde (Ref. 136). But other research, published as a letter to the editor of the *New England Journal of Medicine*, reported that ENDS devices operated at 5 volts delivered a mean of 390+/−90 µg per 10 puff sample which is greater than 150 µg, the estimated average delivery of formaldehyde than conventional cigarettes. No formaldehyde-releasing agents were detected when ENDS were operated at 3.3 volts (Ref. 128). A subsequent peer-reviewed article on 5 variable-power ENDS devices found large variations in formaldehyde delivery across devices (Ref. 129). The first device yielded more formaldehyde than combustible cigarettes at every power level tested, and the second device delivered more formaldehyde at the highest power level tested; the remaining three devices delivered less formaldehyde than combustible cigarettes at all power levels tested (*id.*) The same research found that aldehyde delivery varied by 750-fold from one ENDS device to another (*id.*). The article referenced in one comment (Ref. 67) reported that increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4-fold to over 200-fold.

(Comment 118) The comments in support of limited or no regulation for e-cigarettes cited studies showing that e-cigarette use resulted in improvements in many health indicators of former cigarette smokers. Most of these comments relied upon published literature concluding that, despite the lack of long-term health data, e-cigarettes are "likely to be much less, if at all, harmful to users and bystanders" (Ref. 132). They also noted that clinical studies to date indicate that e-cigarettes generally are well-tolerated and do not produce serious adverse events following use for up to 24 months (Refs. 107, 137). Many relied upon an analysis of the 47 e-cigarette adverse event reports FDA received from 2007 to 2012, which found that only 8 of them were considered serious (*e.g.*, pneumonia, congestive heart failure, disorientation, seizure, hypotension, facial burns, chest pain and rapid heartbeat, infant choking on an e-cigarette cartridge, loss of vision) (Ref. 138).

Some comments also stated that e-cigarettes provide subjective health benefits to current smokers. For example, in one Internet survey of 1,347 current e-cigarette users, among those who were former smokers, 75 percent reported improved breathing, less coughing, and feeling healthier overall after switching to e-cigarettes (Ref. 139). They also claimed that e-cigarette use leads to improved sense of smell and taste and general physical status (Ref. 109). In addition, they stated that some of the harms caused by smoking can be reversed by switching to e-cigarettes (Ref. 140).

(Response) FDA agrees that the majority of reported adverse events appear to have been not serious. The FDA adverse event reporting system has inherent limitations as a measure of the impact of e-cigarettes since ENDS are a newly deemed product and reporting adverse events associated with tobacco products (including e-cigarettes and other ENDS) is voluntary; therefore, the reports received may have underrepresented the true number and types of adverse events associated with ENDS. The data cannot be used to calculate incidence (occurrence) rates or to estimate risk. Moreover, FDA has concerns with relying upon the types of short-term studies provided in the comments. Short-term studies fail to analyze the exposure risk of tobacco use and inhalation that damage health over a lifetime of repeated, extended exposure. Given the relatively new entrance of ENDS on the market, consumers have not had the duration of use for researchers to fully assess the morbidity and mortality effects for ENDS on either the individual or the population.

FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products. A recent review from Public Health England (discussed in greater detail in response to Comment 117) suggests substantial reductions in the exposure to harmful constituents typically associated with smoking in ENDS products compared to cigarettes, and that most of the chemicals causing smoking-related

[14] In addition, at least one source has identified other flaws with the expert panel employed in the Nutt et al. report, including potential conflicts of interest and no prespecified expertise on tobacco control among the panel members (Ref. 133).

disease from combusted tobacco use are absent and the chemicals that are present pose limited danger (Ref. 131). A scientific review of published studies of the toxicity of certain e-liquids found that "[e-cigarette] aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of [e-cigarette] use are unknown but compared with cigarettes, [e-cigarettes] are likely to be much less, if at all, harmful to users or bystanders" (Ref. 132). ENDS products have been found in some studies to release aldehydes at much lower levels than that in cigarette smoke, with one Web site posting stating that, across several Japanese brands, under some use conditions, that ENDS products release 1/50th the level of formaldehyde released in cigarettes (Ref. 133).

However, study results have been inconsistent about the effects of these products. Some short-term studies suggest that ENDs may not affect heart rate, cardiac function, lung function, or complete blood count indices to the extent of conventional cigarettes (Refs. 130, 141, 142). A literature search, however, concluded that the current scientific evidence on short-term effects are limited and there are no adequate data on long-term health effects (Ref. 143). Other studies have demonstrated increase in mean heart rate and inflammatory measures (such as white blood cells) and changes in lung function after use (Refs. 141, 142, 144, 145). Some research has found that there are some ENDS devices and some power levels of operating ENDS devices that deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129). Further, the review by Hajek et al. (Ref. 132) referred to in this comment as showing health benefits and finding a lack of negative health effects of e-cigarettes, may have limited generalizability due to the variability of e-cigarette products. The authors expressly recognized that there are many deficiencies in the available data.

(Comment 119) Some comments believed that FDA should not be concerned about e-liquids because they are restricted to the same nicotine levels as other products (*e.g.*, cigarettes, hookah, smokeless tobacco, NRTs).

(Response) FDA disagrees with comments stating that the Agency should not be concerned with ENDS use. First, a direct comparison of the nicotine level in cigarettes (and other currently regulated tobacco products) with the nicotine level in e-liquids is not a particularly helpful or relevant comparison. More helpful and clinically meaningful is the comparison between the amount of nicotine delivered to the user after using a cigarette (or other conventional tobacco product) versus the amount of nicotine delivered after using an ENDS (Ref. 146). Therefore, even if an e-liquid has the same nicotine level, it may deliver a different level of nicotine than the comparator product. It is also possible that comparable nicotine delivery consistently produced by ENDS that meet the requirements of the Tobacco Control Act may increase the facilitation of product switching from cigarettes to ENDS—which could (with appropriate regulatory oversight) potentially reduce the overall health harm caused by combusted tobacco. Further research is necessary to determine the causal factors that influence product switching from cigarettes to ENDS (or vice versa) and the subsequent health impacts.

Second, FDA disagrees with the notion that e-liquids are restricted to the same level of nicotine as other tobacco products. E-liquids are available in a wide range of nicotine concentrations, but delivery to the user is based on multiple factors, including the humectant in the e-liquid, the temperature to which the e-liquid is heated, the user experience, device designs, and design modifications (Ref. 147). Data suggest that experienced ENDS users are able to achieve clinically significant nicotine levels and levels similar to those generated by traditional cigarettes (Refs. 114, 148, 149, 150). Moreover, heating the e-liquids to higher temperatures and using the ENDS in ways other than intended (*e.g.*, dripping the e-liquid directly onto the atomizer) may result in nicotine delivery that is actually higher than that of a conventional cigarette (Ref. 16).

Third, FDA disagrees with the premise that the Agency should not be concerned with tobacco products that may have lower nicotine levels than cigarettes or other tobacco products, as may be the case with some ENDS. Even if ENDS products have lower levels of nicotine, they still have the potential to addict users, particularly youth and young adults, as discussed in section VIII.C. As the Surgeon General has stated, nicotine is the primary addictive substance in tobacco products (Ref. 9). Regardless of the nicotine content of the tobacco products, FDA believes that deeming tobacco products will result in significant public health benefits and that the additional restrictions imposed by this rule are appropriate for the protection of the public health.

(Comment 120) One comment expressed concern about the lack of research regarding the environmental impacts of e-cigarette use and storage.

(Response) FDA is funding studies regarding environmental impacts due to ENDS manufacturing, use, and disposal following use. In addition, FDA has been conducting a series of public workshops to obtain information on e-cigarettes and their impact on public health. Potential environmental impacts were discussed during the first workshop (79 FR 55815, September 17, 2014).

(Comment 121) Some comments expressed concern about the health effects of propylene glycol exposure from e-cigarette use. They also stated that the use of glycerol and propylene glycol, both of which are humectants, may cause uninformed users to become inadvertently dehydrated.

(Response) FDA recognizes that information about the health effects of the constituents in e-liquids and ENDS aerosols in both users and nonusers is limited and that this issue should be explored to better understand the impacts of these products on the population health.

(Comment 122) As FDA noted in the NPRM, one study detected diethylene glycol in one e-cigarette cartridge (79 FR 23142 at 23157). A few comments took issue with FDA's reliance on the study, because the amount of diethylene glycol reported was so low that it was unlikely to cause harm to consumers and had not been replicated in other scientific studies to date.

(Response) FDA appropriately characterized this study in the NPRM, stating that diethylene glycol "was found in only 1 of 18 cartridges studied and it was not found at all in another 16 studies" (79 FR 23142 at 23157). FDA agrees that the amount found was low, but reiterates that diethylene glycol is a toxicant and, therefore, is a cause for concern.

(Comment 123) We received many comments regarding the safety of the aerosol that is emitted from e-cigarettes. These comments expressed concern that individuals incorrectly believe that the aerosol emitted from e-cigarettes is harmless and stated that e-cigarette aerosol is not simply water "vapor," as is sometimes advertised (Ref. 151). They provided studies indicating that the primary or mainstream and exhaled or secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects, or other reproductive harm (Ref. 65). They also noted that potentially harmful constituents have been identified in some e-liquids and their aerosol, including tobacco-specific nitrosamines, heavy metals, and

carbonyls, albeit at significantly lower levels than in cigarette smoke (Refs. 65, 118, 152, 153, 154, 155, 156). Studies have shown that the primary aerosol contains measurable amounts of nicotine, which can have an impact on both users and nonusers (Ref. 144, 147).

We also received comments stating that the aerosol is completely harmless or significantly less harmful than tobacco smoke from combusted tobacco products; the comments included data from peer-reviewed publications (Refs. 144, 156, 157, 158), a presentation at a professional conference (Ref. 159), and individual company testing. These comments also submitted research that was not peer-reviewed, which stated that there were no key tobacco smoke toxicants in e-cigarettes (Ref. 160).

(Response) FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. (See section XII regarding the potential for product standards and tobacco product manufacturing practices on manufacturers of newly deemed products.) In the absence of short- and long-term studies on the potential impact of secondary exposure to aerosol, FDA cannot conclude that the aerosol is harmless. Moreover, as stated throughout this document, the Tobacco Control Act does not require that FDA make a finding that a product is harmful in order to deem it to be subject to chapter IX of the FD&C Act; FDA is authorized to deem any product that meets the definition of a "tobacco product" pursuant to section 901 of the FD&C Act.

(Comment 124) A few comments stated that the aerosol must be safe because the primary constituents of the liquid that generate the e-cigarette aerosol are propylene glycol and glycerin. They stated that inhalation of such constituents is harmless because they are designated as "generally recognized as safe" (GRAS) by FDA. They cited animal inhalation studies showing limited toxicological effects from either propylene glycol or glycerin (*e.g.*, Ref. 161).

(Response) FDA disagrees with comments claiming that the aerosol is safe due to certain components being recognized as GRAS. It is important to note that the definition of food additive in section 201(s), and its exclusion of GRAS substances, relates to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (section 201(s) of the FD&C Act). E-liquid is not food or intended for ingestion; therefore, the fact that propylene glycol and glycerin have been designated GRAS for food does not necessarily mean that these components are safe for inhalation. (See additional responses in this section of the document regarding FDA's concerns with ENDS aerosol.)

(Comment 125) Several comments that stated that e-cigarettes are harmless cited one study in which the author concluded that there "is no serious concern about the contaminants such as volatile organic compounds" in the e-cigarette "vapor" and that tobacco-specific nitrosamine (TSNA) levels in the "vapor" are just as hazardous as those TSNAs in NRT products (Ref. 162). Some of these comments specifically asked why FDA did not include this study in the proposed deeming rule.

(Response) FDA has considered these findings and agrees that the exhaled aerosol from ENDS users is potentially less hazardous than secondhand smoke from combusted cigarettes. However, FDA disagrees with the author's conclusion that exposure to aerosol ("vapor") "pose[s] no apparent concern" (Ref. 162). FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. FDA has repeatedly noted the potential benefits and need for additional information regarding ENDS and, therefore, the research included in the NPRM accurately summarized the state of the research on e-cigarettes (and the other newly deemed products) at the time it was drafted.

(Comment 126) A few comments claimed that there are many e-liquids on the market that do not contain nicotine and, therefore, e-liquids should not be regulated. Other comments provided studies that showed that e-cigarettes deliver nicotine but noted that delivery is dependent on the e-cigarette apparatus and liquid type, the rate at which the nicotine is delivered, and the user's experience with e-cigarette use (Ref. 130).

(Response) FDA is aware that, although some ENDS and e-liquids are *marketed* as nicotine free, as stated in section VIII.D, studies have found that certain types of ENDS do not have consistent quality and the labels may not accurately reflect the amount of nicotine in the e-liquid. The World Health Organization (WHO) also has noted that the level of nicotine delivered in currently marketed ENDS varies widely depending on product characteristics, user puffing behavior and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving (Ref. 163). In addition, FDA agrees that many factors influence the delivery of nicotine. For example, an experienced ENDS user may be exposed to amounts of nicotine similar to those delivered by cigarette smoking (Ref. 114). Also, as stated earlier, nicotine-free e-liquid that is intended or reasonably expected to be used with or for the human consumption of tobacco products in most cases would be a component or part of a tobacco product and, therefore, within the scope of this rule. These products will be evaluated on a case-by-case basis.

(Comment 127) Many comments discussed the possibility of nicotine poisoning due to improper access to, or use of, e-liquids. Most of these comments expressed concerns about the growing number of calls to poison control centers due to accidental nicotine poisoning. Others believed this concern was overstated and noted that many drugs can cause poisoning if stored improperly. They stated that the addition of child-resistant containers would alleviate this concern. Some also noted that e-cigarette users self-titrate the nicotine dosage, so concerns about overdosing should be minimal (Ref. 84).

(Response) FDA is concerned about the risk of nicotine poisoning in both users and nonusers. The CDC has reported more than 2,400 calls to U.S. poison control centers for e-liquid exposure between September 2010 and February 2014 (Ref. 164). In another study of 1,700 e-liquid exposures reported to U.S. poison control centers from June 2010 through September 2013, children 5 years of age or younger represented the largest proportion of e-liquid exposures and the group with the greatest increase in exposures per month in the first three quarters of 2013 (Ref. 165). Studies show that nicotine in sufficient concentrations, either when ingested or in contact with the skin, can result in serious or fatal poisoning and is concerning (Refs. 166, 167). Symptoms of toxicity include nausea, vomiting, seizures, coma, cardiovascular instability, respiratory arrest, and sometimes death. Although there was disagreement among the comments as to the level of nicotine that causes

poisoning, the nicotine content of many refillable vials could be toxic to adults and children regardless of the measurement used. Accordingly, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of the public health. In addition, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging.

(Comment 128) Some comments compared the poison risks of nicotine against other household products, noting that the incidence of nicotine poisoning is significantly lower than for other household products (Ref. 168).

(Response) Regardless of the incidence of nicotine poisoning in comparison to poisonings attributed to other household products, the dramatic rise in nicotine poisoning from e-liquid exposures is very concerning. FDA is taking under advisement the submitted data regarding nicotine poisoning and suggestions for measures that FDA can take in a separate rulemaking to address the issue, including establishment of tobacco product manufacturing practice regulations under section 906(e) and tobacco product standards under section 907 of the FD&C Act. In addition, as stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health.

(Comment 129) Comments were divided as to whether nicotine is dangerous to humans. Some comments stated that liquid nicotine is completely benign (and that FDA should not regulate e-cigarettes given the lack of harms). They claimed that FDA's findings regarding NRTs illustrate that nicotine is not carcinogenic to humans. (See "Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use," 78 FR 19718, April 2, 2013.) Other comments stated that although nicotine has some side effects, it is significantly less hazardous than the toxicants ingested with combusted products. Still others claimed that nicotine is very dangerous.

Comments that claimed that nicotine is dangerous cited studies showing that although nicotine may not be a primary carcinogen, it likely promotes cancers established through angiogenic (promoting of blood vessels in tumors) effects (*e.g.*, Ref. 169). The comments also noted that the 2014 Surgeon General's Report stated that the health risks of nicotine are more serious than previously thought and that FDA should consider this when evaluating the impacts of the newly deemed products on vulnerable populations. Others believed that nicotine is so dangerous that individuals should be required to obtain a certification before being permitted to acquire and handle it.

(Response) In the proposed deeming rule, FDA recognized the impact of nicotine on a youth's brain (see 79 FR 23142 at 23153 and 23154) and also noted poisoning concerns. The inhalation of nicotine (*i.e.*, nicotine without the production of combustion) is of less risk to a user than the inhalation of nicotine delivered by smoke from combusted tobacco products. However, limited data suggests that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's Report noted that there are risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Nicotine exposure during fetal development has lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.). Further, data suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15). See also section VIII.C discussing the increase in poisoning due to accidental nicotine ingestion.

FDA is not stating that nicotine is harmless. Unlike ENDS, which have not been reviewed by FDA, the NRT products mentioned in the comments are regulated and have undergone premarket review by FDA's Center for Drug Evaluation and Research (CDER) and been found to be safe and effective before obtaining authorization to enter the market (sections 505 and 506 of the FD&C Act). The Agency does not have sufficient data to be able to conclude that consumers are inhaling only nicotine, and no other chemicals or toxicants, when using ENDS. Although ENDS likely do not deliver the same level of toxicants as cigarettes, studies show that there are dangers associated with ENDS use and that exhaled aerosol is not simply "water vapor," as some believe. (See section VIII.C for additional discussion about the toxicants in ENDS vapor.)

(Comment 130) At least one comment suggested that to help address the dangers of nicotine and its use in future tobacco products, manufacturers registering future products with FDA should provide documents demonstrating the accuracy of stated nicotine levels and that the products are diacetyl and acetyl propionyl free.

(Response) FDA agrees with the need to carefully monitor future tobacco products and to evaluate the toxicological concern of chemical ingredients, such as diacetyl and acetyl propionyl, in e-liquids and that statements about the nicotine concentration in the e-liquid as well as the amount of nicotine that will be delivered to the user are accurate. FDA's review of SE reports and PMTAs under sections 905 and 910 of the FD&C Act will often include analysis of the chemicals included in the products. In addition, the requirements to submit ingredient listings under section 904 and HPHC testing data under sections 904 and 915 are expected to alert FDA to the existence of these HPHCs in e-liquids.

(Comment 131) Many comments expressed concerns regarding the high

cost associated with testing for HPHCs in each individual e-liquid and e-cigarette product. They suggested that FDA use enforcement discretion, as the Agency has done previously, to reduce the regulatory burden for e-cigarette manufacturers. For example, they noted that FDA has compliance policies for the submission of SE reports for certain product modifications and HPHC reporting. To reduce the regulatory burden, they suggested that FDA not require ingredient disclosure of all unique e-liquid products under section 904(a)(1) of the FD&C Act because such a requirement is unreasonable given the many different e-liquid formulations in these retail establishments. They stated that in lieu of ingredient listings, FDA should accept a table of all ingredients used in e-liquids along with use-level (concentration) ranges (*i.e.*, minimum and maximum percentages) of those ingredients in their products. These comments further suggested that FDA allow companies to simply amend their ingredients lists when altering products rather than requiring them to submit PMTAs.

(Response) Once this rule becomes effective, newly deemed products automatically become subject to chapter IX and all of its provisions applicable to tobacco products, without exception. Therefore, all manufacturers and importers of the newly deemed products will be subject to the requirements under sections 910, 905, and 904 of the FD&C Act upon the effective date of this final rule.

However, FDA has established a compliance policy for certain circumstances. See section IV.D describing the compliance policy regarding certain provisions and small-scale tobacco product manufacturers.

D. Quality Control

In the NPRM, FDA recognized previous instances of lack of quality control for certain e-cigarette products (79 FR 23142 at 23149). FDA indicated that the premarket review requirements that will automatically apply to the newly deemed products can help to address quality control concerns.

(Comment 132) Many comments expressed concern regarding the lack of controls in place for the mixing of e-liquids. They stated that these liquids are often mixed by individual consumers or employees of e-cigarette retail establishments who may lack training or knowledge of guidelines for handling such products. Several retailers of e-liquids submitted comments stating that they have controls in place to ensure the safety of their e-liquids.

(Response) FDA understands the comments' concerns about the safety of e-liquids. As stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Also, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when finalized will provide FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health. FDA also intends to consider these and other issues during its premarket review of these products. Further, after the effective date of this rule, FDA can exercise its authorities under the Tobacco Control Act to take additional steps to address the safety of e-liquids.

(Comment 133) Some comments included data regarding the variations among the nicotine levels in e-liquids, including data showing that the nicotine levels of the products are not accurately reflected in the nicotine concentration stated on the labels. For example, one study found nicotine content labels to be highly inaccurate and determined that products claiming to be nicotine-free actually contained high levels of nicotine (Ref. 170). Other comments stated that the variations are no longer as significant among the newer e-cigarette products, and that newer studies reported more consistent nicotine levels (Ref. 171).

Many comments cited several studies of newer e-cigarettes which continued to find wide variability in e-cigarette engineering, including nicotine concentrations in e-liquid, that were inconsistent with the information contained on the product label (Ref. 16). For example, one 2014 study of e-liquid refills found that the actual nicotine level of 65 percent of the e-liquids deviated by more than 10 percent from the nicotine concentrations printed on the labels (Ref. 17). Other studies found variability among nicotine concentrations, but the nicotine levels were equivalent to or lower than advertised (Refs. 18, 19). In one study, researchers stated that the total amount of nicotine in the e-liquid studied was potentially lethal if an individual were to drink it or absorb it through the skin (Ref. 18). They based this finding on the lethal level of nicotine being in the 10 to 60 milligram (mg) range; however, other comments claimed the lethal dose of nicotine is actually much greater (Ref. 172).

Some comments expressed concern that this rule does not address the possibility of a dangerous contamination of a batch of e-liquid because it does not include quality control measures or product standards that could prevent such contamination. They believed that FDA's authority to establish tobacco product manufacturing requirements or product standards in the future was insufficient to address this concern.

(Response) FDA is aware of the variability of nicotine among certain ENDS and that the labeling may not accurately reflect the nicotine levels. After this rule becomes effective, FDA has the authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act to address this issue. The PMTA process (particularly, the requirement to submit information on manufacturing methods) also provides a mechanism through which products that are more harmful or addictive than products on the market at the time of submission would be denied entrance to the market. Moreover, immediately upon the effective date of this rule, if FDA determines that an e-liquid has been contaminated and is therefore adulterated under section 902 or that it is misbranded under section 903 of the FD&C Act because its labeling is false or misleading, it can initiate enforcement action such as a seizure, injunction, or criminal prosecution.

(Comment 134) A few comments expressed concern that FDA may limit the availability of e-liquids to established manufacturers only and prohibit individuals from mixing their own e-liquids. These comments stated that they need access to products of reasonable potency, high purity, and high quality.

(Response) This final deeming rule places some restrictions on the sale and distribution of tobacco products, such as minimum age restrictions, but it does not bar sales to individuals generally.

(Comment 135) At least one comment noted that, although there have been fires due to mishandling of e-cigarette batteries, cases of accidental poisoning, and concerns about functionality, the "de facto regulations" that are in place, "namely brand equity, potential civil liability, and word-of-mouth" have been effective in helping the market evolve and controlling behavior.

(Response) FDA disagrees. FDA's adverse event reporting system has

E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General

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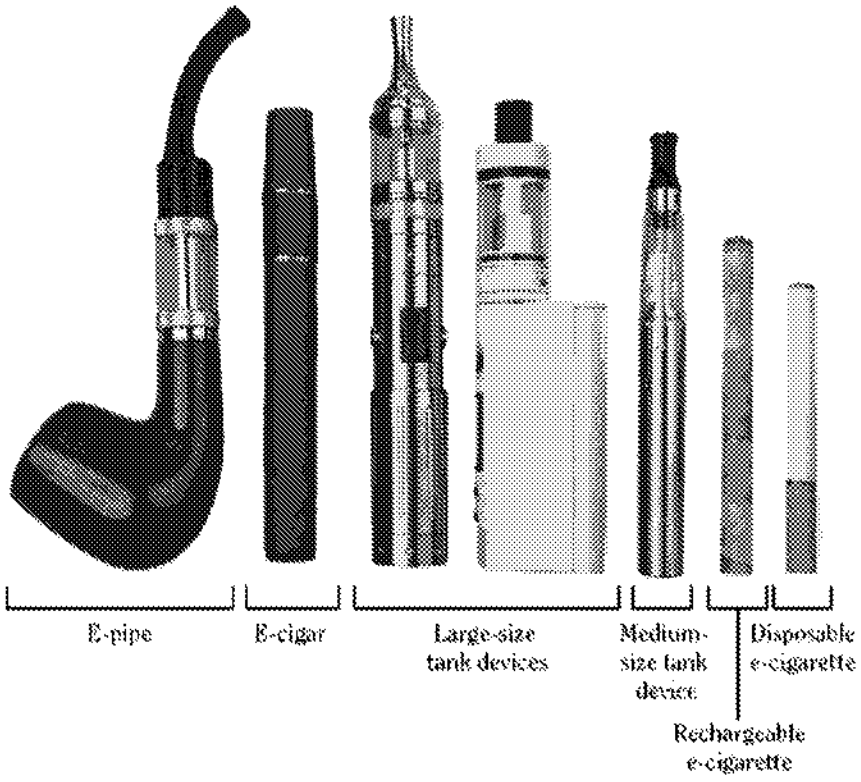
Use of trade names is for identification only and does not constitute endorsement by the U.S. Department of Health and Human Services.

Introduction

Although conventional cigarette smoking has declined markedly over the past several decades among youth and young adults in the United States (U.S. Department of Health and Human Services [USDHHS] 2012), there have been substantial increases in the use of emerging tobacco products among these populations in recent years (Centers for Disease Control and Prevention [CDC] 2015c). Among these increases has been a dramatic rise in electronic cigarette (e-cigarette) use among youth and young adults. It is crucial that the progress made in reducing cigarette smoking among youth and young adults not be compromised by the initiation and use of e-cigarettes. This Surgeon General's report focuses on the history, epidemiology, and health effects of e-cigarette use among youth and young adults; the companies involved with marketing and promoting these products; and existing and proposed public health policies regarding the use of these products by youth and young adults.

E-cigarettes include a diverse group of devices that allow users to inhale an aerosol, which typically contains nicotine, flavorings, and other additives. E-cigarettes vary widely in design and appearance, but generally operate in a similar manner and are composed of similar components (Figure 1.1). A key challenge for surveillance of the products and understanding their patterns of use is the diverse and nonstandard nomenclature for the devices (Alexander et al. 2016). These devices are referred to, by the companies themselves, and by consumers, as "e-cigarettes," "e-cigs," "cigalikes," "e-hookahs," "mods," "vape pens," "vapes," and "tank systems." In this report, the term "e-cigarette" is used to represent all of the various products in this rapidly diversifying product category. The terms may differ by geographic region or simply by the prevailing preferences among young users. For example, some refer to all cigarette-shaped products as "e-cigarettes" or as "cigalikes," and some may refer to the pen-style e-cigarettes as "hookah pens" or "vape pens" (Richtel 2014; Lempert et al. 2016).

Figure 1.1 Diversity of e-cigarette products



Source: Photo by Mandie Mills, CDC.

This report focuses on research conducted among youth and young adults because of the implications of e-cigarette use in this population, particularly the potential for future public health problems. Understanding e-cigarette use among young persons is critical because previous research suggests that about 9 in 10 adult smokers first try conventional cigarettes during adolescence (USDHHS 2012). Similarly, youth e-cigarette experimentation and use could also extend into adulthood; however, e-cigarette use in this population has not been examined in previous reports of the Surgeon General. The first Surgeon General's report on the health consequences of smoking was published in 1964; of the subsequent reports, those published in 1994 and 2012 focused solely on youth and young adults (USDHHS 1994, 2012). More recently, the 2012 report documented the evidence regarding tobacco use among youth and young adults, concluding that declines in cigarette smoking had slowed and that decreases in the use of smokeless tobacco had stalled. That report also found that the tobacco industry's advertising and promotional activities are causal to the onset of smoking in youth and young adults and the continuation of such use as adults (USDHHS 2012). However, the 2012 report was prepared before e-cigarettes were as widely promoted and used in the United States as they are now. Therefore, this 2016 report documents the scientific literature on these new products and their marketing, within the context of youth and young adults. This report also looks to the future by examining the potential impact of e-cigarette use among youth and young adults, while also summarizing the research on current use, health consequences, and marketing as it applies to youth and young adults.

Evidence for this report was gathered from studies that included one or more of three age groups. We defined these age groups to be young adolescents (11–13 years of age), adolescents (14–17 years of age), and young adults (18–24 years of age). Some studies refer to the younger groups more generally as *youth*. Despite important issues related to e-cigarette use in adult populations, clinical and otherwise (e.g., their potential for use in conventional smoking cessation), that literature will generally not be included in this report unless it also discusses youth and young adults (Farsalinos and Polosa 2014; Franck et al. 2014; Grana et al. 2014).

Given the recency of the research that pertains to e-cigarettes, compared with the decades of research on cigarette smoking, the "precautionary principle" is used to guide actions to address e-cigarette use among youth and young adults. This principle supports intervention to avoid possible health risks when the potential risks remain uncertain and have been as yet partially undefined (Bialous and Sarma 2014; Saitta et al. 2014; Hagopian et al. 2015). Still, the report underscores and draws its conclusions from the known health risks of e-cigarette use in this age group.

Organization of the Report

This chapter presents a brief introduction to this report and includes its major conclusions followed by the conclusions of the chapters, the historical background of e-cigarettes, descriptions of the products, a review of the marketing and promotional activities of e-cigarette companies, and the current status of regulations from the U.S. Food and Drug Administration (FDA). Chapter 2 ("Patterns of E-Cigarette Use Among U.S. Youth and Young Adults") describes the epidemiology of e-cigarette use, including current use (i.e., past 30 day); ever use; co-occurrence of using e-cigarettes with other tobacco products, like cigarettes; and psychosocial factors associated with using e-cigarettes, relying on data from the most recent nationally representative studies available at the time this report was prepared. Chapter 3 ("Health Effects of E-Cigarette Use Among U.S. Youth and Young Adults") documents the evidence related to the health effects of e-cigarette use, including those that are associated with direct aerosol inhalation by users, the indirect health effects of e-cigarette use, other non-aerosol health effects of e-cigarette use, and secondhand exposure to constituents of the aerosol. Chapter 4 ("Activities of the E-Cigarette Companies") describes e-cigarette companies' influences on e-cigarette use and considers manufacturing and price; the impact of price on sales and use; the rapid changes in the industry, particularly the e-cigarette companies; and the marketing and promotion of e-cigarettes. Chapter 5 ("E-Cigarette Policy and Practice Implications") discusses the implications for policy and practice at the national, state, and local levels. The report ends with a Call to Action to stakeholders—including policymakers, public health practitioners and clinicians, researchers, and the public—to work to prevent harms from e-cigarette use and secondhand aerosol exposure among youth and young adults.

Preparation of this Report

This Surgeon General's report was prepared by the Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, which is part of USDHHS. The initial drafts of the chapters were written by 27 experts who were selected for their knowledge of the topics addressed. These contributions are summarized in five chapters that were evaluated by

approximately 30 peer reviewers. After peer review, the entire manuscript was sent to more than 20 scientists and other experts, who examined it for its scientific integrity. After each review cycle, the drafts were revised by the report's scientific editors on the basis of reviewers' comments. Subsequently, the report was reviewed by various institutes and agencies within USDHHS.

Scientific Basis of the Report

The statements and conclusions throughout this report are documented by the citation of studies published in the scientific literature. Publication lags have prevented an up-to-the-minute inclusion of all recently published articles and data. This overall report primarily cites peer-reviewed journal articles, including reviews that integrate findings from numerous studies and books that were published through December 2015. However, selected studies from 2016 have been added during the review process that provide further support for the conclusions in this report. When a cited study has been accepted for publication, but the publication has not yet occurred because of the delay between acceptance and final publication, the study is referred to as "in press." This report also refers, on occasion, to unpublished research, such as presentations at a professional meeting, personal communications from a researcher, or information available in various media. These references are employed when acknowledged by the editors and reviewers as being from reliable sources, which add to the emerging literature on a topic.

Major Conclusions

1. E-cigarettes are a rapidly emerging and diversified product class. These devices typically deliver nicotine, flavorings, and other additives to users via an inhaled aerosol. These devices are referred to by a variety of names, including "e-cigs," "e-hookahs," "mods," "vape pens," "vapes," and "tank systems."

2. E-cigarette use among youth and young adults has become a public health concern. In 2014, current use of e-cigarettes by young adults 18–24 years of age surpassed that of adults 25 years of age and older.

3. E-cigarettes are now the most commonly used tobacco product among youth, surpassing conventional cigarettes in 2014. E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products.

4. The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.

5. E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful constituents, including nicotine. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.

6. E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.

7. Action can be taken at the national, state, local, tribal, and territorial levels to address e-cigarette use among youth and young adults. Actions could include incorporating e-cigarettes into smokefree policies, preventing access to e-cigarettes by youth, price and tax policies, retail licensure, regulation of e-cigarette marketing likely to attract youth, and educational initiatives targeting youth and young adults.

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https://www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246

HEALTH & WELLNESS

Schools and Parents Fight a Juul E-Cigarette Epidemic

As illicit Juul use sweeps through high schools and middle schools, administrators and parents struggle to stem teens' access to the vaping device, which delivers a powerful dose of nicotine.

By Anne Marie Chaker

Updated April 4, 2018 4:49 p.m. ET

At Northern High School in Dillsburg, Pa., Principal Steve Lehman's locked safe, which once contained the occasional pack of confiscated cigarettes, is now filled with around 40 devices that look like flash drives.

The device is called a Juul and it is a type of e-cigarette that delivers a powerful dose of nicotine, derived from tobacco, in a patented salt solution that smokers say closely mimics the feeling of inhaling cigarettes. It has become a coveted teen status symbol and a growing problem in high schools and middle schools, spreading with a speed that has taken teachers, parents and school administrators by surprise.

Mr. Lehman says he now asks teachers and administrators to closely monitor bathrooms—a popular meeting spot for Juul use—in the four minutes between classes. "We go for a walk. We stop in the bathroom. It's not uncommon to see a circle of kids passing it around," he says. "That's where we confiscate."

After two decades of declining teen cigarette use, "Juuling" is exploding. The Juul liquid's 5% nicotine concentration is significantly higher than that of most other commercially available e-cigarettes. Juul Labs Inc., maker of the device, says one liquid pod delivers nicotine comparable to that delivered by a pack of cigarettes, or 200 puffs—important for adult smokers trying to switch to an e-cigarette. It is also part of what attracts teens to the product, which some experts say is potentially as addictive as cigarettes and has schools and parents scrambling to get a grip on the problem.

Medical and advocacy groups, including the American Academy of Pediatrics and the Campaign for Tobacco-Free Kids, last week sued the Food and Drug Administration, challenging its decision last summer to extend certain deadlines for e-cigarette makers seeking FDA approval for their products. "The need for FDA to regulate individual e-cigarette products has never been

more urgent," says Matthew Myers, president of the Campaign for Tobacco-Free Kids. "Juul swept through high schools across America without most parents even knowing it existed."

An FDA spokesman declined to comment on the lawsuit filed in federal district court in Maryland.

Mr. Lehman stores confiscated Juuls in a locked safe along with other illicit goods. The Juuls are in manila envelopes logged with a date and time. **PHOTO:** JEFF LAUTENBERGER FOR THE WALL STREET JOURNAL

One big concern, addiction researchers say, is that Juul lacks many characteristics that deter people from smoking in the first place, such as a harsh smell and burnt-tobacco taste. Juul flavors include "Creme Brulee," "Fruit Medley" and "Mango," in addition to "Classic Tobacco."

"This could be a highly addictive product for youth," says Adam Leventhal, director of the Health, Emotion and Addiction Laboratory at the University of Southern California.

A Juul device fits easily in a pocket and looks nondescript when plugged into a laptop's USB drive to recharge or sitting on a desk. Teachers say students gather in bathrooms, library carrels and locker rooms to pass Juuls. The minimal vapor and barely there smell makes it harder to detect than some other e-cigarettes.

Juul Labs says minors shouldn't use any tobacco products, including its own. Criticism that it was designed to appeal to kids is "absolutely false," says Ashley Gould, Juul Labs chief administrative officer. "It's non-cylindrical because when smokers move away from cigarettes they don't want to be reminded of cigarettes." Something that could be plugged directly into a USB port was also convenient, she says.

As underage use became a growing problem, she says, Juul in August raised the minimum age requirement for buying products on its website to 21 from 18. Ms. Gould says the company is trying to find more ways of working with local law enforcement to prevent sales to under-age

customers. It is also looking at technologies that could disable the device on school grounds, she says.

While schools have long included discussion of tobacco use in their rule books, many have never addressed vaping, where nicotine is delivered through a process involving heat without burning.

"The kids are saying, 'I'm not smoking, it's not against the rules,'" says Ember Conley, superintendent of the Park City School District in Park City, Utah. She has met with school principals to clarify that possession of Juul and other vaping devices is forbidden on school grounds, as with any tobacco product. She is in the process of amending the district's policy.

New York City's private Grace Church School has ordered specialized sensors for its high school bathrooms, specifically for detecting vaping such as Juul use. If the sensors detect vapor, administrators get an email or a text message with a time stamp. A hallway camera can provide further information on who entered or exited around that time, says spokesman Topher Nichols. "We don't want any of our students suspended for what we think is a stupid way to injure your career," he says.

It has also entered middle school. Sabot at Stony Point, a pre-K to 8 private school in Richmond, Va., has incorporated teaching on the dangers of Juul into its health classes for sixth, seventh and eighth graders. "They're telling me their friends are doing it, and asking them to do it, in eighth grade," says teacher Kara Page.

Federal regulation prohibits anyone under 18 from purchasing e-cigarettes. Some states have even higher minimum ages of up to 21. A secondary market for Juul has emerged among younger teens.

"I've had customers who just turned 18 and bought a bunch of Juuls," presumably to distribute or sell to younger friends, says Alexander Terc, a sales associate at the Noon, a smoke shop in Silver Spring, Md. "We can't stop them from buying a bunch."

In the last few years, vaping with e-cigarettes has taken off. In 2017, 18.5% of 8th graders said they had ever vaped, up from 17.5% the previous year. That compared with 9.4% who had ever smoked cigarettes, down from 9.8% the previous year, according to researchers at the University of Michigan-Ann Arbor.

Juul Labs began as Ploom Inc., co-founded by James Monsees and Adam Bowen, graduate students at Stanford University who were smokers and wanted to create an alternative to cigarettes. In 2015, the company became Pax Labs Inc., which focused on vaporizing technology that could work with different materials, including cannabis. Juul Labs Inc. was spun off as a closely-held company in July 2017.

Industry analysts say Juul's rapid rise in the estimated $2 billion e-cigarette category is

Juul devices come in sleek packaging reminiscent of high-tech products. CREDIT: Richard B. Levine/Newscom/ZUMA Press)
PHOTO: RICHARD B. LEVINE/ZUMA PRESS

remarkable. In recent months, Juul has captured close to half of the business, according to a Wells Fargo analysis of Nielsen data. That is a big lead, says Wells Fargo tobacco analyst Bonnie Herzog, placing it ahead of established companies such as Altria Group Inc. and British American Tobacco PLC, which make their own branded forms. Juul's success "has had a lot to do with sleek and simple design and their superior technology" that more closely mimics cigarette smoking, she says.

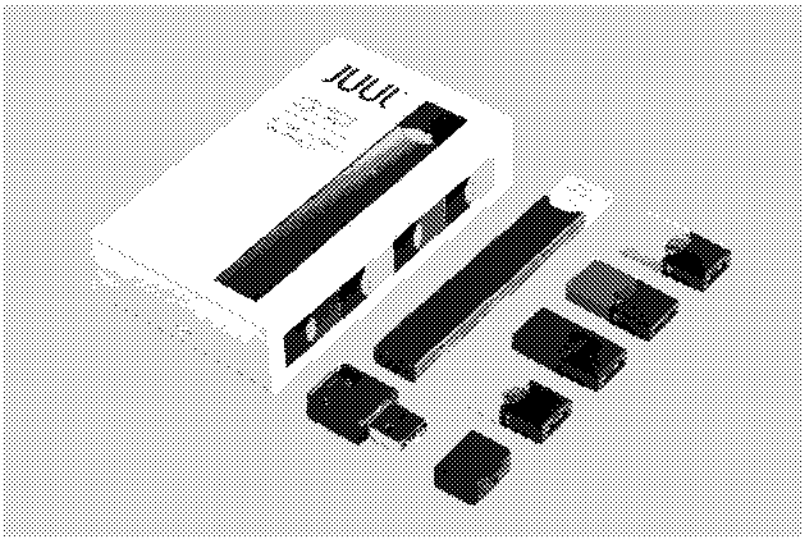
Altria spokesman Steve Callahan says the company takes a broad "portfolio approach to meet the different interests of adult smokers and vapers." BAT and its U.S. subsidiary Reynolds American Inc. said they don't comment on competitors.

The Juul starter kit—with device, charger and four flavor pods—retails for $50. Pods are also sold separately, at $4.25 on average—less than the average retail price for a pack of cigarettes. The pods come in packs of four for around $16, and many retailers sell out quickly. The device's ease of use changes the cigarette-break ritual for many people: The Juul can be picked up and put down without switching on or off—or having to go outside to smoke. Some ex-smokers say that means they reach for it more frequently.

Research shows that sweet flavors in e-cigarettes are particularly attractive to young people, says Meghan Morean, a substance-abuse researcher at Oberlin College who has studied the relationship between flavors and teenage use of e-cigarettes. She says many of Juul's fruitier flavors could be appealing to underage users. Other brands of e-cigarette liquids also come in fruit flavors such as cherry, blueberry and melon.

Juul Labs says the flavors can be important for adults who are trying to quit smoking. "Their palates change when they come off of cigarettes," says Ms. Gould. "They don't want to be reminded of smoking."

Some former cigarette smokers say the device has helped them kick what can become an expensive smoking habit. Paul Masmejean, a 25-year-old wellness and sobriety coach in New York, says his Juul helped him quit cigarettes. He now spends $40 a week on pods, compared with $140 a week when he was smoking. He also says he feels better. "Now cigarettes gross me out," he says.



A Juul starter kit comes with the device, a charger and four pods of a flavored 5% nicotine solution. CREDIT: Juul Labs **PHOTO:** JUUL

Meghan Moriarty, a 49-year-old business manager for a physical therapy company in Washington D.C., has struggled with smoking since her teens. After her 19-year-old son Tucker started smoking cigarettes regularly, she decided to buy him a Juul from the company's website last June. She also bought one for herself. "I hate the fact that he's addicted to nicotine," she says, "but I'd rather he has the Juul and not cigarettes."

Write to Anne Marie Chaker at anne-marie.chaker@wsj.com

Appeared in the April 3, 2018, print edition as 'Schools and Parents Fight a 'Juul' Epidemic.'

E-CIGARETTES AND ADDICTION

Is Juuling better than smoking?

It is a question that doctors, researchers and scientists are grappling with as they weigh the potential public health benefits of cigarette alternatives with new addiction risks for a younger generation. One thing is clear: There is still much the science community doesn't know about e-cigarettes, which were first imported to the U.S. market in 2006.

A growing body of research links e-cigarette use among teens to later use of cigarettes. Teens and young adults who try e-cigarettes are about three times more likely to try cigarettes later, according to an analysis published last August in JAMA Pediatrics.

The long-term effects of e-cigarettes aren't completely understood, according to a 2016 report from the Surgeon General. They have only been included in the Food and Drug Administration's umbrella of regulated tobacco products since August 8, 2016.

Tobacco use remains the leading cause of preventable death and disease in the U.S., according to the FDA. E-cigarettes, which typically contain nicotine derived from tobacco that is heated rather than burned, are increasingly recognized by researchers, consumers and doctors as a less-harmful alternative to cigarettes.

E-cigarette vapor generally contains fewer toxic substances at lower levels than smoke from cigarettes, according to a report from the National Academies of Sciences, Engineering and Medicine published earlier this year. While the vapor may be less hazardous than tobacco smoke, it isn't risk-free. A study of 103 high-school students in the San Francisco area published last month in Pediatrics showed that measured levels of toxic substances such as acrolein and propylene oxide were significantly higher in teen e-cigarette users than non-users. "This is not water vapor," says Mark Rubinstein, a medical professor at the University of California San Francisco, who led the research.

Still, no e-cigarette—including Juul—has received FDA approval to be sold as a smoking-cessation device similar to nicotine gums and patches. Juul Labs says it is looking into that possibility as it continues to conduct studies.

"Right now we can talk about it as a switching product," says Ashley Gould, Juul Labs chief administrative officer. "Not as a cessation product."

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes

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For Immediate Release

April 24, 2018

Statement

- **FDA cites 40 retailers for violations related to youth sales of JUUL e-cigarettes**
- **Agency announces a new blitz of retail establishments targeting youth sale violations**
- **Agency takes new action to examine youth appeal of JUUL**
- **Agency takes steps to foreclose online sales of JUUL to minors**
- **These are the first steps in a new effort aimed at stopping youth use of e-cigarettes**

Protecting our nation's youth from the dangers of tobacco products is among the most important responsibilities of the U.S. Food and Drug Administration – and it's an obligation I take personally. We recognize that if the FDA is to end the tragic cycle of successive generations of nicotine and tobacco addiction, we must take every opportunity to disrupt that process where it starts: youth access to and use of tobacco products.

That's why, as part of our comprehensive plan announced in July, we're pursuing a policy to prevent future generations from becoming addicted in the first place by rendering cigarettes minimally or non-addictive. A key part of that plan was establishing the foundational framework for regulating non-combustible tobacco products for adults, like e-cigarettes.

But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it's imperative that we also make sure children and teenagers aren't getting hooked on more novel nicotine-delivery products.

Today, we're announcing several new actions and efforts aimed at doing just that as the first steps in a new Youth Tobacco Prevention Plan focused on stopping youth use of tobacco products, and in particular, e-cigarettes.

The troubling reality is that electronic nicotine delivery systems (ENDS) such as e-cigarettes have become wildly popular with kids. We understand, by all accounts, many of them may be using products that closely resemble a USB flash drive, have high levels of nicotine and emissions that are hard to see. These characteristics may facilitate youth use, by making the products more attractive to children and teens.

These products are also more difficult for parents and teachers to recognize or detect. Several of these products fall under the JUUL brand, but other brands, such as myblu and KandyPens, that have similar characteristics are emerging. In some cases, our kids are trying these products and liking them without even knowing they contain nicotine. And that's a problem, because as we know the nicotine in these products can rewire an adolescent's brain, leading to years of addiction. For this reason, the FDA must – and will – move quickly to reverse these disturbing trends, and, in particular, address the surging youth uptake of JUUL and other products.

To address all of these concerns, the FDA is announcing a series of new enforcement and regulatory steps.

First, we're announcing that the FDA has been conducting a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes – specifically JUUL products – to minors at both brick-and-mortar and online retailers. The blitz, which started April 6 and will continue to the end of the month, has already revealed numerous violations of the law.

The illegal sale of these JUUL products to minors is concerning. In fact, just since the beginning of March, FDA compliance checks have uncovered 40 violations for illegal sales of JUUL products to youth. The FDA has issued 40 warning letters for those violations, which we are also announcing today. This includes warning letters that are the result of the blitz. Others are a result of our sustained enforcement efforts to reduce tobacco product sales to minors. And we anticipate taking many more similar actions as a result of the ongoing blitz and our focus on enforcement related to youth

access.

We'll hold retailers accountable for continued violations. Let me be clear to retailers. This blitz, and resulting actions, should serve as notice that we will not tolerate the sale of any tobacco products to youth.

This isn't the first time we've taken action against retailers for selling these e-cigarettes and other tobacco products to minors, and it won't be the last. In fact, the FDA has conducted 908,280 inspections of retail establishments that sell tobacco products, issued 70,350 warning letters to retailers for violating the law and initiated about 17,000 civil money penalty cases. We have also issued more than 110 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from even selling tobacco products for specified periods of time.

It's clear there's need for strong federal enforcement of these important youth access restrictions and we'll continue to hold retailers accountable by vigorously enforcing the law with the help of our state partners. Today's action should serve to put retailers on notice to stop selling products to minors.

Second, as part of this effort, we also recently contacted eBay to raise concerns over several listings for JUUL products on its website. We're thankful for eBay's swift action to remove the listings and voluntarily implement new measures to prevent new listings from being posted to the web retailer's site. Our overarching goal – one we hope everyone shares – is to make sure JUUL, and any other e-cigarettes or tobacco products, aren't getting into kids' hands in the first place.

Third, we're also taking additional steps to contact the manufacturers directly, and hold them accountable. We need to examine all the available information to understand why kids are finding these products so appealing – and address it.

That's why today, the FDA also sent an official request for information directly to JUUL Labs, requiring the company to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of these products. The information we're requesting includes: documents related to product marketing; research on the health, toxicological, behavioral or physiologic effects of the products, including youth initiation and use; whether certain product design features, ingredients or specifications appeal to different age groups; and youth-related adverse events and consumer complaints associated with the products. We don't yet fully understand why these products are so popular among youth. But it's imperative that we figure it out, and fast. These documents may help us get there.

We plan to issue additional letters to other manufacturers of products that raise similar concerns about youth use. If these companies, including JUUL, don't comply with our requests, they will be in violation of the law and subject to enforcement.

Fourth, we are planning additional enforcement actions focused on companies that

we think are marketing products in ways that are misleading to kids. I will have more to say on this in the coming weeks.

These actions are just the first in a series of efforts we're pursuing as part of our newly formed Youth Tobacco Prevention Plan. We will announce additional steps in the coming weeks and months. And I hope that this sends a clear message to all tobacco product manufacturers and retailers that the FDA is taking on this issue with urgency, and if kids are flocking to your product or you're illegally selling these products to kids, you're on the agency's radar.

We appreciate that JUUL Labs has already expressed recognition of this problem and has reached out to the FDA and other stakeholders to discuss these concerns. But we must all recognize that more needs to be done. As we've said before, there is no acceptable number of children using tobacco products. We share the belief that these products should never be marketed to, sold to, or used by kids – and we need to make every effort to prevent kids from getting hooked on nicotine. This responsibility falls not only to the FDA, but also the companies making these products, the retailers selling them, and the online venues that help to fuel the teen popularity of, and access to, these products.

Finally, as we pursue additional steps to keep kids from using tobacco products, we're also continuing to invest in our compelling, science-based campaigns to educate youth about the dangers of all tobacco products including e-cigarettes.

Last fall, the first content from our youth e-cigarette prevention campaign – an ad showing youth using a USB-like tobacco product – launched online. A full-scale e-cigarette prevention effort under "The Real Cost" brand umbrella is planned for a September launch.

We're also exploring clear and meaningful measures to make tobacco products less toxic, appealing and addictive with an intense focus on youth. Specifically, as part of our comprehensive plan, we intend to pursue product standards and other regulations for electronic nicotine delivery systems, such as e-cigarettes, to address known hazards and concerns, including exploding batteries and accidental ingestion. Ultimately, our work on tobacco and nicotine regulation is aimed at achieving the greatest public health benefit.

Make no mistake. We see the possibility for ENDS products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco. But we've got to step in to protect our kids.

As the FDA considers regulating nicotine levels in cigarettes to render combustible cigarettes minimally or non-addictive, products such as e-cigarettes may offer a potentially lower risk alternative for individual adult smokers. These ENDS products

will still need to be put through an appropriate series of regulatory gates by the FDA. But the viability of these products is severely undermined if those products entice youth to start using tobacco and nicotine.

The youth-focused steps we're taking are consistent with our responsibility to protect kids and significantly reduce tobacco-related disease and death, and I intend to do everything within my power to fulfill that duty.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Consumers

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PAX Labs, Inc. Introduces Revolutionary Technologies with Powerful E-Cigarette JUUL

New Premium Product JUUL Delivers a Simple, Smart, Satisfying Vapor Experience that Represents an Industry Breakthrough

April 21, 2015 08:00 AM Eastern Daylight Time

SAN FRANCISCO--(BUSINESS WIRE)--PAX Labs, Inc., developers of products that provide a cleaner, modern alternative to smoking, today announced the release of its highly anticipated technology breakthrough in smoking alternatives: JUUL. With liquid-nicotine cartridges available in four robust flavors, powered by proprietary technology, JUUL is now the only alternative smoking product that delivers a nicotine experience truly akin to a cigarette, with two times the nicotine strength and three times the vapor quality of leading competitive products.

Unlike other e-liquids, JUUL is the only e-cigarette that uses nicotine salts found in leaf tobacco, rather than free-base nicotine, as its core ingredient. Offering a powerfully satisfying vapor experience and a first-of-its-kind form factor, JUUL combines beauty and intelligent design – the hallmarks of PAX Labs – with new chemistry and patented technology to create a fundamentally different, compelling alternative to traditional cigarettes.

"There is a huge, unsatisfied demand for a product like JUUL," said James Monsees, cofounder and CEO of PAX Labs, Inc. "The most conservative estimate is that 60 percent of smokers have tried e-cigs. That's more than 24 million smokers; however, only about 2.4 million became regular e-cig users, as most consumers returned to combustibles. That's a huge gulf between what consumers want and what the industry has been able to offer, until now. JUUL is the product that smokers want. Smokers will try it and keep it, because it delivers the satisfaction they demand."

"Since launching PAX Labs, Inc. in 2007, our innovative and powerful vaporization products have consistently exceeded consumer expectation in the category and have quickly become market-leading brands," Mr. Monsees continued. "Packaged in sleek, stylish hardware that is convenient and practical, JUUL represents a major step change in this new and constantly evolving industry."

JUUL features:

- Uses liquid-to-wick cartridge system
- Small battery with a high discharge rate – 200 puffs per day
- Internal temperature regulation

Ease of use: simply insert JUULpod into JUUL and draw

- Battery charges two times faster than the average e-cigarette
- Indicator light communicates battery life and pull strength
- Unrivaled patented technology
- USB charger with magnetic contact
- Available in four flavors: tabaac, miint, fruut, bruulé

JUUL will be available for purchase in June 2015 at select stores nationwide and online at www.JUULvapor.com. The JUUL starter kit, which includes a device, one of each JUULpod and a USB charger, retails for $49.99; each JUULpod 4-pack retails for $15.99.

About PAX Labs, Inc.

Founded in 2007 by two Stanford Design Masters program graduates, PAX Labs (formerly known as Ploom, Inc.) has reinvented the smoking experience, fusing applied design principles with technology. Headquartered in San Francisco, the company produces innovative premium vaporizers that provide a cleaner, modern alternative to smoking. The company recently launched its PAX 2 vaporizer, the second generation of its PAX product line. The company's impeccable eye for intelligent design led to JUUL winning the gold in the 2014 International Design Awards, recognizing the smart vision and hard work that went into the device creation. For more information, please visit www.PAX-Labs.com.

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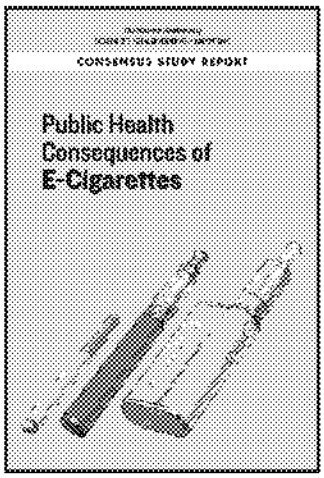
PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES

CONCLUSIONS BY OUTCOME

January 2018



In the report *Public Health Consequences of E-Cigarettes*, an expert committee of the National Academies of Sciences, Engineering, and Medicine presents 47 conclusions related to outcomes of e-cigarettes, including their key constituents, human health effects, initiation and cessation of combustible tobacco cigarette use, and harm reduction.

The conclusions below are organized by outcome. To see the conclusions organized by level of evidence and to read the full report and related resources, please visit **nationalacademies.org/eCigHealthEffects.**

CONSTITUENTS OF E-CIGARETTES

Conclusion 3-1. There is *conclusive evidence* that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels.

Conclusion 3-2. There is *limited evidence* that e-cigarette use increases levels of nicotine and other e-cigarette constituents on a variety of indoor surfaces compared with background levels.

Conclusion 4-1. There is *conclusive evidence* that exposure to nicotine from e-cigarettes is highly variable and depends on product characteristics (including device and e-liquid characteristics) and how the device is operated.

Conclusion 4-2. There is *substantial evidence* that nicotine intake from e-cigarette devices among experienced adult e-cigarette users can be comparable to that from combustible tobacco cigarettes.

Conclusion 5-1. There is *conclusive evidence* that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances.

Conclusion 5-2. There is *conclusive evidence* that, other than nicotine, the number, quantity, and characteristics of potentially toxic substances emitted from e-cigarettes is highly variable and depends on product characteristics (including device and e-liquid characteristics) and how the device is operated.

Conclusion 5-3. There is *substantial evidence* that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

Conclusion 5-4. There is *substantial evidence* that e-cigarette aerosol contains metals. The origin of the metals could be the metallic coil used to heat the e-liquid, other parts of the e-cigarette device, or e-liquids. Product characteristics and use-patterns may contribute to differences in the actual metals and metal concentrations measured in e-cigarette aerosol.

Conclusion 5-5. There is *limited evidence* that the number of metals in e-cigarette aerosol could be greater than the number of metals in combustible tobacco cigarettes, except for cadmium, which is markedly lower in e-cigarettes compared with combustible tobacco cigarettes.

HEALTH EFFECTS OF E-CIGARETTES

Conclusion 7-1. There is *substantial evidence* that e-cigarette aerosols can induce acute endothelial cell dysfunction, although the long-term consequences and outcomes on these parameters with long-term exposure to e-cigarette aerosol are uncertain.

Conclusion 7-2. There is *substantial evidence* that components of e-cigarette aerosols can promote formation of reactive oxygen species/oxidative stress. Although this supports the biological plausibility of tissue injury and disease from long-term exposure to e-cigarette aerosols, generation of reactive oxygen species and oxidative stress induction is generally lower from e-cigarettes than from combustible tobacco cigarette smoke.

Conclusion 8-1. There is *substantial evidence* that e-cigarette use results in symptoms of dependence on e-cigarettes.

Conclusion 8-2. There is *moderate evidence* that risk and severity of dependence are lower for e-cigarettes than combustible tobacco cigarettes.

Conclusion 8-3. There is *moderate evidence* that variability in e-cigarette product characteristics (nicotine concentration, flavoring, device type, and brand) is an important determinant of risk and severity of e-cigarette dependence.

Conclusion 9-1. There is *no available evidence* whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima media-thickness and coronary artery calcification).

Conclusion 9-2. There is *substantial evidence* that heart rate increases after nicotine intake from e-cigarettes.

Conclusion 9-3. There is *moderate evidence* that diastolic blood pressure increases after nicotine intake from e-cigarettes.

Conclusion 9-4. There is *limited evidence* that e-cigarette use is associated with a short-term increase in systolic blood pressure, changes in biomarkers of oxidative stress, increased endothelial dysfunction and arterial stiffness, and autonomic control.

Conclusion 9-5. There is *insufficient evidence* that e-cigarette use is associated with long-term changes in heart rate, blood pressure, and cardiac geometry and function.

LEVELS OF EVIDENCE DEFINED

Conclusive evidence: There are many supportive findings from good-quality controlled studies (including randomized and non-randomized controlled trials) with no credible opposing findings. A firm conclusion can be made, and the limitations to the evidence, including chance, bias, and confounding factors, can be ruled out with reasonable confidence.

Substantial evidence: There are several supportive findings from good-quality observational studies or controlled trials with few or no credible opposing findings. A firm conclusion can be made, but minor limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

Moderate evidence: There are several supportive findings from fair-quality studies with few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

Limited evidence: There are supportive findings from fair-quality studies or mixed findings with most favoring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.

Insufficient evidence: There are mixed findings or a single poor study. No conclusion can be made because of substantial uncertainty due to chance, bias, and confounding factors.

No available evidence: There are no available studies; health endpoint has not been studied at all. No conclusion can be made.

HEALTH EFFECTS OF E-CIGARETTES (CONTINUED)

Conclusion 10-1. There is *no available evidence* whether or not e-cigarette use is associated with intermediate cancer endpoints in humans. This holds true for comparisons of e-cigarette use compared with combustible tobacco cigarettes and e-cigarette use compared with no use of tobacco products.

Conclusion 10-2. There is *limited evidence* from in vivo animal studies using intermediate biomarkers of cancer to support the hypothesis that long-term e-cigarette use could increase the risk of cancer; there is no available evidence from adequate long-term animal bioassays of e-cigarette aerosol exposures to inform cancer risk.

Conclusion 10-3. There is *limited evidence* that e-cigarette aerosol can be mutagenic or cause DNA damage in humans, animal models, and human cells in culture.

Conclusion 10-4. There is *substantial evidence* that some chemicals present in e-cigarette aerosols (e.g., formaldehyde, acrolein) are capable of causing DNA damage and mutagenesis. This supports the biological plausibility that long-term exposure to e-cigarette aerosols could increase risk of cancer and adverse reproductive outcomes. Whether or not the levels of exposure are high enough to contribute to human carcinogenesis remains to be determined.

Conclusion 11-1. There is *no available evidence* whether or not e-cigarettes cause respiratory diseases in humans.

Conclusion 11-2. There is *limited evidence* for improvement in lung function and respiratory symptoms among adult smokers with asthma who switch to e-cigarettes completely or in part (dual use).

Conclusion 11-3. There is *limited evidence* for reduction of chronic obstructive pulmonary disease (COPD) exacerbations among adult smokers with COPD who switch to e-cigarettes completely or in part (dual use).

Conclusion 11-4. There is *moderate evidence* for increased cough and wheeze in adolescents who use e-cigarettes and an association with e-cigarette use and an increase in asthma exacerbations.

Conclusion 11-5. There is *limited evidence* of adverse effects of e-cigarette exposure on the respiratory system from animal and in vitro studies.

Conclusion 12-1. There is *limited evidence* suggesting that switching to e-cigarettes will improve periodontal disease in smokers.

Conclusion 12-2. There is *limited evidence* suggesting that nicotine and non-nicotine containing e-cigarette aerosol can adversely affect cell viability and cause cell damage of oral tissue in non-smokers.

Conclusion 13-1. There is *no available evidence* whether or not e-cigarettes affect pregnancy outcomes.

Conclusion 13-2. There is *insufficient evidence* whether or not maternal e-cigarette use affects fetal development.

Conclusion 14-1. There is *conclusive evidence* that e-cigarette devices can explode and cause burns and projectile injuries. Such risk is significantly increased when batteries are of poor quality, stored improperly or are being modified by users.

Conclusion 14-2. There is *conclusive evidence* that intentional or accidental exposure to e-liquids (from drinking, eye contact, or dermal contact) can result in adverse health effects including but not limited to seizures, anoxic brain injury, vomiting, and lactic acidosis.

Conclusion 14-3. There is *conclusive evidence* that intentionally or unintentionally drinking or injecting e-liquids can be fatal.

INITIATION AND CESSATION

Conclusion 16-1. There is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.

Conclusion 16-2. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *moderate evidence* that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.

Conclusion 16-3. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *limited evidence* that e-cigarette use increases, in the near term, the duration of subsequent combustible tobacco cigarette smoking.

Conclusion 17-1. Overall, there is *limited evidence* that e-cigarettes may be effective aids to promote smoking cessation.

Conclusion 17-2. There is *moderate evidence* from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation.

Conclusion 17-3. There is *insufficient evidence* from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration–approved smoking cessation treatments.

Conclusion 17-4. While the overall evidence from observational trials is mixed, there is *moderate evidence* from observational studies that more frequent use of e-cigarettes is associated with increased likelihood of cessation.

HARM REDUCTION

Conclusion 18-1. There is *conclusive evidence* that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.

Conclusion 18-2. There is *substantial evidence* that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems.

Conclusion 18-3. There is *no available evidence* whether or not long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes.

Conclusion 18-4. There is *insufficient evidence* that e-cigarette use changes short-term adverse health outcomes in several organ systems in smokers who continue to smoke combustible tobacco cigarettes (dual users).

Conclusion 18-5. There is *moderate evidence* that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes.

TO READ THE FULL REPORT AND VIEW RELATED RESOURCES, PLEASE VISIT
NATIONALACADEMIES.ORG/ECIGHEALTHEFFECTS

Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products

Committee on the Public Health Implications of
Raising the Minimum Age for Purchasing Tobacco Products

Board on Population Health and Public Health Practice

Richard J. Bonnie, Kathleen Stratton, and Leslie Y. Kwan, *Editors*

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Summary

Smoking rates in the United States have declined substantially since the release of *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* in 1964, when the prevalence of current cigarette smoking was around 42 percent. Recent estimates reveal that since 1964, tobacco control in the United States has led to 8 million fewer premature deaths and has extended the mean life span at age 40 by about 2 years (Holford et al., 2014). However, tobacco use continues to have major public health implications; while the prevalence of current cigarette smoking among U.S. adults has declined to around 18 percent (Schiller et al., 2014), more than 42 million American adults still smoke (HHS, 2014).

STATEMENT OF TASK

The Family Smoking Prevention and Tobacco Control Act of 2009 (hereafter referred to as the Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act, granting the Food and Drug Administration (FDA) broad authorities over tobacco products. The Tobacco Control Act directed FDA to, among other things, issue regulations to restrict cigarette and smokeless tobacco retail sales to youth and to restrict tobacco product advertising and marketing to youth. The act, however, prohibits FDA from taking several specific steps, including establishing a minimum age of sale

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of tobacco products to persons over 18 years of age.[1] On the other hand, the Tobacco Control Act directed FDA to convene a panel of experts to conduct a study on "the public health implications of raising the minimum age to purchase tobacco products" and to submit a report to Congress on the issue.

In August 2013 FDA contracted with the Institute of Medicine (IOM) to convene a committee to:

1. Examine existing literature on tobacco use initiation, and
2. Use modeling and other methods, as appropriate, to predict the likely public health outcomes of raising the minimum age for purchase of tobacco products to 21 years and 25 years.

The resulting IOM Committee on the Public Health Implications of Raising the Minimum Age for Purchasing Tobacco Products, assembled to address these issues, was composed of experts in public health law, the epidemiology of tobacco use and tobacco risks, adolescent and young adult development, risk behaviors and perceptions, public health policy and practice, and public policy modeling.

Interpreting the Statement of Task

During a discussion at the first public meeting of the committee, a representative of the Center for Tobacco Products of FDA urged the committee to include in its analysis the impact of raising the minimum age of legal access to tobacco products (MLA) to 19 years of age. The public health impacts examined in this report include tobacco initiation, prevalence, morbidity, and mortality. The committee uses the term "tobacco product" to mean any product covered by FDA regulatory authority, although most of the literature and the modeling focus on cigarettes. The committee did not consider the economic impact of raising the MLA, nor did it compare the effects of raising the MLA with other youth-oriented tobacco control policies.

The Tobacco Control Act refers to both minimum age for purchase[2] and minimum age for sale.[3] The committee focused on the implications of raising the MLA in the context of the body of youth access laws and enforcement policies currently in place across the country. These laws and policies vary considerably, not only in the scope of conduct that is prohib-

[1] Family Smoking Prevention and Tobacco Control Act of 2009, Public Law 111-31 § 906. 111th Cong. (June 22, 2009).

[2] Id. § 104.

[3] Id. § 906.

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ited but also in the prescribed penalties for violations. What they all have in common, however, is a focus on curtailing retail access to tobacco products by underage persons, with little, if any, emphasis on punishing the underage users of tobacco products. The committee's charge requests conclusions regarding the public health implications of raising the MLA without any recommendations regarding whether the MLA should be raised.

ADOLESCENT AND YOUNG ADULT DEVELOPMENTAL TRAJECTORIES AND PATTERNS OF TOBACCO USE

Brain development continues until about age 25. While the development of some cognitive abilities is achieved by age 16, the parts of the brain most responsible for decision making, impulse control, sensation seeking, future perspective taking, and peer susceptibility and conformity continue to develop and change through young adulthood. Adolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction. Adolescent and young adult developmental trajectories may be altered by social and environmental contextual influences, including normative developmental transitions into and out of school or work or changes in living arrangements or relationships.

According to the most recent results from an annual survey of adolescents in grades 8, 10, and 12, American teens are smoking less than ever before (Johnston et al., 2014b). Cigarette smoking in this age group peaked in 1996–1997 before beginning a fairly steady and substantial decline that continued through the mid-2000s. This decline in adolescent smoking has continued since then, but at a slower rate (HHS, 2014). Data from 2012 show that 34.1 percent of Americans between 21 and 25 were current cigarette users, making that the age group with the highest prevalence of cigarette smoking (SAMHSA, 2013). While almost 90 percent of people who have ever smoked daily first tried a cigarette before 19 years of age, the fact that nearly all others who ever smoked daily tried their first cigarette before the age of 26 should not be overlooked (see Table 2-8 in Chapter 2). Additionally, only 54 percent of daily smokers are smoking daily before age 18, but 85 percent are doing so by age 21 and 94 percent before age 25. These data strongly suggest that if someone is not a regular tobacco user by 25 years of age, it is highly unlikely they will become one.

CURRENT PRACTICES REGARDING YOUTH ACCESS RESTRICTIONS

Although most states currently set the minimum age of legal access to tobacco at 18, four states set it at 19, and New York City and several other localities around the country have raised the MLA to 21. All 50 states and

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the District of Columbia prohibit commercial transfers to underage persons, while 48 states and the District of Columbia also prohibit noncommercial transfers (e.g., giving, exchanging, bartering, furnishing, or otherwise distributing tobacco). Based on random, unannounced compliance inspections of tobacco retailers, the national average rate of tobacco sales to underage individuals (i.e., noncompliance) in 2013 was 9.6 percent.

Active enforcement of tobacco minimum age restrictions, including meaningful penalties for violations, increases retailer compliance and decreases the availability of retail tobacco to underage persons. However, it is difficult to know precisely how much increasing retailer compliance reduces the availability of retail tobacco to underage persons or how much the decreased retail availability of tobacco affects underage tobacco use because of the continued availability of tobacco from noncommercial sources. Underage users rely primarily on "social sources" (friends and relatives) to get tobacco, and there is little evidence that underage individuals are obtaining tobacco from the illegal commercial market. Bans on the noncommercial distribution of tobacco by friends, proxy purchasers, and other social sources are not well-enforced.

EFFECTS OF RAISING THE MLA ON TOBACCO USE

Through an iterative and consensus-driven process, the committee considered how these age-related effects would translate into potential changes in the rates of initiation across different age segments through adolescence and young adulthood for each of the three policy options (raising the MLA to 19, 21, or 25 years of age). The committee assigned ordered, categorical labels to its estimates as small, medium, or large. The committee attached numeric ranges to each of the magnitude estimate descriptors for use in the modeling. The committee used increments of 5 percent, ranging from 5 to 30 percent, to quantify the range of possible changes in initiation rates for use in the models. The committee has more confidence in its estimates pertaining to raising the MLA to 19 or 21 than in its estimates pertaining to raising the MLA to 25 because of the greater level of extrapolation needed for estimating change and also other factors that appear with increased age.

Conclusion 7-1: Increasing the minimum age of legal access to tobacco products will likely prevent or delay initiation of tobacco use by adolescents and young adults.

The definition of "initiation" used in this report, including in the modeling, is having smoked 100 cigarettes. This definition is based on data obtained from the National Health Interview Survey. Smoking at least 100 cigarettes in one's lifetime goes beyond occasional trying or "experimenta-

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tion." To achieve the benchmark of 100 cigarettes, one must have access to cigarettes over a period of time and have developed symptoms of dependence and stronger motives for use beyond perceived peer or social group pressure (Dierker and Mermelstein, 2010).

A critical component in the development of dependence and continued tobacco use is the reinforcing effects of nicotine. Adolescent brains have a heightened sensitivity to the rewarding effects of nicotine, and this sensitivity diminishes with age (Adriani et al., 2006; Jamner et al., 2003). Thus, the probability that a user escalates to dependence after the first few trials is likely to decrease the further one moves away from adolescence.

Changes in the initiation of tobacco use would not necessarily be linear with increases in the MLA or be equal for all segments of underage individuals. Changing the MLA has an indirect effect of helping to change norms about the acceptability of tobacco use, but this effect may take time to build. In addition, the norms about acceptability of tobacco use are also likely to vary by age, with greater perceived unacceptability for those the farther away from the MLA. If the MLA increases to 21, the social unacceptability of smoking will be greater for a 16-year-old than for a 20-year-old.

Given the assumption that changes in the MLA could have differential effects on adolescents at different ages, the committee considered possible changes in initiation rates for three age divisions: (1) adolescents under age 15; (2) adolescents between the ages of 15 and 17; and (3) individuals at age 18 for estimates with an MLA of 19, or individuals at ages 18 to 20 or 21 to 24 for an MLA of 21 or 25, respectively. These age groupings reflect not just differences in years from the MLA but also several important developmental transitions that play a role in tobacco use.

Conclusion 7-2: Although changes in the minimum age of legal access to tobacco products will directly pertain to individuals who are age 18 or older, the largest proportionate reduction in the initiation of tobacco use will likely occur among adolescents 15 to 17 years old.

Conclusion 7-3: The impact on initiation of tobacco use of raising the minimum age of legal access to tobacco products (MLA) to 21 will likely be substantially higher than raising it to 19, but the added effect of raising the MLA beyond age 21 to age 25 will likely be considerably smaller.

Adolescents Less Than 18 Years of Age

Many adolescents under age 15 are not yet in high school or of driving age. Adolescents under age 15 are less likely to have coworkers or members

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of their peer networks who are over the MLA (with the likelihood decreasing as the MLA increases). Thus, social network sources and mobility are most restricted for adolescents under age 15. For adolescents under 15 years of age, raising the MLA from 18 to 19 may have only a modest impact on reducing social sources, given the small difference in age. Increasing the MLA to 21, however, would provide a greater distancing of social sources. Although 19-year-olds may still be in high schools and thus potentially influence those under 15, it is far less likely that 21-year-olds are in the same social networks. On the other hand, increasing the MLA from 21 to 25 will not be likely to achieve many additional notable reductions in social sources for those under 15 beyond what is achieved with an MLA of 21.

Although social sources play a central role in establishing adolescent tobacco use patterns, other factors that contribute to early adolescent tobacco use (for those who initiate before age 15) may limit the reductions that would be achieved with increases in the MLA. Adolescents who reach a level of 100 cigarettes before 15 may be those who are most susceptible to the reinforcing effects of nicotine, who have higher levels of psychological or substance use comorbidities, who have a combination of problem behaviors (of which tobacco use is one manifestation), and who have social networks within which tobacco and other substances are more readily available, regardless of age. Thus, the committee also expects that there may be limits to how much changes in the MLA will affect this subset of adolescents. Considering the balance of these factors, the committee estimates that for adolescents under age 15 reductions in initiation will be small for an MLA of 19 and medium for an MLA of 21 and an MLA of 25.

The committee expects that the greatest gains in reducing tobacco use will be achieved for adolescents between the ages of 15 and 17. Negative consequences for tobacco use, through parental or school controls, are still relevant, and changes in the MLA are likely to increase these negative consequences as social norms adjust. Adolescents in this age group are still most likely to get tobacco through social sources (committee analysis of Arrazola et al., 2014; Johnston et al., 2014a). Between the ages of 15 and 17 adolescent mobility increases with driving privileges. Social networks and potential social sources of tobacco start to increase as some adolescents take on formal, part-time jobs with coworkers who may be over the MLA. Changing the MLA to 19 may not change social sources substantially for these adolescents, but the committee expects that raising the MLA to 21 will substantially impact initiation. Raising the MLA to 25 may provide only a modest additional reduction in initiation over that achieved with an MLA of 21, given that changes to social network sources may not be substantially different.

Balancing these factors, the committee estimates that the reduction in initiation in this age group will likely exceed that seen in adolescents less than

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15 years of age for all policy options. Furthermore, the committee estimates that the higher the MLA, the greater the effect on initiation rates will be.

Young Adults 18 to 20 Years of Age

By age 18, many adolescents graduate from high school and have numerous life transitions, including entering higher education, exposure to more adults in the workforce, leaving home, and significant changes in social networks. Patterns of initiation to date also show a tailing off of initiation by age 18 (committee analysis of Johnston et al., 2014a). Given that the social networks of 18-year-olds overlap more with 19-year-olds, the committee expects a small reduction in initiation for 18-year-olds for an MLA of 19. The committee expects similar effects on initiation rates for 19- and 20-year-olds as for 18-year-olds with an MLA of 21 or 25. This expectation of increased effect is due primarily to the increased social distancing expected when the MLA is raised to 21 or 25, but it also takes into account the benefit of the additional maturing of executive functions among young adults, the decreased sensitivity to the rewarding properties of nicotine, the additional social norms proscribing tobacco use, and tobacco's decreased social value and the decreased motives for use as individuals enter the workforce or parenthood.

Young Adults 21 to 24 Years of Age

Changes in initiation for young adults in the 21–24 age group were considered only for the case of raising the MLA to 25. Even under the current MLA of 18, the probability of initiation at these ages is substantially lower than for adolescents and younger adults. However, current patterns of tobacco marketing suggest that young adults are increasingly targeted in tobacco promotions (Ling and Glantz, 2002), and tobacco promotions are frequently linked with bar settings and alcohol consumption, which may also keep this age group susceptible to initiation (Ling and Glantz, 2002). In addition, the committee considered that there may be more lax enforcement for an MLA of 25. Considering the balance of factors, the committee expects that some reduction in initiation will still occur with an MLA of 25 but that this reduction will be small.

Conclusion 7-4: Based on the modeling, raising the minimum age of legal access to tobacco products, particularly to age 21 or 25, will likely lead to substantial reductions in smoking prevalence.

Two tobacco simulation models commissioned by the committee, SimSmoke and the Cancer Intervention and Surveillance Modeling Net-

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work (CISNET) smoking population model, suggest significant reductions in smoking prevalence from 2015 to 2100 in the United States, even under a status quo scenario with regard to the MLA; these declines reflect ongoing benefits from prior tobacco control policies. The models predict that raising the MLA would lead to considerable additional reductions in smoking prevalence based on the committee's conclusions about the likely reductions in smoking initiation described above. Specifically, both models estimate that raising the MLA will lead to approximately a 3 percent decrease in smoking prevalence for an MLA of 19, a 12 percent decrease for an MLA of 21, and a 16 percent decrease for an MLA of 25 above and beyond the decrease predicted in the status quo scenario.

HEALTH EFFECTS OF RAISING THE MLA

Given the likelihood that raising the MLA would decrease the rates of initiation of tobacco use by adolescents and young adults, it follows that tobacco-related disease and death would also decrease, generally in proportion to the decrease in tobacco use.

Conclusion 8-1: Based on the modeling, raising the minimum age of legal access to tobacco products will likely lead to substantial reductions in smoking-related mortality.

Conclusion 8-2: Based on a review of the literature, raising the minimum age of legal access to tobacco products (MLA) will likely immediately improve the health of adolescents and young adults by reducing the number of those with smoking-caused diminished health status. As the initial birth cohorts affected by the policy change age into adulthood, the benefits of the reductions of the intermediate and long-term adverse health effects will also begin to manifest. Raising the MLA will also likely reduce the prevalence of other tobacco products and exposure to secondhand smoke, further reducing tobacco-caused adverse health effects, both immediately and over time.

Adolescents and adults most commonly use tobacco in the form of cigarettes, and the adverse health effects of cigarettes are best documented among all the various forms of tobacco use. Cigarette smoking is causally associated with a broad spectrum of adverse health effects that begin soon after the onset of regular smoking and significantly diminish the health status of the smoker compared to nonsmokers. Cigarette smoking causes many adverse health effects with an intermediate latency, such as subclinical atherosclerosis, impaired lung development and function, diabetes, periodontitis, exacerbation of asthma, subclinical organ injury, and adverse sur-

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gical outcomes. Cigarette smoking is also causally associated with a broad spectrum of long-latency adverse health effects, such as chronic obstructive pulmonary disease, coronary heart disease, and numerous cancers, that cause suffering, impaired quality of life, and premature death. Results from both models suggest that reductions in smoking-related mortality following an increase in the MLA will be large but will not be observed for at least 30 years after the increased MLA takes effect. For example, if the MLA were raised now to age 21 nationwide, modeling suggests that for the cohort of people born between 2000 and 2019 there would be approximately 10 percent fewer lifetime premature deaths, lung cancer deaths, and years of life lost (YLL) from cigarette smoking. Given the status quo projections, this translates to approximately 249,000 fewer premature deaths, 45,000 fewer deaths from lung cancer, and 4.2 million fewer YLL.[4]

Smoking combustible tobacco products other than cigarettes, such as pipes and cigars, is causally associated with a broad spectrum of adverse health effects. The impact of raising the MLA on morbidity and mortality from these products would depend on the risk profile of each product and the degree to which that product is used in the population over time. Raising the MLA can also be expected to lessen exposure to secondhand smoke from cigarettes and other combustible tobacco products. Secondhand smoke exposure is causally associated with a number of adverse health effects.

Conclusion 8-3: Based on a review of the literature and on the modeling, an increase in the minimum age of legal access to tobacco products will likely improve maternal, fetal, and infant outcomes by reducing the likelihood of maternal and paternal smoking.

Maternal smoking during pregnancy and secondhand smoke exposure during infancy are causally associated with many adverse health outcomes. Such exposures not only leave exposed infants prone to various short- and long-term health risks but can also result in death. The SimSmoke model projected the effects of raising the MLA on the incidence of select maternal–child outcomes. Relative to the status quo, if the MLA were raised now to age 21 nationwide, modeling projects that by 2100 there would be an estimated 286,000 fewer pre-term births, 438,000 fewer cases of low birth

[4] All absolute differences, including the numbers of premature deaths, lung cancer deaths, and YLL, are relative to underlying status quo projections. These status quo projections estimate decreases in smoking prevalence and thus smoking-attributable morbidity and mortality. As such, the committee encourages the reader to focus on the percentage reduction rather than on the absolute numerical estimates.

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weight, and roughly 4,000 fewer sudden infant death syndrome (SIDS) cases among mothers age 15 to 49.[5]

CONSIDERATIONS FOR POLICY MAKERS

The Tobacco Control Act sets a "floor" of 18 on the MLA, while allowing states and localities to raise the age. Unless Congress acts to raise the age on a national basis or delegates authority to FDA to do so, one might expect a patchwork of different MLAs in different states and localities, as existed for alcohol for many decades, rather than a uniform MLA across all of the 51 jurisdictions. The simulations described in Chapters 7 and 8 model a situation in which increases in the MLA would be adopted and implemented on a nationwide basis. In the absence of a national MLA, the public health impact of raising the MLA for tobacco would be dependent, first and foremost, upon the degree to which local and state governments take up this policy. To the extent that states choose not to raise the MLA, the effects estimated in Chapters 7 and 8 are not likely to be realized.

The strength and efficacy of existing state and local tobacco control programs vary significantly, reflecting differences in the number and intensity of tobacco control activities and the resources allocated to support them. The modeling essentially aggregates each state's tobacco control activities, whether they are strong or weak. To the extent that policy makers in individual states want to derive state-based estimates from the findings of a national modeling exercise, they will have to take into account whether the existing levels of tobacco control activity in their states are comparable to the "average" state. If they are much weaker or stronger, extrapolation from the modeling used in this report may not be suitable.

The committee expects social sources, especially proxy purchases, to remain the primary sources of tobacco for underage persons, and it has been realistic about the high level of continuing availability to underage adolescents and young adults who are in the workforce or in college environments. Our estimates in this respect are predicated on relatively conservative assumptions. Although access to social sources could be reduced significantly if the laws prohibiting transfers to underage persons were aggressively enforced, the committee does not expect such a radical change in enforcement policy in the foreseeable future, especially under a higher MLA, because of likely public resistance. However, if a state or locality ramped up the threat of detection and punishment against social sources,

[5] All absolute differences, including the numbers of cases of pre-term births, low birth weight, and SIDS, are relative to underlying status quo projections. These status quo projections predict that there will be decreases in smoking prevalence, and thus smoking-attributable morbidity and mortality.

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the impact on adolescent and young adult consumption could be greater than the committee has projected.

Concerns about adolescent vulnerability to addiction and immaturity of judgment support an underage access restriction, but they do not resolve the policy question about the specific age at which the line should be drawn. The argument against raising the MLA above 18 is predicated on the assumption that adolescents older than 17 are mature enough to make their own decisions about what is in their best interests. However, evidence suggests that capacities related to mature judgment, especially in emotionally charged situations or in situations in which peer influence plays a role, are still developing into the early 20s. Many young people in their late teens and early 20s may also still be at elevated risk, developmentally speaking, to becoming addicted to nicotine. A balance needs to be struck between the personal interest of young adults in making their own choices and society's legitimate concerns about protecting the public health and discouraging young people from making decisions they may later regret (IOM, 2007; IOM and NRC, 2004). Although some line is required, 18 is not the only developmentally plausible place to draw it. Every state sets the legal age for certain activities higher or lower for different policy purposes, and state legislators will likely continue to draw the line in different places in different policy contexts (Bonnie and Scott, 2013; Hamilton, 2010; Steinberg, 2012).

The committee assumes that the MLA will be increased for all tobacco products, including electronic nicotine delivery systems (ENDS), and that the intensity of enforcement will be the same for all products. The committee sees no reason to believe that the effects of the legal norm and its enforcement on retailer compliance, retail availability, or access to social sources would differ materially for ENDS as compared with other tobacco products. Given the evidence that adolescents who currently initiate tobacco use with ENDS rather than with conventional tobacco products are younger (Wills et al., 2014), the main effect of raising the MLA for ENDS will likely be to reduce the number of adolescents and young adults who initiate tobacco use with ENDS. However, recent trends suggest that ENDS initiation is already increasing and is likely to increase even if the MLA is raised. Increased initiation of ENDS use may reduce initiation of cigarette use because some adolescents and young adults who otherwise would have initiated cigarette users will become ENDS users instead. It may also delay initiation of cigarette use for others, including some proportion who would not have otherwise used traditional cigarettes. Presumably FDA and state policy makers will take these possibilities into account in setting the MLA and will carefully monitor the promotion and use of ENDS, especially by adolescents and young adults.

Although the full benefits of preventing initiation of tobacco use will take decades to accrue, some direct health benefits, including those from

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reduced secondhand smoke exposure, will be immediate. Perhaps the greatest uncertainty in the committee's assessment is the currently unpredictable effects of the marketing and use of ENDS and other novel tobacco products. However, in the absence of transformative changes in the tobacco market, social norms and attitudes, or the epidemiology of tobacco use, the committee is reasonably confident that raising the MLA will reduce tobacco initiation, particularly among adolescents 15 to 17 years of age, will improve health across the life span, and will save lives.

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TABLE 2-8 Cumulative Percentage of Recalled Ages at Which Respondents First Used a Cigarette and Began Smoking Daily, by Smoking Status Among 30- to 34-Year-Olds, NSDUH, 2012

	All Persons		Persons Who Had Ever Tried a Cigarette	Persons Who Ever Smoked Daily	
Age	First Tried a Cigarette	Began Smoking Daily	First Tried a Cigarette	First Tried a Cigarette	Began Smoking Daily
≤10	3.8	0.4	5.4	7.0	1.1
11	5.9	1.1	8.5	11.4	2.7
12	11.9	2.3	17.0	21.4	5.8
13	17.4	3.9	25.0	30.6	9.8
14	25.2	6.1	36.2	45.6	15.4
15	34.6	9.8	49.7	62.3	24.8
16	43.5	15.9	62.4	75.0	40.1
17	48.9	21.3	70.2	81.9	53.9
18	56.7	27.3	81.5	89.8	69.0
19	60.0	30.5	86.1	94.1	77.0
20	63.0	33.6	90.5	95.9	84.9
21	64.9	35.1	93.3	97.1	88.5
22	66.1	36.0	94.9	98.0	90.7
23	66.8	36.4	95.9	98.5	92.0
24	67.1	37.1	96.4	98.5	93.6

continued

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TABLE 2-8 Continued

Age	All Persons		Persons Who Had Ever Tried a Cigarette	Persons Who Ever Smoked Daily	
	First Tried a Cigarette	Began Smoking Daily	First Tried a Cigarette	First Tried a Cigarette	Began Smoking Daily
25	68.0	38.4	97.7	99.2	96.8
26	68.4	38.6	98.2	99.4	97.5
27	68.8	38.8	98.9	99.5	98.0
28	69.0	38.9	99.1	99.7	98.1
29	69.2	39.2	99.3	99.9	98.9
30	69.5	39.5	99.8	100.0	99.8
31	69.5	39.5	99.8	100.0	99.8
32	69.6	39.5	100.0	100.0	99.8
33	69.6	39.6	100.0	100.0	99.9
34	69.6	39.6	100.0	100.0	100.0
Never smoked	100	100	NA	NA	NA

SOURCE: Committee analysis of data from HHS et al., 2014.

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3

The Developmental and Environmental Context of Adolescent and Young Adult Tobacco Use

Tobacco use is the result of a complex and dynamic interplay of multiple converging developmental, social, and environmental factors. Many of these factors are developmentally related, with adolescence and young adulthood as a key period of vulnerability to tobacco use and the progression to nicotine dependence (Jamner et al., 2003).

The development of adult decision-making skills and abilities is a continuous process that begins in early adolescence and continues into and through young adulthood, with no firm age periods for when specific developmental milestones occur. Furthermore, there are individual variations, with spurts of change and disjuncture resulting from social and environmental factors that influence the normative developmental process. These social influences are particularly salient in later adolescence and young adulthood.

Although previously considered a relatively short transition period, the late teens through the early 20s (ages approximately 18 to 26) is now considered a distinct period of life known as young adulthood (IOM and NRC, 2014). The newfound focus on this developmental period is due in part to prolonged education, delayed marriage, and delayed parenthood—events that historically marked adulthood, adult roles, and adult responsibility (Settersten and Ray, 2010)—and in part to studies showing that the brain continues to develop until the mid-20s (Giedd, 2008; Luna et al., 2004). Individuals in young adulthood face developmental and life changes that may make them particularly susceptible to drug use for several reasons: a desire to explore their identity, a response to the instability and disruption associated with life changes, or because of a tendency to focus on the pos-

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sible positive consequences of drug use rather than negative consequences. Additionally, this is a time period when experimentation with risky behavior is most tolerated (IOM and NRC, 2014).

The unique psychosocial maturation of the adolescent and young adult developmental period, coupled with various environmental and social influences, results in a milieu that increases the desire for engaging in health-risk behaviors, including tobacco use. Furthermore, brain function and heightened sensitivity to nicotine characteristic of this period of development provides the biological context underlying the psychosocial and environmental influences related to adolescents' and young adults' decisions to start and continue to use tobacco.

The chapter begins with a review of the complex and layered cognitive, psychosocial, and biological aspects of adolescent and young adult development, with a focus on factors most likely to explain the heightened likelihood of tobacco initiation, continued use, and dependence. The chapter then ties these factors into the decision-making capabilities of adolescents and young adults. The chapter concludes with a discussion of the environmental context of tobacco use, including salient residential, school, and work changes and the role of tobacco marketing on adolescent and young adult tobacco use.

COGNITIVE, PSYCHOSOCIAL, AND BIOLOGICAL DEVELOPMENT IN ADOLESCENTS AND YOUNG ADULTS

Adolescence and young adulthood is a period of change with respect to cognitive, psychosocial, neurobiological, and physical development. These changes often result in increased vulnerabilities to using tobacco. These factors are reviewed next.

Cognitive Development

During adolescence, thinking becomes less concrete and more abstract, giving adolescents the ability to consider many components necessary for competent decision making at one time, consider potential positive and negative outcomes associated with each decision, and plan for the future. Studies have shown that by the time adolescents reach age 16, their general cognitive abilities, such as the ability to understand consequences—including the risks and benefits of their decisions—to process information, and to reason, are essentially identical to those of adults (Albert and Steinberg, 2011; Halpern-Felsher and Cauffman, 2001; Steinberg et al., 2009a). For example, in a study of 935 individuals ranging from age 10 to 30, Steinberg and colleagues (2009a) found no significant differences in cognitive skills between older adolescents (as young as ages 15–16) and adults.

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Although there are individual differences and within-age-group variation, most adolescents reach a level of cognitive maturity comparable to adults by age 16. Despite the fact that cognitive maturity is reached by mid-adolescence, other aspects of psychosocial maturity, such as peer influence, sensation seeking, reward seeking, and impulse control, are still developing (as discussed later in this chapter). These different developmental systems explain in part why adolescents and young adults may have the cognitive ability to make safe and healthy decisions, yet are more prone than adults to make risky decisions. As shown below, even though adolescents have the ability to think abstractly and judge risks, they do not always adequately employ these abilities. Instead, adolescents are often seeking rewards and pleasures and therefore may decide to use tobacco despite knowing and understanding both the short-term and long-term risks.

Perceptions of Risks and Benefits

A hallmark of cognitive development is the ability to identify and understand consequences associated with a particular behavior. Perceptions of social, physical, and health risks associated with any given behavior as well as the perceived benefits, including both social and physical benefits, are key components of any competent decision. Research has shown that such perceptions actually predict the onset of behavior (Song et al., 2009b).

Adolescents, young adults, and adults are generally similar in their ability to identify and consider positive and negative consequences of their decisions. In some cases, adolescents actually perceive greater risks than do adults (e.g., Millstein and Halpern-Felsher, 2002). Several studies have shown that adolescents and young adults consider risks, benefits, and the value of behavior-related outcomes just prior to deciding on a particular behavior and that adolescents and young adults are keenly aware of risks (e.g., Halpern-Felsher and Cauffman, 2001; Lewis, 1981; Michels et al., 2005). In a review article, Albert and Steinberg (2011) concluded that there are few differences between the evaluations that adolescents (with ages varying depending on the study sample) and adults make of the risks inherent in various risky behaviors and few differences in their perceptions of the seriousness of these consequences (see also Kuther, 2003). Despite adolescents' general understanding—and often overestimation—of risks, the perceptions of risks are only one part of the equation that adolescents and young adults use to make decisions. Adolescents naturally consider the importance of the social and physical benefits that they perceive they will gain from any given behavior (Song et al., 2009b). Furthermore, adolescents' emotional immaturity and psychosocial factors influencing their behavior, such as impulsivity and peer pressure, often override the cognitive understanding of a risk.

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Perceptions of Tobacco-Related Risks and Benefits Associated with Tobacco Use

Many studies have examined risk and benefit perceptions related to tobacco use. In general, studies show that people who smoke perceive less harm and greater benefits from cigarettes than do nonsmokers (Chassin et al., 2000; Fischhoff et al., 2010; Halpern-Felsher et al., 2004; Morrell et al., 2010; Soldz and Cui, 2002; Song et al., 2009b). Compared to nonsmokers, those who have smoked believe that they are less likely to experience long-term risks, such as lung cancer, heart attack, addiction, and death, and less likely to experience short-term consequences, such as smelling bad or having trouble breathing (Halpern-Felsher et al., 2004; Morrell et al., 2010; Song et al., 2009a). Smokers also believe that they are more likely to experience pleasure, feel relaxed, and "look cool" from smoking when compared to nonsmokers (Halpern-Felsher et al., 2004; Morrell et al., 2010; Song et al., 2009b). A prospective study of adolescents 14 to 16 years old demonstrated that perceptions of low long- and short-term risk and greater benefits predict the onset of tobacco use (Song et al., 2009b).

A much smaller body of work has examined whether perceptions of risks and benefits vary by type, brand, or packaging of the tobacco product. Historically, this research has focused on light and ultra-light cigarettes, with studies showing that most adults and adolescents incorrectly perceive that light cigarettes deliver less tar and nicotine, produce milder sensations, result in less health risk, and can make cessation easier (Etter et al., 2003; Gilpin et al., 2002; Kozlowski et al., 1998; Kropp and Halpern-Felsher, 2004; Shiffman et al., 2001; Tindle et al., 2006). More recent research has shown that consumers perceive that menthol-flavored cigarettes are less harmful than non-menthol-flavored cigarettes (Anderson, 2011; Klausner, 2011). Similarly, perceptions of the harms associated with snus (Choi et al., 2012; Øverland et al., 2008), smokeless tobacco (Callery et al., 2011), and cigars (Nyman et al., 2002) are lower compared to the perceived harms of cigarettes, and people perceive differences in risk based on type and color of product packaging (Bansal-Travers et al., 2011).

Psychosocial Development

In addition to developing the ability to consider the possible consequences of actions, including the likelihood and value of each consequence, adolescents and young adults are also maturing with respect to their psychosocial abilities. Psychosocial components relevant to tobacco decision making include social and peer comparison, sensation seeking and impulsivity, peer affiliation, susceptibility to peer pressure, the ability to understand and plan for the future, and perceived social norms.

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While individuals vary even within the same age range, generally speaking most adolescents are on par with adults by age 16 with respect to thinking about the future (e.g., Albert and Steinberg, 2011; Halpern-Felsher and Cauffman, 2001; Steinberg et al., 2009b). However, other critical aspects of psychosocial development, such as those associated with peer pressure, sensation seeking, reward seeking, and impulse control, are much less developed during adolescence than during adulthood (Halpern-Felsher and Cauffman, 2001; Steinberg, 2008; Steinberg et al., 2008, 2009a; Zuckerman, 1979). "Dynamic accounts of factors that predict adolescent decisions" take into consideration the social, emotional, and self-regulatory factors that help explain why adolescents can make decisions just as rationally as adults, but often do not (Albert and Steinberg, 2011, p. 211). These areas of immaturity help explain why adolescents and young adults are more susceptible than older adults to initiating tobacco use.

Future Perspective Taking

Future perspective taking includes the ability to project into the future, to consider possible positive and negative outcomes associated with choices, and to plan for the future (Steinberg et al., 2009b), and is a hallmark of decision-making competence. Without an adequate understanding of future consequences and without the ability to have the future be part of present planning, it is more difficult to make decisions about behavior, including whether or not to use tobacco. It is not enough to have a working understanding of the possible risks and benefits that might come from using tobacco; it is equally important to be able to apply that information to making decisions about behaviors that could have an effect in the future. Steinberg and colleagues (2009b) found that the ability to plan for the future and to anticipate future consequences continues to develop through the mid-20s (see also Halpern-Felsher and Cauffman, 2001).

Sensation Seeking and Impulsivity

Sensation seeking refers to the drive to seek out experiences that are new, different, exciting, and highly stimulating as well as the willingness to take risks in order to have these experiences (Steinberg, 2008; Zuckerman, 1979). Higher sensation seeking is associated with drug use in early and middle adolescence (e.g., ages 12–16) (Kosten et al., 1994; Teichman et al., 1989) and with pubertal development; early maturers tend to rate higher on sensation-seeking scales and also on drug-seeking behavior (Martin et al., 2001; Steinberg, 2008). While sensation seeking follows a developmental trajectory, it is also viewed as a stable trait that is associated with risky behavior (Zuckerman, 2007).

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Impulsivity refers to a tendency to make decisions in a quick fashion, without much thought or information. Impulsivity steadily declines from age 10 on (Steinberg et al., 2008). Becoming competent to make decisions requires that adolescents be able to control their desires and resist impulsive actions. Recent studies have highlighted the complex relationship among impulsivity, peer pressure, and delinquent behavior. Vitulano and colleagues (2010) have found that individuals with low impulsivity are actually more vulnerable to delinquent peer influences than those with high impulsivity. Thus, adolescents find themselves in a bit of a quagmire in that those with high impulsivity are likely to engage in risky behavior and those with low impulsivity are particularly sensitive to peer pressure that may also lead them to engage in risky behavior.

While impulsivity and sensation seeking are related, they are distinct features of decision making. Impulsive behavior may lead to experiences that are neither stimulating nor rewarding, and individuals may make the decision to engage in sensation-seeking behavior in a deliberate and non-impulsive manner (Steinberg et al., 2008). Additionally, while impulsive behavior decreases in a linear fashion from age 10 on, sensation-seeking patterns of development follow a curvilinear pattern in which sensation seeking increases between childhood and early adolescence and then either declines or remains stable in late adolescence and adulthood (Steinberg et al., 2008). For example, Steinberg and colleagues found that while 16- to 17-year-olds and 18- to 21-year-olds exhibit more impulse control than 10- to 15-year-olds, they exhibit significantly less impulse control than 22- to 25-year-olds and 26- to 30-year-olds.

Thus, adolescence and young adulthood is a time of low impulse control coupled with high rates of sensation seeking, which results in a greater likelihood that individuals in these development periods will engage in risky behavior. The coupling of low impulse control and high sensation seeking is especially harmful in more emotionally charged situations, in which adolescents are seeking rewards and pleasure yet do not have the ability to control these desires. Hence, adolescents are more likely to seek rewards such as those associated with tobacco use than they will be later in life, once the connections between their rewards pathways and impulse control are more in sync, which occurs in their mid-20s (Steinberg, 2013).

Social Norms

Social norms refer to common codes of behavior for a social group. The construct is used in a number of disciplines and theories of health behavior, including the Theory of Planned Behavior (Ajzen, 1985), Social Cognitive Theory (Bandura, 2001), and the Theory of Normative Social Behavior (Rimal and Real, 2005). Social norms are often classified as either descrip-

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tive norms, which are perceptions of how people actually behave (which are often operationalized as perceived prevalence rates), and injunctive norms, which are perceptions of how people should behave (and are often operationalized by asking who would approve or disapprove of you engaging in a behavior) (Cialdini et al., 1990; Kallgren et al., 2000).

Both injunctive and descriptive norms are associated with smoking behaviors among adolescents and young adults. Alexander and colleagues (2001) analyzed data from the National Longitudinal Study of Adolescent Health and found that among 7th through 12th graders, adolescents in peer groups where 50 percent or more members smoked, or whose best friends smoked, were two times more likely to also smoke than those in peer groups in which fewer than half of the members smoked. Additionally, popular students who went to schools with higher smoking rates were more likely to smoke than non-popular students, while popular students in schools with low smoking rates were less likely to smoke. Etcheverry and Agnew (2008) found that among college students, friends, and romantic partners, smoking and injunctive norms were predictive of smoking behavior.

Peer Affiliation and Susceptibility to Peer Pressure

The ability to make rational decisions is mediated by a number of factors and, for adolescents, social factors in particular play a very large role in behavioral decision making. The transition to adolescence is marked by a decrease in time spent with parents and an increase in time spent either alone or with peers (Steinberg and Morris, 2001). This is a time period in which the opinions and actions of peers become increasingly important in influencing behavior (Crone and Dahl, 2012). Observational studies show that adolescents who engage in delinquent behavior are more likely to do so in groups (as opposed to adults, who are more likely to engage in delinquent behavior alone) (Albert et al., 2013; IOM and NRC, 2011; Zimring, 2000). Experimental studies have also shown that adolescents are more likely to make riskier decisions when they are told that they are being observed by peers than when they believe they are working alone (Albert et al., 2013). Compared with adults, adolescents exhibit exaggerated responses to positive social cues, and this reaction is coupled with more impulsive responses to stimuli (Albert et al., 2013; Gardner and Steinberg, 2005).

Generally, susceptibility to peer pressure that is undesirable or that goes against an individual's goals decreases steadily from age 14 to 18 (Steinberg and Monahan, 2007). In order to make competent decisions, individuals must have the ability to resist undue pressure from others. That being said, studies also show that peers remain powerful influences and reinforcers of behavior even in late adolescence and young adulthood. For example, Duncan and colleagues found that males entering college with a history of

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INCREASING THE MINIMUM LEGAL SALE AGE FOR TOBACCO PRODUCTS TO 21

"Raising the legal minimum age for cigarette purchaser to 21 could gut our key young adult market (17-20) where we sell about 25 billion cigarettes and enjoy a 70 percent market share."[1]
— Philip Morris report, January 21, 1986

Tobacco use remains the leading cause of preventable death in the United States, killing more than 480,000 people each year.[2] It is known to cause cancer, heart disease and respiratory diseases, among other health disorders, and costs the U.S. as much as $170 billion in health care expenditures each year.[3] Each day, 350 kids under the age of 18 become regular, daily smokers; and almost one-third will eventually die from smoking.[4] If current trends continue, 5.6 million of today's youth will die prematurely from a smoking-related illness.[5]

High tobacco taxes, comprehensive smoke-free laws and comprehensive tobacco prevention and cessation programs are proven strategies to reduce tobacco use and save lives. Increasing the minimum legal sale age (MLSA) for tobacco products to 21 complements these approaches to reduce youth tobacco use and to help users quit.

Six states – California, New Jersey, Massachusetts, Oregon, Hawaii and Maine – have raised the tobacco age to 21, along with at least 340 localities, including New York City, Chicago, San Antonio, Boston, Cleveland, Minneapolis, and both Kansas Cities.[6]

Raising the legal sale age is popular with the public, including smokers. A July 2015 CDC report found that three quarters of adults favor raising the tobacco age to 21, including seven in 10 smokers. The idea has broad-based support across the country, including support among men and women, and Americans of all income, education, race/ethnicity and age groups."[7]

There is strong reason to believe that MLSA 21 will contribute to reductions in youth tobacco use. Central to the MLSA strategy are the facts that many smokers transition to regular, daily use between the ages of 18 and 21; many young adult smokers serve as a social source of tobacco products for youth; and tobacco companies have long viewed young adults ages 18 to 21 as a target market group. The key facts supporting the policy derive from the 2015 Institute of Medicine report on raising the tobacco sale age; evidence from jurisdictions that have adopted the policy; research on youth and young adult tobacco use and access, and research on industry marketing tactics.

The IOM Predicts MLSA 21 Will Reduce Smoking and Save Lives

A March 2015 report by the Institute of Medicine (IOM), one of the most prestigious scientific authorities in the United States, strongly concluded that raising the tobacco sale age to 21 will have a substantial positive impact on public health and save lives.[8] Based on a review of the literature and predictive modelling, it finds that raising the tobacco sale age will significantly reduce the number of adolescents and young adults who start smoking; reduce smoking-caused deaths; and immediately improve the health of adolescents, young adults and young mothers who would be deterred from smoking, as well as their children. Specifically, the report predicts that raising the minimum age for the sale of tobacco products to 21 will, over time, reduce the smoking rate by about 12 percent and smoking-related deaths by 10 percent, which translates into 223,000 fewer premature deaths, 50,000 fewer deaths from lung cancer, and 4.2 million fewer years of life lost.

Emerging Evidence Is Promising

Because it is a relatively new strategy, data on the impact of increasing the MLSA to 21 is limited; but, the data that are available provide strong reason to believe that it will contribute to reductions in youth tobacco use.

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Based on preliminary data available from California, New York City, and Chicago, raising the tobacco sale age to 21 can be easily implemented and can help reduce youth access to and use of tobacco.

California

California's Tobacco 21 law became effective in June 2016. Initial evaluation results indicate that there is high awareness and support for the new law among tobacco retailers and young adults, two key audiences for ensuring compliance with the law. In addition, tobacco purchase data show that there is high compliance with the law among retailers.[9]

- Implementation: Virtually all retailers (98.6%) were aware of the new law 7 months after its effective date, and a large majority of retailers supported the law (60.6%). Nearly two-thirds of young adults were aware of the law.

- Retail sales to teens: Tobacco purchase data show a significant decline in tobacco sales to younger teens following implementation of the law. Specifically, compliance data for 15-16 year olds showed a 45% reduction in sales of tobacco products to underage buyers before and after the law. Before the law, 10.3% of sampled retailers sold tobacco to 15 to 16 year olds. After the law, 5.7% of sampled retailers sold tobacco to 15-16 year olds. Prior to the higher sale age law, for this age group, the retailer violation rate had been flat since 2009, suggesting strongly that the higher age limit is related to the decline. There was also a significant decrease in illegal tobacco sales among tobacco-only retailers after the law was implemented.

New York City

In August of 2014, New York City simultaneously implemented policies to raise the tobacco sale age to 21 and to reduce sources of cheap tobacco. While reductions in smoking cannot be attributed solely to the Tobacco 21 law, preliminary findings suggest that the law is contributing to reductions in youth tobacco use:

- Data from the Youth Risk Behavior Survey show that there was a 29 percent decline in current cigarette smoking among high school students between 2013 and 2015. There were also reductions in ever trying cigarettes (-18%) and smoking initiation in the past 12 months (-13%), over the same time period.[10]

Chicago

Chicago has taken a number of actions to reduce tobacco use in recent years including increasing the cost of tobacco and restricting the sale of flavored tobacco products. In addition, in July 2016, Chicago implemented a policy to raise the tobacco sale age to 21. Data show that Chicago's comprehensive approach is reducing smoking:

- Data from the Youth Risk Behavior Survey show only 6% of Chicago high school students reported current cigarette smoking in 2017, an all-time low. This represents a 56% decrease in cigarette smoking among youth since 2011.

- Chicago's annual Healthy Chicago survey found that current smoking of cigarettes and e-cigarettes among 18-20 year olds declined by over one third between 2015 and 2016, from 15.2% to 9.7%.[11]

Most Adult Smokers Start Smoking Before Age 21

National data show that about 95 percent of adult smokers begin smoking before they turn 21, and a substantial number of smokers start even younger— about 80 percent of adult smokers first try smoking before age 18.[12] While less than half (47%) of adult smokers become regular, daily smokers before age 18, four out of five become regular, daily smokers before they turn 21.[13] This means the 18 to 21 age range is a time when many smokers transition to regular use of cigarettes.[14] According to one national survey, the prevalence of current smoking among 18-20 year olds is more than double that of 16-17 year olds (21.2% vs. 9.2%).[15]

Tobacco companies have admitted in their own internal documents that, if they don't capture new users by their early 20's, it is very unlikely that they ever will. In 1982, one RJ Reynolds researcher stated:

> *"If a man has never smoked by age 18, the odds are three-to-one he never will. By age 24, the odds are twenty-to-one."*[16]

Delaying the age when young people first experiment or begin using tobacco can reduce the risk that they transition to regular or daily tobacco use and increase their chances of successfully quitting, if they do become regular users.[17] The IOM report notes that the age of initiation is critical and predicts that "Increasing the minimum age of legal access to tobacco products will likely prevent or delay initiation of tobacco use by adolescents and young adults."[18]

Adolescents are particularly vulnerable to the addictive effects of nicotine. The IOM report found that "The parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood, and adolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction."[19] The U.S. Surgeon General has stated that "the potential long-term cognitive effects of exposure to nicotine in this age group are of great concern."[20] Because adolescence and young adulthood are critical periods of growth and development, exposure to nicotine may have lasting, adverse consequences on brain development. The IOM report's review of the literature on the developmental context of youth tobacco use emphasizes that the brain continues to develop "until about age 25."[21] As reported by the U.S. Surgeon General:

> *"This earlier age of onset of smoking marks the beginning of the exposure to the many harmful components of smoking. This is during an age range when growth is not complete and susceptibility to the damaging effects of tobacco smoke may be enhanced. In addition, an earlier age of initiation extends the potential duration of smoking throughout the lifespan. For the major chronic diseases caused by smoking, the epidemiologic evidence indicates that risk rises progressively with increasing duration of smoking; indeed, for lung cancer, the risk rises more steeply with duration of smoking than with number of cigarettes smoked per day."*[22]

Adding to the concern is the fact that young people can often feel dependent earlier than adults.[23] Though there is considerable variation in the amount of time young people report it takes to become addicted to using tobacco, key symptoms of dependence—withdrawal and tolerance—can be apparent after just minimal exposure to nicotine.[24] According to the 2014 Report of the Surgeon General, "the addiction caused by the nicotine in tobacco smoke is critical in the transition of smokers from experimentation to sustained smoking and, subsequently, in the maintenance of smoking for the majority of smokers who want to quit."[25] IOM's recent review summed up the evidence:

> *"It is clear that the juxtaposition of numerous risk factors during the adolescent and young adult years is likely to increase the probability that first trials of tobacco use will turn into persistent use. These factors include the sequence of neurodevelopment in the adolescent years, the unique sensitivity of the adolescent brain to the rewarding properties of nicotine, the early development of symptoms of dependence in an adolescent's smoking experience (well before reaching the 100-cigarette lifetime threshold), and the difficulties that adolescents have in stopping smoking."*[26]

As a result of nicotine addiction, about three out of four teen smokers end up smoking into adulthood, even if they intend to quit after a few years.[27] As noted above, smoking-related health problems are influenced by both the duration (years) and intensity (amount) of use. Unfortunately, individuals who start smoking at younger ages are more likely to smoke as adults, and they also are among the heaviest users.[28] In addition to longer-term health risks such as cancer and heart disease, young people who smoke are at risk for more immediate health harms, like increased blood pressure, asthma and reduced lung growth.[29]

Over the past several years, there has been a rapid rise in youth use of electronic cigarettes. This is a concern because as stated by the Surgeon General, "E-cigarette use poses a significant – and avoidable

– health risk to young people in the United States. Besides increasing the possibility of addiction and long-term harm to brain development and respiratory health, e-cigarette use is associated with the use of other tobacco products that can do even more damage to the body."[30]

E-cigarettes are now the most popular tobacco product among young people. According to the National Youth Tobacco Survey, 11.7 percent of high schoolers and 3.3 percent of middle schoolers reported current use of e-cigarettes in 2017.[31] A 2018 report by the National Academies of Science, Engineering and Medicine (NASEM) found the effect of e-cigarette use on cigarette smoking initiation to be causal, concluding that "There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."[32]

Older Adolescents and Young Adults Are a Source of Cigarettes for Youth

According to the 2016 Monitoring the Future Survey, more than 60% of 10th grade students and nearly half (46.2%) of 8th grade students say it is easy to get cigarettes.[33] This perception that getting cigarettes is easy exists despite the fact that fewer retailers are selling tobacco to underage youth than before. In 2014 (federal fiscal year), the national retailer violation rate was 9.8 percent.[34] This suggests that youth are obtaining cigarettes from sources other than direct store purchases.

Research shows that youth smokers identify social sources, such as friends and classmates, as a common source of cigarettes. Although older and more established youth smokers are more likely to attempt to purchase their cigarettes directly than kids who smoke less frequently or are only "experimenting," they are also major suppliers for kids who do not purchase their own cigarettes but instead rely on getting them from others.[35] And with more 18- and 19-year olds in high school now than in previous years, younger adolescents have daily contact with students who can legally purchase tobacco for them.[36]

A 2005 study based on the California Tobacco Survey found that 82 percent of adolescent ever smokers obtained their cigarettes from others, most of whom were friends. A substantial percentage (40.9%) of the people buying or giving the cigarettes were of legal age (18 years or older) to purchase them, with most (31.3%) being between 18 and 20 years of age. 16- to 17-year-olds were more likely to get their cigarettes from 18- to 20-year olds than were younger adolescents.[37] Another study found that smokers aged 18 and 19 years were most likely to have been asked to provide tobacco to a minor, followed by smokers aged 20 to 24 years and nonsmokers aged 18 and 19 years, respectively.[38]

National studies find that underage youth commonly obtain cigarettes from social networks. The Population Assessment of Tobacco and Health study found that 75% of 15-17 year old current smokers obtained cigarettes from social sources.[39] Data from the National Survey on Drug Use and Health (NSDUH) show that nearly two-thirds (63.3%) of 12- to 17-year olds who had smoked in the last month had given money to others to buy cigarettes for them. One-third (30.5%) had purchased cigarettes from a friend, family member or someone at school. In addition, six out of ten (62%) had "bummed" cigarettes from others.[40]

Raising the sale age of tobacco to 21 is likely to make both direct retail purchase and social source acquisition more difficult for underage youth, especially for 15-,16-, and 17- year olds, "who are most likely to get tobacco from social sources, including from students and co-workers above the [minimum legal age of access] MLA."[41] With the minimum legal sale age set at 21 instead of 18, legal purchasers would be less likely to be in the same social networks as high school students and therefore less able to sell or give cigarettes to them.

Tobacco Companies Target Young Adults Ages 18 to 21

Tobacco industry advertising and promotional activities cause youth and young adults to start smoking, and nicotine addiction keeps people smoking past those ages.[42] Tobacco companies heavily target young adults ages 18 to 21 through a variety of marketing activities—such as music and sporting events, bar promotions, college marketing programs, college scholarships and parties—because they know it is a

critical time period for solidifying tobacco addiction.[43] It is also a time when the industry tries to deter cessation and recapture recent quitters.[44]

Tobacco companies realize that the transition into regular smoking that occurs during young adulthood is accompanied by an increase in consumption, partly because the stresses of life transitions during that time—going to college, leaving home, starting a new job, joining the military, etc.—invite the use of cigarettes for the effects of nicotine.[45] Statements obtained from the tobacco industry's internal documents emphasize the importance of increasing consumption within this target market in order to maintain a profitable business:

> *"…eighteen to twenty-four year olds will be "[c]ritical to long term brand vitality as consumption increases with age."*[46]

> *"…[t]he number one priority for 1990 is to obtain younger adult smoker trial and grow younger adult smoker share of market."*[47]

> *"To stabilize RJR's share of total smokers, it must raise share among 18-20 from 13.8% to 40%...ASAP."*[48]

> *"Our aggressive Plan calls for gains of about 5.5 share points of smokers 18-20 per year, 1990-93 (about 120,000 smokers per year). Achieving this goal would produce an incremental cash contribution of only about $442MM during the Plan period (excluding promotion response in other age groups and other side benefits). However, if we hold these YAS [young adult smokers] for the market average of 7 years, they would be worth* ***over $2.1 billion in aggregate incremental profit.*** *I certainly agree with you that this payout should be worth a decent sized investment." [emphasis in original]*[49]

In 2006, after reviewing the evidence against the tobacco companies in a civil racketeering case brought forth by the U.S. Department of Justice, U.S. District Court Judge Gladys Kessler made this conclusion about the industry's marketing practices:

> *"From the 1950s to the Present, Different Defendants, at Different Times and Using Different Methods, Have Intentionally Marketed to Young People Under the Age of Twenty-one in Order to Recruit 'Replacement Smokers' to Ensure the Economic Future of the Tobacco Industry."*[50]

And in 2014, the U.S. Surgeon General eliminated all doubt regarding the industry's role in perpetuating our nation's tobacco epidemic. He stated:

> *"…the root cause of the smoking epidemic is also evident: the tobacco industry aggressively markets and promotes lethal and addictive products, and continues to recruit youth and young adults as new consumers of these products."*[51]

Increasing the Minimum Drinking Age Law to 21 Reduced Youth Drinking and Fatalities

The public health benefits and lessons learned from increasing the minimum drinking age to 21 offer additional support for pursuing a higher MLSA for tobacco products. In the early 1980's, many states raised the legal drinking age to 21. By 1988, all states had minimum drinking age laws of 21.[52] Data from the Monitoring the Future Survey show that past month and binge drinking among high school seniors decreased by 22 percent between 1982 and 1998, while youth drinking driver involvement in fatal crashes decreased by 61 percent over this same time period. The decrease in drinking may account for some of the decrease in drinking and driving.[53]

Subsequent research suggests that raising the minimum drinking age to 21 is associated with reduced alcohol consumption among youth and young adults and fewer alcohol-related crashes.[54] In fact, the National Highway Traffic Safety Administration reports that, since 1975, increasing the minimum drinking age has saved more than 21,000 lives.[55] Moreover, research shows that, when the drinking age is 21,

individuals under 21 drink less and continue to drink less through their early twenties.[56] With increased enforcement of the law, these impacts could be even greater.[57]

The IOM concluded in its review that "raising the minimum legal drinking age for alcohol coupled with rigorous enforcement and penalties for violations has been associated with lowered rates of alcohol consumption among adolescents and adults as well as with reduced rates of alcohol-related adverse events (e. g. traffic crashes and hospitalizations)."[58]

Benefits of Raising the MLSA to 21

Comprehensive approaches to addressing public health problems work. Much like increasing the minimum drinking age has not eliminated underage drinking, a higher MLSA is not likely to eliminate underage tobacco use. Rather, it is one more part of a comprehensive tobacco control effort that offers several benefits that could help reduce youth tobacco use and increase the likelihood that youth will grow up to be tobacco-free:

- Delaying the age when young people first begin using tobacco would reduce the risk that they will transition to regular or daily tobacco use and increase their chances of quitting, if they become regular users.[59]
- Raising the MLSA to 21 would increase the age gap between adolescents initiating tobacco use and those who can legally provide them with tobacco products by helping to keep tobacco out of schools.[60]
- Younger adolescents would also have a harder time passing themselves off as 21-year-olds than they would 18-year-olds, which could reduce underage sales.[61]
- MLSA of 21 may simplify identification checks for retailers, since many state drivers' licenses indicate that a driver is under the age of 21 (e.g. license format, color or photo placement).[62]

Campaign for Tobacco-Free Kids, August 1, 2018/Becca Knox

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UNITED STATES of America, Plaintiff,

and

Tobacco–Free Kids Action Fund, American Cancer Society, American Heart Association, American Lung Association, Americans for Nonsmokers' Rights, and National African American Tobacco Prevention Network, Intervenors,

v.

PHILIP MORRIS USA, INC., (f/k/a Philip Morris, Inc.), et al., Defendants.

No. CIV.A. 99–2496(GK).

United States District Court, District of Columbia.

Aug. 17, 2006.

Background: United States brought action alleging that cigarette manufacturers and tobacco-related trade organizations violated, and continued to violate, Racketeer Influenced and Corrupt Organizations Act (RICO) by engaging in conspiracy to deceive American public about health effects of smoking and environmental tobacco smoke, addictiveness of nicotine, and health benefits from low tar "light" cigarettes, and to manipulate design and composition of cigarettes in order to sustain nicotine addiction. Bench trial was held.

Holdings: The District Court, Kessler, J., held that:

(1) defendants comprised association-in-fact "enterprise" under RICO;

(2) defendants' statements regarding health effects of smoking evidenced specific intent to defraud; and

(3) defendants would be required to issue corrective statements.

Ordered accordingly.

1. Commerce ⇐82.60

Tobacco trade organization engaged in and conducted activities affecting interstate commerce within meaning of Racketeer Influenced and Corrupt Organizations Act (RICO), where cigarette manufacturers declared contributions of over $618.4 million to organization, organization spent more than $169 million for public relations and advertising, organization's press releases and other public statements were disseminated to public via newspapers and magazines, and organization engaged in lobbying efforts in various states. 18 U.S.C.A. § 1962(c, d).

2. Commerce ⇐82.60

Tobacco research organization engaged in and conducted activities affecting interstate commerce within meaning of Racketeer Influenced and Corrupt Organizations Act (RICO), where cigarette manufacturers contributed total of approximately $505.4 million to organization, which payments were processed through interstate banking system, organization funded 1,657 research grants-in-aid, research contracts, and scientific conferences, totaling approximately $317 million, in United States and abroad, and organization administered manufacturers' special project funding via checks processed through interstate banking system and delivered via United States Mail. 18 U.S.C.A. § 1962.

3. Racketeer Influenced and Corrupt Organizations ⇐7

Cigarette manufacturers did not deliberately choose not to develop, market, and profit from less hazardous cigarettes in order to insulate their existing brands from competition and to reduce their litigation exposure, and thus manufacturers

Milstein TT, 1/7/05, 9338:16–9342:3, 9384:15–25.

3126. Defendants have engaged in a large post-MSA spending increase on various forms of promotion at the retail level. In 2000, tobacco companies spent $9.57 billion dollars to market their products, the overwhelming majority of which was spent on marketing aimed at retail locations such as convenience stores. In those retail locations in 2000, tobacco companies spent $4.26 billion on point of sale advertising (e.g., in-store signs) and promotional allowances (payments to retailers for prime shelf space and in-store displays, as well as volume discounts and buydowns or rebates) and $3.52 billion on retail value added items such as purchase-related gifts and multi-pack discounts. Combining the figures for point of sale advertising and promotional allowances, tobacco companies spent approximately 81.2% of their marketing expenditures at retail locations. Chaloupka WD, 73:16–91:7.

3127. Philip Morris's spending on Marlboro promotion at retail increased more than a hundred-fold between 1987 and 1997, and then doubled again from 1997 to 2000. Philip Morris's retail promotions budget for Marlboro increased from $16.7 million in 1987 to $469.4 million in 1997. 2085296400–6461 at 6412 (U.S. 45702).

3128. According to its "2003–2007 Five Year Plan," dated April 3, 2003, Philip Morris planned to "test concepts for a new wallet-sized Marlboro rewards card among young adult smokers in the fall of 2003 ... to reinforce our equity messages and use an innovative approach to deliver incremental value that will continue to set our brands apart from those of our competitors." The proposed card would be preloaded with a fixed dollar amount that allows Marlboro smokers to make purchases wherever a major credit card is honored. *Id.* at PM3000540103–0118 at 0107, 0116 (U.S. 88649) (Confidential).

3129. Post–MSA, RJR has also increased its promotional spending and discounting. Leary PD, *United States v. Philip Morris*, 5/2/02, 16:4–17:19, 25:7–27:15, 63:3–64:17; 526293849–4014 (U.S. 87845).

e. Defendants' Promotional Items, Events and Sponsorships Attract Youth

(1) Events

3130. Defendants continue to hold and advertise events such as "Bar Nights" that reach youth.

3131. The cigarette company Defendants have increased their event budgets since signing the MSA. 2085296400–6461 at 6412 (U.S. 45702).

3132. Defendants often promote their events—and therefore their cigarette brands—in free newspapers available to anyone. For example, in 2002, Philip Morris continued to place advertisements for its events program Marlboro Bar Nights in "alternative" newspapers, such as the Village Voice, that are free and widely distributed. Camisa PD, *United States v. Philip Morris*, 7/11/03, 354:18–24, 356:7–18.

3133. Beginning in 1999, B & W sponsored the Kool Mixx DJ Competition. The objective of the Competition was to

> contemporize the Kool image by creating grassroots programs that fuse or mix different elements of hip-hop that will showcase artists' skills and stretch the brand muscles ... [and][b]uild awareness, trial and image of Kool among Urban ASU [Adult Smoker Under] 26 year old smokers, both male and female for all cultures.

Competition events were scheduled in major United States cities such as New York, Chicago, Detroit, and Los Angeles. "Communication Vehicles" used to publicize the Competition included an 800 number, radio spots, pack sleeves, and retail tie-ins. B & W continued to sponsor the Kool Mixx DJ Competition in 2002 and 2003. 432210032–0067 at 0036, 0038, 0047 (U.S. 22226); ARU6432538–2543 (US78267).

3134. In 2000, B & W sponsored the "Band to Band" 2000 Music Competition, "a rock-oriented, nationwide band-based talent search" which offered over $100,000 in cash and prizes and promoted one of B & W's flagship brands, LuckyStrike. B & W support for the program, which began in 1996, included "promotions, posters and media buys for the bands." In 2000, "Band to Band" program events were scheduled to take place in major cities such as Washington D.C., Chicago, Miami, Los Angeles, and Houston. 239040063–0065 (U.S. 22201).

3135. The age of individuals attending these events was not always verified. An internal Lorillard document describes how David Desandre, a Lorillard marketing employee, and Beth Crehan, an employee of a marketing promotion firm, were able to attend a Lucky Strike "Band to Band" event held at Park West Concert Hall in Chicago on November 11, 2000 without being asked for any identification. Inside the Concert Hall were "pole banners with the Lucky Strike Band to Band tag-line" as well as additional banners and signs. Desandre described how, while he was filling out a form to receive a free CD, a Lucky Strike staff member "threw me a pack of Lucky Strike cigarettes ... she did not ask me if I was 21 or a smoker. She also did not ask for my id. Beth Crehan was also not asked if she was 21 or a smoker. Beth was also not asked for id." 986002720273 (U.S. 22212).

(2) Sponsorships

3136. Defendants sponsor televised racing events which have great appeal with youth. As a result, millions of youth watching these events are exposed to Defendants' cigarette marketing imagery.

3137. The cigarette company Defendants have increased their sponsorship budgets since signing the MSA. In 1999, Defendants spent $267.4 million on sponsorships, an increase of 7.6 % from 1998. 1900082–0107 at 5 (U.S. 60663).

3138. Sponsorships allow the cigarette company Defendants to garner national television exposure, despite the broadcast ban on televised cigarette advertising. Races are broadcast on television and radio, and are covered in newspapers and magazines; each of these types of media coverage mention the cigarette brand that sponsors the race itself or the individual race car and driver. For example, the Winston Cup NASCAR race series with over thirty races annually was broadcast on radio and television; race highlights were also shown on television news programs and in newspapers and were featured in magazine sports columns. 507424927–4929 (U.S. 24261). Often, broadcast coverage of Defendant-sponsored races is required under the broadcast contract. For example, in connection with the May 21, 1989 Winston NASCAR race in Charlotte, North Carolina, the broadcast contract called for "a 'mid-race recap' which will air immediately after the second race segment .... a [60 second] length [recap] with a superslide of the Winston race logo at the top of the screen with the Nabisco logo displayed below and to the left." 507424864–4864 (U.S. 22895).

3139. Races are preceded by preliminary events (including qualifying races and announcement of pole positions) and followed by highlight footage or the an-

nouncement of awards, such as the Winston "No Bull" race awards. In connection with the 1989 Winston NASCAR race in Charlotte, North Carolina, RJR, through its parent RJR Nabisco and Charlotte Motor Speedway, provided prerace events for broadcast to target markets. For example, RJR, Nabisco, and Charlotte Motor Speedway prepared six to eight driver's columns, video and audio news releases, video feed of open practice sessions, radio promotions and giveaways where "the grand prize will be a first rate weekend at The Winston [Cup]," stories and photographs of practice sessions and color slides of the drivers with the Winston logo, pre-race tours by drivers, as well as post-race coverage of the Winston Million. 507424862–4863 (U.S. 51200); 507424872–4874 (U.S. 51201).

3140. Cigarette brand names are reinforced not only on the race cars themselves, but also on drivers' uniforms, team uniforms, hats, and the large transporters used to move cars from event to event. The events themselves offer marketing opportunities for trackside billboards, sampling, hospitality tents, and promotional giveaways, like hats, sunglasses, and programs. 2072516263–6267 (U.S. 41558); 520809149–9152 (U.S. 52643*).

3141. Defendants falsely deny that the television exposure their cigarette brands garner does not motivate their continued sponsorship of racing events. For example, RJR asserted in its August 1994 statement before the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Health and Environment that "radio and television exposure is not a motivating consideration for Reynolds in deciding whether to sponsor an event or a vehicle participating in an event." 509321275–1290 (U.S. 21993). However, Susan Ivey, President and CEO of Reynolds American, acknowledged that one of the benefits of brand sponsorship of televised sporting events is exposure of the brand name on television. Ivey WD, 48:6–49:4.

3142. The television exposure gained by Defendants' sponsorship of racing events is obviously extremely valuable—especially in light of the ban on broadcast advertising. For example, in 1999, for the three main tobacco-sponsored auto racing series—NASCAR Winston Cup, CART FedEx Championship (where Marlboro and Kool sponsor racing teams and Philip Morris offers the Marlboro Pole Award), and NHRA Winston Drag Racing—the tobacco industry received over $120 million of television exposure in the United States alone. Krugman WD, 116:3–122:7.

3143. Joyce Julius and Associates is an independent company which provides measurement and estimates monetary values of cigarette brand exposures in independent sports and special event programs. *Id.* According to Joyce Julius data, Defendants' cigarette brands continue to receive considerable television coverage. For instance, in 2002 alone, across all airings of the measured televised racing events, 533,301,591 television viewers tuned in to shows where Defendants' cigarette brands were mentioned or exposed (this is a count of viewing instances and not of unique viewers), whereas only eleven million people actually attended these same races. *Id.*

3144. Joyce Julius valued the total exposure received by Philip Morris of its cigarette brands at televised racing events during 2002 to be $197 million. *Id.* The Marlboro cigarette brand was exposed or mentioned to approximately 54 million television viewers and 2.4 million racing event attendees in 2002. Id.

3145. Joyce Julius valued the total exposure received by B & W of its cigarette brands at televised racing events during

2002 to be $44 million. *Id.* The Kool cigarette brand was exposed or mentioned to approximately 136 million television viewers and over five million racing event attendees in 2002. *Id.*

3146. Joyce Julius data valued the total exposure received by RJR of its cigarette brands at televised racing events during 2002 to be $1.2 billion. *Id.* The Winston cigarette brand was mentioned or exposed at every one of the televised racing events in 2002, reaching over 533 million television viewers and eleven million race attendees. *Id.*

3147. Minutes from a November 5, 1992 BATCo Management Board Meeting revealed that the company was aware of the monetary value of cigarette brand exposure through the sponsorship of televised sporting events. Specifically, BATCo estimated the value of the television airtime that its brand State Express 555 would receive through its sponsorship of the Subaru International Rally Works Team in the 1993 World and Asian Specific Rallies Championship. The cost of sponsorship would be £5.9 million but it would provide £15.3 million "in television air time benefit and other unquantified media benefits." 320010638–0640 at 0639 (U.S. 28201); 321440293–0311 at 0294 (U.S. 85217).

3148. Races continue to be very popular televised programs. Millions of young people under the age of eighteen watch Defendants' racing events. In April 2000, NASCAR television ratings were double those of an NBA playoff game in a competing time slot. TLT0741089–1089 (U.S. 88741).

3149. Defendants use their race sponsorships, as well as the television broadcast exposure, to promote their cigarette brands at retail. In 1996, RJR displayed at retail locations such as grocery and convenience stores: the Winston Motorsports simulator; the Winston or Camel show car; "well known Winston Cup or Smokin' Joe driver, surrounded by a small army of fans ... complete with autograph session"; extensive signage; and an inflatable Winston or Camel cigarette pack that was "an awe inspiring 15 feet tall." 514238599–8634 at 8604 (U.S. 51832).

3150. Similarly, Philip Morris's Marlboro Racing Program included various magazine, newspaper, billboard, and retail advertising components. A Philip Morris planning document for its 1995 Marlboro Racing Program stated:

> Philip Morris will implement a comprehensive advertising program to support Marlboro racing and will include the following: Outdoor advertising ... ROP [free newspapers] ... USA Today ... [and] Insertions in racing enthusiast books and national magazines.

Philip Morris planned to "[d]ominate retail environment thirty days prior to the race with three tier wave promotion ... [and] Display racing POS for 30 days prior to the race." The document also noted that the Marlboro Pole Award "provides Philip Morris with ... Year-long visibility at all venues." 2060138575–8585 at 8577, 8580, 8581 (U.S. 24004).

3151. Further exposure to the Marlboro trademark occurs through media coverage in the United States of Philip Morris International sponsored races. Szymanczyk TT, 4/11/05, 18372:518413:25. Philip Morris also sponsors an auto racing team, called Marlboro Team Penske, in the Indy Racing League ("IRL") series. The IRL is a racing organization that sponsors a series of races in the United States, the best-known of which is the Indianapolis 500. Szymanczyk WD, 115:14–18; Szymanczyk TT, 18381:2–5.

3152. Philip Morris has long understood how important its use of racing imagery is to attracting young smokers. In

a December 1992 marketing review titled "Motorsports Sponsorship," Philip Morris evaluated its racing sponsorships and adjusted its "marketing strategy for motorsports" going forward. To the question of whether Philip Morris should remain in motorsports sponsorships, the answer was: "Yes: It enables us to reach millions of our target market with TV media coverage, and is particularly important in restricted markets." The identified objectives were: (1) to "Regain momentum in the hearts and minds of our target market—young adult smokers under 25"; and (2) to "look at current and new program opportunities to extend our reach with starters and young adult smokers." One specific Formula 1, a European racing league, marketing strategy was to create a Formula 1 "team of young talent which is not necessarily a winning team, more rebellious, fun, daredevil, more easily identifiable with the young adult target market." The team would feature "[a]nti-establishment gear (jeans/boots)" and a "[c]razy car design." 2501058650–8680 at 86578658, 8661 (U.S. 21702).

(3) Promotional Items

3153. Defendants' marketing reaches youth by providing promotional items—gifts such as t-shirts, mugs, or lighters—at retail and via direct mail.

3154. A 1992 Gallup survey revealed that almost half of adolescent smokers and one quarter of nonsmoking adolescents had received promotional items from tobacco companies. Krugman WD, 107:18–20.

3155. Defendants currently continue to provide individuals with promotional items that appeal to youth. For example, on May 7, 2003, B & W issued a press release titled "Kool Connects Consumers with Free Motorola Pager Offer." The press release described an opportunity for consumers to purchase specially marked packs of Kool and receive coupons redeemable for a Motorola pager. The press release quoted Ledo Cremers, Divisional Vice President for Kool brand marketing, as stating: "Kool celebrates urban living ... [t]he Motorola pager promotion fits into the liftstyle of Kool consumers who want to be connected." The press release indicated that the Motorola pager promotion would "be supported by advertising in newspapers, national magazines, and alternative media." TLT074110–0110 (U.S. 86668).

3156. In an April 22, 1981 internal memorandum to Dick Veatch, B & W Brand Promotion Manager, from P.W. Stebbins, B & W employee, memorialized a telephone conversation with Betty Carr regarding a Barclay sampling program, in which Carr reported that her Houston store, Tobacco Road, had been inundated with teenagers trying to sell or exchange the cigarettes they received as part of a Barclay promotion. Carr indicated that a similar situation had occurred with a Kool milds sampling in Houston. 666006105–6106 (U.S. 20959).

6. Defendants' Youth Smoking Prevention Programs Are Not Designed to Effectively Prevent Youth Smoking

3157. Defendants have widely publicized their policies not to market to youth, their intent to prevent youth smoking, and the corporate programs they have adopted to achieve those goals. MNAT00280070–0070 (U.S. 21724). Defendants' "youth programs" and youth smoking prevention efforts are not only minimally funded—given the vast sums they spend on marketing and promotion to youth—and understaffed both qualitatively and quantitatively, but no efforts have been made to

validate their effectiveness amongst the total population. Biglan WD, 381:5–17.

3158. There are four strategies that have proven effective in preventing adolescent smoking: (a) increase the cost of cigarettes; (b) eliminate marketing practices that make smoking appealing; (c) implement empirically validated school-based prevention programs; and (d) conduct media campaigns directed at youth, using spots that have been shown to influence adolescent smoking. Defendants have not adopted or implemented any of these four strategies. *Id.* at 386:7–398:16, 401:12–411:8; Chaloupka WD, 30:15–32:20.

3159. In contrast to these four proven strategies, Defendants have adopted YSP Programs focusing on: (a) school-based and community prevention programs; (b) media campaigns; and (c) programs targeting parents. Personnel assigned to these YSP Programs by Defendants are often given impressive sounding titles but lack experience or skills relevant to the task of preventing youth smoking and face an inherent conflict of interest.

3160. Philip Morris continues to increase its marketing expenditures in grossly disproportionate amounts to its spending on youth smoking prevention. Philip Morris's 2003 Financial Forecast Budget includes a budget of $110 million for youth smoking prevention, $8.9 million greater than its 2002 spending, "primarily due to increased spending for adult cessation programs." In contrast, in that year, Philip Morris spent more than $7.1 billion on sales incentives and product promotions. PM3000172220–2256 at 2234–2235, 2242 (U.S. 88646) (Confidential).

3161. School-based programs, which generally take place in classrooms for grades seven through nine, focus on sensitizing young people to influences that encourage smoking and teaching them skills to resist such influences. One of the largest programs is Life Skills Training, funded by Philip Morris and B & W. RJR implemented a similar Right Decisions, Right Now Program. Although Philip Morris, RJR, and B & W have each supported the implementation of school-based youth smoking prevention programs, they are often not effective because of the failure to implement the program as rigorously as the research study justifying it calls for. Lorillard also funded a school based program, "Making it H.I.P. Not to Smoke" which consisted of scholarship programs and other cash awards. A randomized control trial on the Lorillard program found that it did not deter adolescent smoking. Biglan WD, 382:18–396:17.

3162. Of greater concern is the fact that Philip Morris, RJR, Lorillard, and B & W direct their youth smoking prevention efforts towards early adolescents and ignore older adolescents. About 1,250 young people per day become established smokers (defined as smoking more than 100 cigarettes lifetime) at ages fifteen through seventeen, while about 725 per day become established smokers at ages eleven through fourteen. Thus, nearly two thirds of adolescents who smoke become established smokers in the later age range of fifteen through seventeen. Biglan WD, 403:1–5. The Philip Morris media campaign targeted youth ten to fourteen years old. Levy WD, 71:17–72:4. Lorillard targets ten to fifteen year olds. Watson PD, *United States v. Philip Morris*, 4/2/02, 160:22 162:11. RJR targets twelve to fifteen year olds. 520877431–7484 (U.S. 87873). Several of B & W's activities target children and early adolescents. Biglan WD, 401:18–402:9.

3163. Defendants also support community programs to reduce teenage access to cigarettes. For example, Defendants support the We Card Program, a form of merchant education, to reduce illegal sales

of tobacco to young people at the retail, convenience store level. We Card offers "free training seminars, in-store signage, and educational materials and incorporates an online catalogue which lists signage and training materials available for purchase". Studies show that vigorous enforcement does lead to a reduction in illegal sales. (no bates) (U.S. 73411).

3164. One of Lorillard's Corporate Principles provides that "Lorillard strongly supports the enforcement of laws which requires retailers to check the age of potential purchasers of cigarettes." Milstein TT, 1/7/05, 9382:5–10. However, Lorillard's expenditures for the We Card Program decreased significantly in 1999 and 2000 over its pre-MSA funding level; they decreased from $9.5 million in 1996 to $6.1 million in 1997 and then to $5.05 million in 1998. In 1999, the total program spending decreased to $4.2 million. This reduction in funding significantly limited distribution of We Card materials and training sessions. *Id.* at 9327:6–9331:14; 2085092888–2894 (U.S. 89180).

3165. There is no evidence that any Defendant has evaluated whether tobacco outlets participating in the We Card Program were actually not selling tobacco to young people or whether the program reduced the overall adolescent smoking prevalence rate. Biglan WD, 439:11–443:26. In fact, according to the Philip Morris commissioned 2003 TABS (Teenage Attitude and Behavior Survey), almost 70% of adolescent eleven to seventeen year old smokers who had bought cigarettes in the previous month purchased their cigarettes directly from the retail clerk where the clerk handed them the pack of cigarettes. Specifically, 43.8% of these eleven to fourteen year-olds, and 72.9% of these fifteen to seventeen year old smokers purchased their cigarettes from a retail clerk who handed them cigarettes. Willard TT, 4/12/05, 18694:9–18697:7; UCX0280450–0807 (U.S. 93349).

3166. Defendants also utilize media campaigns in their youth smoking prevention programs. Lorillard, RJR and Philip Morris have run televised national youth smoking prevention media campaigns. Lorillard ran the "Tobacco is Whacko—If You're a Teen" campaign, which included both print and broadcast advertising. Philip Morris has run the "Think. Don't Smoke." campaign, which began in 1998. RJR ran print ads as part of its "Right Decisions. Right Now" campaign.

3167. A study of seven different types of anti-smoking messages on adolescents' (seventh and tenth graders) intentions to smoke found that three types of messages were effective: (a) ads emphasizing the deleterious effects of smoking on families; (b) ads portraying young smokers as unable to achieve popularity, sophistication, or success; and (c) ads depicting attractive individuals refusing to smoke. Basically, to be effective with adolescents, ads must communicate that smoking is socially unacceptable. (no bates) (U.S. 73411).

3168. Instead, both Lorillard's and Philip Morris's media campaigns promote the message that smoking is an adult decision. Emphasizing that smoking is an adult activity underscores the desirability of engaging in adult behavior for adolescents who are particularly motivated to appear mature. Biglan WD, 409:20–21, 433:15–22. Most of Lorillard's and Philip Morris's youth smoking prevention advertisements do not promote the social disapproval of youthful smoking which available research indicates is critical to their effectiveness. *Id.* at 403:21–412:8.

3169. Although they have conducted focus groups on public reactions to the campaigns, no Defendant has evaluated whether its media campaigns are actually effective in reducing adolescent smoking

or intentions to smoke. *Id.* at 403:21–412:8.

3170. On October 26, 1998, Fox Broadcasting Company reviewed Philip Morris's first round of Youth Smoking Prevention ("YSP") ads and rejected them for failing to send a strong enough anti-smoking message to children. Szymanczyk TT, 4/07/05, 18256:9–18258:20, 18262:319; 2069512311–2311 (JD 053821).

3171. On April 13, 2001, California Attorney General Lockyer wrote a letter to Denise Keane, Philip Morris Senior Vice President and General Counsel, requesting immediate discontinuation of the "Think, Don't Smoke" campaign on the basis of research demonstrating that its message was ineffective and in fact diluted the effective anti-smoking messages of the states and the American Legacy Foundation which was created pursuant to the MSA. Philip Morris continued to air the "Think, Don't Smoke" advertisements for nine months after receiving this letter. Szymanczyk TT, 4/07/05, 18264:3–18272:17.

3172. Lorillard utilized the slogan "Tobacco Is Whacko—If You're a Teen" in its youth smoking prevention media campaign. According to a February 2000 Lorillard report on the results of focus groups that were done with ten to fifteen year olds to get their reactions to Lorillard's youth smoking prevention advertisements:

> Respondents remembered the tag line, but had negative responses to it.
>
> They complained that it was very young (younger than they are) and "cheesy."
>
> They particularly disliked the if you're a teen part of "Tobacco is Whacko—If You're a Teen." They complained that this singled them out and that they believe it should apply to all ages.

94691840–1858 (U.S. 87874); Biglan WD, 409:5–18.

3173. Despite these results, Lorillard continued to use the slogan. Victor Lindsley, Lorillard's group brand director who was involved in developing the company's youth smoking prevention media campaign, by email dated April 4, 2000, indicated to General Counsel Milstein that he was "very uncomfortable" about the tag line. In response, Milstein stated that Martin Orlowsky, Lorillard's President's "only comment to me [Milstein] was that he [Orlowsky] did not want to hear again about the tag line ever, and that I [Milstein] should not be influenced by the creative complainers." Lorillard did not remove this unpopular tag line until 2001. Milstein TT, 1/10/05, 9399:25–9410:6; 97011359–1359 (U.S. 89287); 99282955–2955 (U.S. 89288).

3174. Philip Morris, Lorillard, B & W, and RJR have also directed a variety of communications concerning youth smoking prevention to parents, including television advertisements, brochures, and workshops. Biglan WD, 412:9–436:3. Philip Morris started out with television ads and now distributes youth smoking prevention brochures to approximately one million parents who are on the Philip Morris mailing list. Levy WD, 74:4–6, 87:10–89:20. The RJR website describes, and includes the text of, three youth smoking prevention brochures intended for parents. 520877431–7484 (U.S. 87873); Biglan WD, 433:1–434:6. As part of its "Take 10" campaign, Lorillard has placed youth smoking prevention print advertisements directed at parents in a number of magazines. The advertisements emphasize that by the teenage years, young people are often alienated from their parents and encourage parents to talk to their children. *Id.* at 424:14–425:23. B & W has information for parents and an available video on its website.

3175. Beginning in June 2003, Philip Morris USA began to run television commercials directing viewers to its website, where it addresses smoking and disease, addiction, quitting, and talking to kids about smoking. (no bates) (JD 053158). While some of the ads may grab the viewers' attention, the fact remains that those ads have never been evaluated to see if they are actually achieving their intended results, namely, impacting youth smoking incidence. The fact that parents or other adult viewers may find the ads persuasive casts no light on whether the seventeen to twenty-one year olds do.

3176. The evidence is mixed on whether such efforts to mobilize parents actually affect adolescent smoking prevalence. For example, one study randomly assigned parents to receive or not receive a set of four messages designed to encourage parents to set rules about tobacco use. There was no evidence that the messages deterred smoking. Moreover, research has found that flooding a community with pamphlets urging parents to talk to their children about not using tobacco had no discernible effect. Biglan WD, 412:9–413:19.

3177. Youth smoking prevention campaigns targeting parents should be routinely evaluated in terms of: (a) their efficacy in getting parents to talk to their children about not using tobacco or otherwise set limits around smoking; and (b) their actual impact on youth smoking. Defendants have not undertaken any such evaluations. *Id.* at 434:19–435:5, 416:17–19, 427:15–16, 430:3–4, 434:9–10.

3178. Despite the fact that most smokers want to quit, RJR advises parents who smoke that, "[i]f you are like most smokers, you smoke because you enjoy it." The B & W website advises, "[t]ell your children that laws exist to enforce smoking as a choice made by informed adults." VXA 1240104–0567 (U.S. 64316).

3179. Defendants never recommend that parents inform their children that smoking kills more than 400,000 people each year, involves an addiction that most smokers desire to end, and will harm those around the smoker. Nor do Defendants ever suggest that parents, as role models for their children, stop smoking.

3180. Defendants have failed to staff their YSP programs with individuals with experience or background in smoking prevention, prevention generally, or even youth issues. While it is understandable, as Defendants suggest, that YSP programs must be led by long-time employees with corporate credibility, that is no excuse for the total failure to hire persons with skills relevant to identifying and developing effective, empirically validated programs to prevent youth smoking. For example, Carolyn Levy, former Director of Youth Smoking Prevention at Philip Morris and a former research scientist, had no experience or background in prevention or youth smoking or youth issues and was unaware of even the basic prevention journals relied upon by prevention experts. Her successor and the current Senior Vice President for Youth Smoking Prevention, Howard Willard, had served previously as Senior Vice President of Quality and Compliance for Philip Morris, with no background in youth smoking prevention. Levy WD, 55:16–19, 57:14–59:24, 63:13–64:19.

3181. Neither Claudia Newton, B & W Tobacco Corporation's Vice President, Corporate Responsibility and Youth Smoking Prevention, nor Theresa Burch, the head of B & W Tobacco Corporation's youth smoking prevention programs, had any experience in youth smoking prevention. Newton PD, *United States v. Philip Morris*, 4/17/02, 70:23–71:2, 78:10–81:12, 192:24–193:9.

3182. Brennan Dawson, the longtime industry spokeswoman for the Tobacco Institute, had been B & W's Vice President for External Affairs (which includes YSP) and MSA Section III(1) designee, after Claudia Newton. Dawson had no college degree, no formal educational background in science or medicine, and no experience with youth smoking prevention or teen behavioral research prior to taking the position. Dawson WD, 4:10–20.

3183. Steven Watson, Vice President of External Affairs for Lorillard, prior to joining Lorillard with responsibility for the oversight of Lorillard's Youth Smoking Prevention Program, had never done any research on risk perception or any work that required him to develop programs for youth. Nor was he asked if he had such experience when he was interviewing for the position at Lorillard. Watson PD, *United States v. Philip Morris*, 4/2/02, 24:18–26:1. Interestingly, Watson did not even apply for the position of Vice President of External Affairs, but was contacted by Lorillard regarding the position. *Id.* at 21:6–19.

3184. Internal documents suggest that Defendants designed their YSP programs for public relations rather than efficacy in youth smoking prevention. A 1991 discussion paper from the Tobacco Institute explained that a "youth program" is important to the industry because it will:

> support the Institute's objective of discouraging unfair and counterproductive federal, state, and local restrictions on cigarette advertising, by: (a) providing on-going and persuasive *evidence* that the industry is actively discouraging youth smoking and independent *verification* that the industry's efforts are valid; (b) Reinforcing the belief that peer pressure—not advertising—is the cause of youth smoking [and] (c) Seizing the political center and forcing the anti-smokers to an extreme.

TIMN0164421–4424 at 4423 (U.S. 34445*) (emphasis in original).

3185. A 1995 Philip Morris document stated: "If we can frame proactive legislation or other kinds of action on the Youth Access issue . . . we will be protecting our industry on into the future." Additionally, the document stated:

> [I]f we don't do something fast to project that sense of industry responsibility regarding the youth access issue, we are going to be looking at severe marketing restrictions in a very short time. Those restrictions will pave the way for equally severe legislation or regulation on where adults are allowed to smoke.

2044046017–6022 at 6021–6022 (U.S. 66716).

7. Despite the Overwhelming Evidence to the Contrary, Defendants' Public Statements and Official Corporate Policies Deny that Their Marketing Targets Youth or Affects Youth Smoking Incidence

a. Defendants Claim They Restrict Their Marketing to People Twenty-one and Older

3186. All Defendants have made numerous public statements that they do not market to persons under twenty-one. From 1964 to 1991, all Defendants voluntarily agreed to abide by the industry's Advertising Code which prohibited marketing to persons under twenty-one. After 1991, when the Code was revised, all Defendants, at different times, adopted, and publicized, internal company policies not to market to persons under twenty-one.

(1) The 1964 Advertising Code

3187. On January 25, 1964, the Federal Trade Commission ("FTC") published a

in trying to persuade any nonsmokers to begin smoking or in persuading any smokers not to quit." Schindler WD, 76:17–77:1, 170:16–171:18, 208:16–18.

3295. According to Lynn Beasley, President and Chief Operating Officer at RJR, prior to its merger with B & W, "Reynolds only permitted those 21 and older to participate in many of our marketing programs." After the merger with B & W, "now we allow legal age adult smokers [i.e., those over eighteen] to participate in our direct mail, sampling and promotional program." Beasley WD, 118:7–17. Beasley confirmed that Reynolds has publicly stated that the company does not market to youth for her entire tenure there. Beasley TT, 17351:19–23.

8. Conclusions

3296. The evidence is clear and convincing—and beyond any reasonable doubt—that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying they do so. Dolan WD, 24:3–16; Krugman WD, 17:2–19:1; Chaloupka WD, 30:832:20; Biglan WD, 100–379.

3297. In response to the mountain of evidence to the contrary, Defendants claim that all the billions of dollars they have spent on cigarette marketing serves the primary purpose of retaining loyal customers ("brand loyalty"), and the secondary purpose of encouraging smokers to switch brands. They deny that any of their marketing efforts are aimed at encouraging young people to initiate smoking or to continue smoking. Dolan WD, 61:6–16.

3298. In fact, the overwhelming evidence set forth in this Section—both Defendants' internal documents, testimony from extraordinarily qualified and experienced experts called by the United States, and the many pictorial and demonstrative exhibits used by the Government—prove that, historically, as well as currently, Defendants do market to young people, including those under twenty-one, as well as those under eighteen. Defendants' marketing activities are intended to bring new, young, and hopefully long-lived smokers into the market in order to replace those who die (largely from tobacco-caused illnesses) or quit. Defendants intensively researched and tracked young people's attitudes, preferences, and habits. As a result of those investigations, Defendants knew that youth were highly susceptible to marketing and advertising appeals, would underestimate the health risks and effects of smoking, would overestimate their ability to stop smoking, and were price sensitive. Defendants used their knowledge of young people to create highly sophisticated and appealing marketing campaigns targeted to lure them into starting smoking and later becoming nicotine addicts. Dolan WD, 24:3–16; Krugman WD, 84:1–99:23; Chaloupka WD, 30:8–32:20; Biglan WD, 100–379.

3299. As a result, 88% of youth smokers buy the three most heavily advertised brands -Marlboro, Camel, and Newport. Fewer than half of smokers over the age of twenty-five purchase these three brands. For example, in 2003, Marlboro, the most heavily marketed brand, held 49.2% of the twelve to seventeen year old market but only 38% of smokers over age twenty-five. Eriksen WD, 52:17–54:10; (no bates) (U.S. 17684A).

3300. Independent scientific studies published in prestigious peer-reviewed scientific journals and in official government reports have confirmed Defendants' knowledge, as demonstrated in their internal documents, that their marketing contributes substantially to the initial demand for and continuing use of cigarettes by young people. Over the past ten years, there have been a number of comprehensive re-

views of the scientific evidence concerning the effects of cigarette marketing, including advertising and promotion, on smoking decisions by young people. The weight of all available evidence, including survey data, scientific studies and experiments, reports of public health and governmental bodies, and the testimony of experts in this case, supports the conclusion that cigarette marketing is a substantial contributing factor to youth smoking initiation and continuation. Eriksen WD, 55:4–20.

3301. Defendants spent billions of dollars every year on their marketing activities in order to encourage young people to try and then continue purchasing their cigarette products in order to provide the replacement smokers they need to survive. Defendants' expenditures on cigarette advertising and promotion have increased dramatically over the past decades, and in particular since the signing of the MSA. Krugman WD, 23:10–24:4. Over the decades, Defendants have used the full range of marketing tools available to them at any particular time, including: advertising on television, radio, and billboards, and in magazines and newspapers; sponsoring events, such as sporting events, bar promotions, festivals, concerts, and contests; providing coupons, price reductions, and free packs with purchases; providing gifts with purchases (known as "continuity items") such as t-shirts, mugs, and sporting goods; direct-mail marketing by sending magazines and other materials directly to individuals' homes; distributing free cigarette samples at retail stores, public events, bars, or other locations; and strategically locating "point of sale" advertising and promotions at retail outlets young people are most likely to frequent, such as convenience stores. Krugman WD, 43:14–2; Dolan WD, 48:6–3.

3302. In the face of this evidence, Defendants have denied, over and over, with great self-righteousness, that they have marketed to youth.

G. Defendants Have Publicly Denied What They Internally Acknowledged: that ETS Is Hazardous to Nonsmokers

1. Introduction

3303. Defendants' collective effort to maintain an open question as to the health effects of cigarette smoking was not limited to whether cigarettes caused disease in smokers themselves. During the 1970s, scientific evidence suggesting that exposure to cigarette smoke was hazardous to nonsmokers began to grow, and public health authorities began to warn of a potential health risk to both adults and children. Fearing government regulation to restrict smoking in public places and sensing a decrease in the social acceptability of smoking, Defendants were faced with a major threat to their profits.

3304. In 1974, Tobacco Institute chairman Horace Kornegay warned that smoking restrictions not only impacted sales but also "could lead to the virtual elimination of cigarette smoking." TIMN0067732–7755 at 7734 (U.S. 22047). Reynolds CEO Ed Horrigan wrote Lorillard executives in 1982: "We all know that probably the biggest threat to our industry is the issue of passive smoking." 93443843–3843 (U.S. 32289). A 1986 BATCo document stated: "The world tobacco industry sees the ETS issue as the most serious threat to our whole business." 1009931583165 at 3158 (U.S. 89556). Philip Morris Companies Vice Chairman Bill Murray was advised at a presentation by Project Down under Conference attendees, in 1987: "The situation can't get any worse. Sales are down, can't be attributed to taxes or price increases. ETS is the link between smokers and non-smokers and is, thus, the anti's

[NOT YET SCHEDULED FOR ORAL ARGUMENT]

No. 17-5196

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NICOPURE LABS, LLC, et al.,

Plaintiffs-Appellants,

v.

FOOD & DRUG ADMINISTRATION, et al.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici. Plaintiffs-appellants are Nicopure Labs, LLC, the Right to be Smoke-Free Coalition, the American E-Liquid Manufacturing Standards Association, the American Vaping Association, the Electronic Vaping Coalition of America, the Georgia Smoke Free Association, the Kentucky Vaping Retailers Association, Inc., the Louisiana Vaping Association, Maryland Vape Professionals, LLC, the New Jersey Vapor Retailers Coalition, the Ohio Vapor Trade Association, and the Tennessee Smoke Free Association.

Defendants-appellees are the U.S. Food and Drug Administration (FDA), Alex M. Azar II, Secretary of the U.S. Department of Health and Human Services, and Scott Gottlieb, MD, FDA Commissioner. Secretary Azar has been automatically substituted pursuant to Federal Rule of Appellate Procedure 43(c)(2).

The following entities and individuals participated as amici in support of plaintiffs in district court or on appeal:

- Consumer Advocates for Smoke-Free Alternatives Association
- NJOY, LLC
- National Center for Public Policy Research
- Smoke-Free Alternatives Trade Association
- State of Iowa
- TechFreedom

- Vape A Vet Project
- Washington Legal Foundation
- Philip Alcabes, Prof. of Public Health, College of Nursing & Public Health, Adelphi Univ.
- Edward Anselm, MD, Assistant Prof. of Medicine Icahn School of Medicine at Mount Sinai, Senior Fellow, R Street Institute
- Scott Ballin, Advisor to the Morven Dialogues on Tobacco, Nicotine, and Alternative Products Harm Reduction at the Univ. of Virginia, former Vice President for Public Policy and Leg. Counsel at the Am. Heart Assoc.
- Clive Bates, Director Counterfactual, Former Director, ASH (UK)
- Ernest Drucker, PhD, Research Scientist & Prof. of Public Health, College of Global Public Health, New York Univ.
- Konstantinos Farsalinos, MD, Research Scientist, Onassis Cardiac Surgery Center, Univ. of Patras, Greece
- William Godshall, MPH, Founder & Exec. Director, Smokefree Penn.
- Jacques LeHouezec, Consultant in Public Health, Président SOVAPE
- Bernd Mayer, PhD, Prof. & Chair, Dep't Pharmacology, University of Graz
- Jeff Nesbit, Exec. Director, Climate Nexus, Former Assoc. FDA Comm'r;
- Joel L. Nitzkin, MD, MPH, DPA, CEO of JLN MD Assocs., Senior Fellow for Tobacco Policy, R Street Institute
- Riccardo Polosa, MD, PhD, Prof. of Internal Medicine, Univ. of Catania
- Gilbert L. Ross, MD, Board-certified in Internal Medicine & Rheumatology
- Sally L. Satel, MD, Resident Scholar, American Enterprise Institute
- Michael B. Siegel, MD, Prof. of Community Health Sciences, Boston Univ. School of Public Health.
- Andrzej Sobczak, PhD, Prof., Head of Dep't Chemical Hazards & Genetic Toxicology, Inst. Occupational Medicine & Environmental Health
- David Sweanor, Adjunct Prof., Faculty of Law, Univ. of Ottawa Centre for Health Law, Policy & Ethics
- Michael B. Siegel, MD, Prof., Community Health Sciences, Dep't of Community Health Sciences, Boston Univ. School of Public Health

The following entities participated as amici in support of defendants in district court:

- American Academy of Pediatrics
- American Cancer Society Cancer Action Network
- American Heart Association
- American Lung Association
- American Thoracic Society
- Campaign for Tobacco-Free Kids
- Tobacco Control Legal Consortium
- Truth Initiative

B. Ruling Under Review. Plaintiffs seek review of the district court's July 21, 2017, Memorandum Opinion and Order (Judge Amy Berman Jackson) in Nos. 16-878 and 16-1210, which were consolidated for review. The opinion granted summary judgment for the government and is reported at 266 F. Supp. 3d 360.

C. Related Cases. The case on review has not previously been before this Court, and there are no related cases in any federal court of appeals. Nine other actions challenging FDA's deeming rule remain pending in district court. *Cigar Ass'n of Am. v. FDA*, No. 16-1460 (D.D.C.); *Cyclops Vapor 2, LLC v. FDA*, No. 16-556 (M.D. Ala.) (stayed); *En Fuego Tobacco Shop LLC v. FDA*, No. 18-28 (E.D. Tex.); *Faircloth v. FDA*, No. 16-5267 (S.D.W. Va.); *Hoban v. FDA*, No. 18-269 (D. Minn.); *Lost Art Liquids, LLC v. FDA*, No. 16-3468 (C.D. Cal.); *Moose Jooce v. FDA*, No. 18-203 (D.D.C.); *Rave Salon, Inc. v. Gottlieb*, No. 18-237 (N.D. Tex.); *Sanchez Icaza v. FDA*, No. 16-21967 (S.D. Fla.) (stayed and administratively closed).

Another case challenging certain compliance dates for the deeming rule is also pending in district court. *American Acad. of Pediatrics v. FDA*, No. 18-883 (D. Md.).

s/ Lindsey Powell
LINDSEY POWELL

authority under Chapter IX of the FDCA, rather than under FDA's preexisting authority to regulate drugs and devices. The opinion emphasized that the agency's authority under Chapter IX would enable it "to mitigate or perhaps extinguish any harm to public health" associated with e-cigarettes. *Id.* at 898. Plaintiffs in this case no longer challenge FDA's authority to deem e-cigarettes subject to Chapter IX.

B. E-cigarettes and FDA's 2016 Rule

1. In a final rule issued in May 2016, FDA exercised its authority under 21 U.S.C. § 387a(b) to deem all products that meet the definition of "tobacco product," excluding accessories of such products, to be subject to Chapter IX of the FDCA. 81 Fed. Reg. 28,974, 28,975 (May 10, 2016). E-cigarettes and their components and parts are among the tobacco products newly regulated as a result of this rule. *Id.*[2]

Although there is significant variation among the hundreds of e-cigarette devices now on the market, AR 23,987, such products generally consist of three basic parts: a cartridge containing "e-liquid," which typically contains nicotine and is frequently flavored; an atomizer with a heating element; and a battery and other electronics. *See Sottera*, 627 F.3d at 893; *see also* 81 Fed. Reg. at 28,975 (discussing e-

[2] FDA defined "component or part" to mean "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product." 81 Fed. Reg. at 28,975; *see* 21 C.F.R. §§ 1100.3, 1143.1.

cigarette components and parts). Typically, when a user breathes in through a mouthpiece, the atomizer vaporizes the e-liquid, which is then inhaled as an aerosol. *See Sottera*, 627 F.3d at 893. E-liquids are available in thousands of varieties, AR 23,987, including many fruit and candy flavors that particularly appeal to youth, AR 18,675; 81 Fed. Reg. at 29,011, 29,014.

Some e-cigarettes, called "cigalikes," are made to resemble conventional cigarettes, while others are not. 81 Fed. Reg. at 29,038. A growing number of new e-cigarette products are made to look like everyday objects, like computer flash drives, and can more easily avoid detection in schools and other places where e-cigarettes are not allowed. Kate Zernike, *'I Can't Stop': Schools Struggle With Vaping Explosion*, N.Y. Times (Apr. 2, 2018).[3] For example, a new device called "JUUL," which is extremely popular among students, "fits easily in a pocket and looks nondescript when plugged into a laptop's USB drive to recharge or sitting on a desk." Anne Marie Chaker, *Schools & Parents Fight a 'Juul' E-Cigarette Epidemic*, Wall Street Journal (Apr. 4, 2018);[4] *see* FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a youth tobacco prevention plan to stop youth use of, and access to, JUUL and other e-cigarettes* (Apr. 2018) (announcing measures to combat youth use of products such as JUUL

[3] Available at https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html.

[4] Available at https://www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246.

that "have become wildly popular with kids" and are "more difficult for parents and teachers to recognize or detect," and noting a high rate of illegal sales to youth).[5] Even though such products do not physically resemble conventional cigarettes, some "closely mimic[] the feeling of inhaling cigarettes," and they "deliver[] a powerful dose of nicotine, derived from tobacco." Chaker, *supra*.

FDA's deeming rule made e-cigarettes subject to the requirements of Chapter IX of the FDCA without any further agency action. 81 Fed. Reg. at 28,975. The rule became effective on August 8, 2016—ninety days after its publication date. With respect to the premarket review provisions for new tobacco products, however, FDA provided a lengthy compliance period for products that were already on the market on the rule's effective date. *Id.* at 29,011. For noncombustible products, including most e-cigarettes, that were on the market as of August 8, 2016, the agency subsequently extended the compliance period until August 8, 2022. *See* FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* 3 (4th ed. rev. Nov. 2017).[6]

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[5] Available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm.

[6] Available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf. Public health groups have filed suit in the U.S. District Court for the District of Maryland challenging FDA's extension of these compliance dates. *American Acad. of Pediatrics v. FDA*, No. 18-883 (D. Md.).

2. In its rulemaking, FDA noted that the full measure of potential risks and benefits presented by e-cigarettes is not yet known. 81 Fed. Reg. at 28,984. But "[w]hether [e-cigarettes] generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of [e-cigarettes] will still benefit public health." *Id.* "This final deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use," in part by giving the agency "critical information regarding the health risks of newly deemed tobacco products." *Id.* at 28,975.

While it is possible that certain e-cigarette products may prove beneficial in some respects for some individuals, the available data suggest that many of these products present substantial risks, and regulation is necessary both to address those harms and to resolve uncertainty about the products' effects. E-cigarettes typically contain and deliver nicotine—"one of the most addictive substances used by humans," 81 Fed. Reg. at 28,988, and a powerful pharmacologic agent that acts in the brain and throughout the body, *id.* at 28,981, 28,986. Nicotine use during adolescence is associated with "long-term effects including decreased attention performance and increased impulsivity," and "can disrupt brain development and have long-term consequences on executive cognitive function." 79 Fed. Reg. 23,142, 23,154 (Apr. 25, 2014).

In the absence of labeling and manufacturing standards, it can be difficult for consumers to ascertain how much nicotine e-cigarettes will deliver. FDA found "significant . . . variability between labeled content and concentration and actual content and concentration," noting that some e-liquids "claiming to be nicotine-free actually contained high levels of nicotine." 81 Fed. Reg. at 28,984. One study found that more than half of the e-liquids examined contained nicotine concentrations that deviated by more than ten percent from the stated amount. *Id.* at 29,034. Variations in device design and performance also affect the amount of nicotine and other chemicals that are actually inhaled by users, all of which leaves users unaware of the nicotine levels they are receiving. *Id.* at 29,029-32. In some instances, e-cigarettes can deliver more nicotine than conventional cigarettes. *Id.* at 29,031.

Many e-liquids also contain other chemicals that pose known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. 81 Fed. Reg. at 29,029-31; *see* Joseph G. Allen, *The Formaldehyde in Your E-Cigs*, N.Y. Times (Apr. 4, 2018) (noting that "[s]tudy after study . . . has confirmed that e-cigs can deliver formaldehyde to the user," and they have "found diacetyl in over 75 percent of e-cigs tested").[7] There is also evidence that toxic heavy metals, including lead and silicates,

[7] Available at https://www.nytimes.com/2018/04/04/opinion/formaldehyde-diacetyl-e-cigs.html. Because the deeming rule was the product of notice-and-comment rulemaking, this action arises under the Administrative Procedure Act, and the Court's review of the rule is confined to the administrative record. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985); *see R.J. Reynolds Tobacco Co. v. FDA*,

can be transferred from e-cigarette parts into the inhaled aerosol. AR 6,977, 15,585; 81 Fed. Reg. at 29,015. In addition, studies show that secondhand e-cigarette vapor may contain substances—including formaldehyde, benzene, and acrolein—that pose a risk to non-users through passive exposure. *See* 81 Fed. Reg. at 29,031-32; *Competitive Enter. Inst. v. U.S. Dep't of Transp.,* 863 F.3d 911, 919 (D.C. Cir. 2017) (upholding regulation banning e-cigarette use on airplanes based in part on studies showing that "e-cigarette vapor in confined aircrafts could harm non-users").

Plaintiffs and their amici cite a 2016 report by Public Health England that asserts that e-cigarettes are 95% safer than conventional cigarettes. Br. 6. But this document reflects a survey, not a research study, and FDA explained at length why this document and a prior paper on which it relied are entitled to little weight. 81 Fed. Reg. at 29,030. In particular, the authors of the prior paper acknowledged the "lack of hard evidence" for their analysis, and they did not follow standard scientific practices. *Id.* Moreover, "population effects appear to be largely outside the scope of this analysis since the manuscript did not address the likelihood that the characteristics of the products would make them more or less likely to appeal to new users, be used in conjunction with other tobacco products[,] or discourage quitting." *Id.* Regardless,

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696 F.3d 1205, 1217-18 (D.C. Cir. 2012). Thus, plaintiffs' reliance on extra-record evidence in challenging the rule should be disregarded. *See Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013). The government principally cites such materials for background and in response to plaintiffs' arguments.

the evidence on e-cigarettes continues to develop, and other studies suggest that cigarette smokers who also use e-cigarettes are less likely to quit smoking than cigarette smokers who do not also use e-cigarettes. *See id.* at 29,028, 29,037.

E-cigarettes are the fastest growing segment of the tobacco market, AR 124, and domestic sales of e-cigarettes are estimated to reach $5.5 billion in 2018, *see* Wells Fargo Sec., *Nielsen: Tobacco 'All Channel' Data 1/27, Marlboro Volume & Share Pressures Continue* 7 (Feb. 6, 2018).[8] The use of these products has surged among middle and high school students in particular, including those with no history of smoking, 81 Fed. Reg. at 28,984-85, 29,028-29, and e-cigarettes are now the tobacco product most commonly used by young people, AR 15,633, 15,635; 83 Fed. Reg. 12,294, 12,296 (Mar. 21, 2018). "After two decades of declining teen cigarette use," teen use of e-cigarettes "is exploding," and schools are struggling to manage the surging use of JUUL and other easily concealed e-cigarette devices. Chaker, *supra*; *see* Zernike, *supra*.

Compounding these concerns, the data also indicate that e-cigarettes may act as a gateway to other tobacco products. "There is *substantial evidence* that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults." National Academies of Sciences, Engineering & Medicine, *Public*

[8] Available at https://1lbxcx1bcuig1rfxaq3rd6w9-wpengine.netdna-ssl.com/wp-content/uploads/2018/02/Nielsen-Tobacco-All-Channel-Report-Period-Ending-1.27.18.pdf.

Health Consequences of E-Cigarettes 16-30 (2018) (*Public Health Consequences*);[9] *see* AR 15,663, 23,909. School officials "fear that the devices are creating a new generation of nicotine addicts." Zernike, *supra*. A recent study estimated that through e-cigarette use in 2014 alone, 168,000 adolescents and young adults would transition to smoking conventional cigarettes in 2015, and eventually become daily cigarette smokers, resulting in more than 1.5 million years of life lost. Samir S. Soneji et al., *Quantifying population-level health benefits & harms of e-cigarette use in the United States*, PLOS ONE 13(3):e0193328, at 1 (Mar. 14, 2018).[10]

Evidence indicates that e-cigarette marketing specifically targets youth, mimicking the strategies historically used by the tobacco industry to devastating effect. AR 18,674-93. Indeed, many of the same companies that dominate the cigarette industry are leading actors in the e-cigarette market. *See* Business Wire, *Technavio Announces Top Six Vendors in the Global E-Cigarette Market from 2016 to 2020* (June 15, 2016).[11] E-cigarette companies have advertised their products "during events and programs with youth viewership," AR 18,686, and in magazines with substantial youth readership, AR 265-70. And they have sponsored or provided free samples at events geared toward youth, including concerts, music festivals, parties, and sporting events.

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[9] Available at http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx.

[10] Available at https://doi.org/10.1371/journal.pone.0193328.

[11] Available at https://www.businesswire.com/news/home/20160615005016/en/Technavio-Announces-Top-Vendors-Global-E-Cigarette-Market.

81 Fed. Reg. at 28,986; AR 18,681-82. The proliferation of sweet-flavored e-cigarette varieties tends to further increase the products' attractiveness to young people. *See* 83 Fed. Reg. at 12,296-97; 81 Fed. Reg. at 29,014; 79 Fed. Reg. at 23,146-47; *see also* FDA, *FDA, FTC take action against companies misleading kids with e-liquids that resemble children's juice boxes, candies and cookies* (May 1, 2018) (reporting that the federal government recently issued warnings to manufacturers that have been marketing e-liquids to resemble kid-friendly products such as juice boxes, candy, and whipped cream, and noting that one product "not only resembles a Unicorn Pop lollipop but is shipped with one").[12]

C. Procedural Background

Plaintiffs, an e-cigarette manufacturer and industry associations, filed this suit in May 2016, alleging as relevant to this appeal that FDA unreasonably applied the statutory requirements of premarket review for new tobacco products to e-cigarettes without modifying those requirements. Plaintiffs further alleged that the requirement of premarket review for modified-risk tobacco products and the prohibition on the distribution of free e-cigarette samples violate the First Amendment.[13]

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[12] Available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm.

[13] Plaintiffs also raised numerous other challenges on which the agency prevailed at the district court, but none is at issue on appeal.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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MAY 2018

PATH
Population Assessment of Tobacco and Health

A collaboration between the NIH and FDA

National Institute on Drug Abuse

March 2016
2016 SRNT Plenary
Chicago, Illinois

Highlighted Findings From Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study

Andrew Hyland, Kevin Conway, Nicolette Borek, Bridget Ambrose, Heather Kimmel, Yu-Ching Chen, Victoria Green, Charles Carusi, David Maklan, Kristie Taylor, Blair Coleman, Geoffrey T. Fong, Karin Kasza, Jennifer Pearson, John Pierce, Samir Soneji, David Strong, Dennis Trinidad, Andrea Villanti, on behalf of the PATH Study Team

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Disclosure

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- The presenter has not received any industry funding.
- No off-label medication use will be discussed.

The analyses/manuscript is in preparation and published results may differ from those reported here. This is not a formal dissemination of information and the views and opinions expressed in this presentation/poster are those of the author only and do not necessarily represent the views, official policy or position of the U.S. Department of Health and Human Services or any of its affiliated institutions or agencies.

Introduction to the PATH Study

Presented by Kevin Conway on behalf of the PATH Study Team

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DISCLOSURE: Dr. Conway has no industry funding.

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PATH
Population Assessment of Tobacco and Health
A collaboration between NIH and FDA

This project is supported with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, and the Food and Drug Administration, Department of Health and Human Services, under a contract to Westat (Contract No. HHSN271201100027C).

National Institute on Drug Abuse

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PATH

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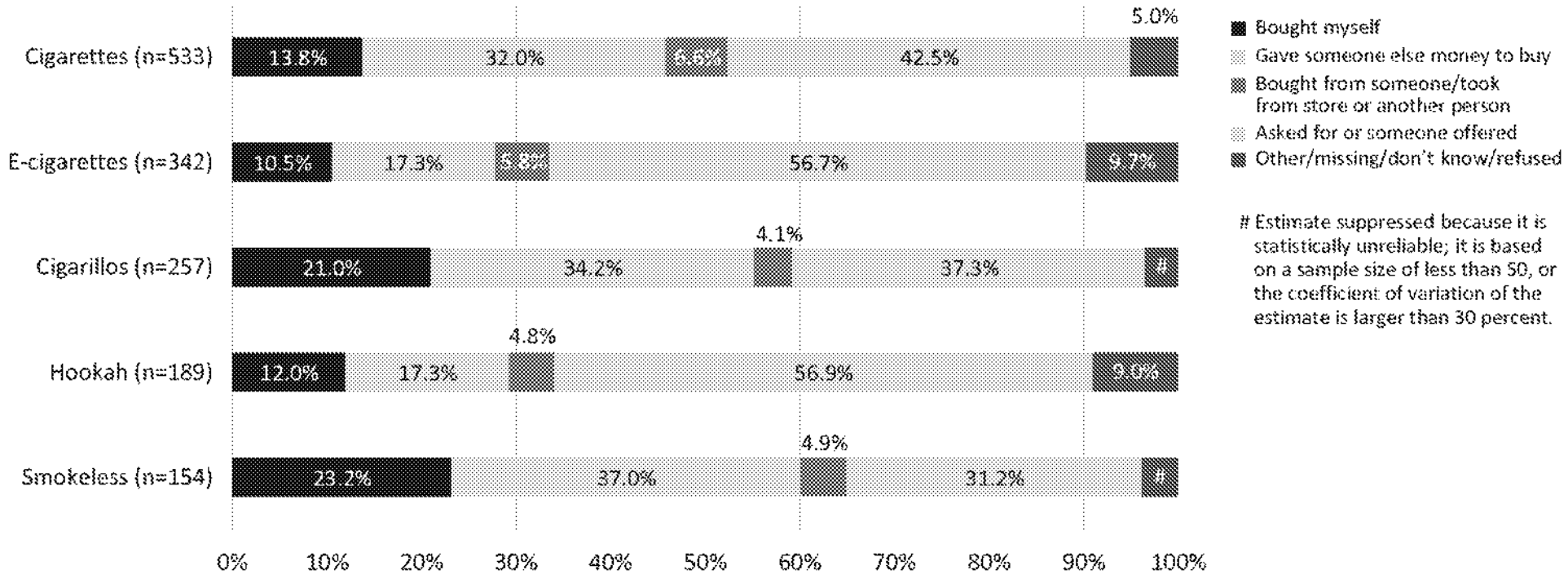
Youth Access to Tobacco Products Among Past 30-Day Users: Where Do Youth Get Tobacco?

Variability in how youth access different tobacco products: smokeless tobacco and cigarillos are often purchased, while e-cigarettes and hookah are more often asked for or offered

Figure 1. Source of access to tobacco product among 15-17 year old current users



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Smoking Control

Facilitating Adolescent Smoking: Who Provides the Cigarettes?

Martha M. White, MS; Elizabeth A. Gilpin, MS; Sherry L. Emery, PhD; John P. Pierce, PhD

Abstract

Purpose. *Most adolescent smokers obtain cigarettes through social sources. We examine the extent to which cigarettes are provided by facilitators of legal age to purchase cigarettes.*

Design. *Analyses of data from the 1999 California Tobacco Survey, a large population-based, random-digit–dialed telephone survey, are reported.*

Setting. *California.*

Subjects. *Data were from a subset of 1239 adolescent (12–17 years) respondents who reported ever having smoked a cigarette. The response rate for all adolescents selected for interview was 75.5%.*

Measures. *We describe cigarette providers to adolescents in social (cigarettes given to the adolescent) and economic (someone else buys cigarettes for the adolescent) transactions by the reported facilitator's age.*

Results. *Of the 82.2% ± 2.6% of adolescents who had ever smoked who usually obtained cigarettes from others, 21.6% ± 2.5% used economic transactions; most (60.6% ± 3.4%) were given cigarettes. The majority (73.3% ± 3.6%) of those relying on social sources were given cigarettes by someone <18 years of age; very few were given cigarettes by someone 21+ years old. Most (90.4% ± 2.0%) usually given cigarettes reported friends as facilitators. Of those who relied on economic transactions, 56.1% ± 6.6% reported facilitators who were 18- to 20-year-olds, another 24.7% ± 6.3% had suppliers ≥21 years of age. Altogether, 80.8% ± 5.8% of facilitators in economic transactions were ≥18 years of age.*

Conclusions. *Until peer approval of smoking and sharing cigarettes and adult facilitation of adolescent smoking is reduced, it will be difficult to significantly reduce adolescents' access to cigarettes.(Am J Health Promot 2005;19[5]:355–360.)*

Key Words: Preventive Research, Descriptive, Nonexperimental, Behavioral, State/National, Smoking Control, Culture Change, Youth, Age, Smoking Level

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INTRODUCTION

Adolescents can obtain their cigarettes from two very different sources: commercial and social. So far, public policy has emphasized restrictions on commercial sources of cigarettes, largely by establishing a minimum legal purchase age. The Synar Amendment, passed by Congress in 1992, required each state to have and enforce an effective law that set the minimum age of cigarette purchase at 18 years of age; monitoring of state compliance included random, unannounced inspections of venues selling tobacco to determine the rate of selling tobacco to underage buyers, with states required to maintain an illegal sales rate of below 20%.

However, previous research showed that the large majority of adolescents do not purchase their own cigarettes and therefore are not affected by minimum-age purchase laws.[1,2] Experimenters are generally given those cigarettes they smoke; even those who smoke heavily enough that they must purchase cigarettes often do so by having someone else buy cigarettes for them. This trend has increased as enforcement of youth purchasing laws has intensified. Looking at trends in cigarette acquisition from the 1995, 1997, and 1999 Youth Risk Behavior surveys (YRBS), Jones et al.[3] found that as enforcement of Public Health Service Act 398 (the Synar Amendment) increased, buying for oneself was replaced by having others buy for one. Strictly social sources ('borrowing') did not change with increased enforcement.

Increased enforcement of youth access laws has not necessarily been followed by decreased smoking prevalence.[4–6] Even studies documenting a decline in prevalence note that adolescents remained able to obtain cigarettes.[7–9] As enforcement increases, theft and illegal sales of cigarettes can still occur, but a more likely source is adults at or above the legal

purchasing age who are willing to supply adolescents with cigarettes, thus facilitating the adolescents' smoking.

Relatively little work has been done in assessing who supplies adolescents with cigarettes. Shive et al.[10] surveyed 250 college students to determine how many had been approached by adolescents and asked to buy cigarettes. Those closest in age to the adolescents were more likely to be approached, with 58.6% of 18- to 19-year-olds, but only 22.7% of 20- to 24-year-olds, reporting that they had been asked to supply cigarettes. Nearly half (46.8%) were approached by friends or family members; 32.6% were asked by strangers. Shive et al.[10] speculated that younger college students were more likely to have friends under 18 years of age who might view them as a cigarette source.

Alternatively, adolescents may see those near their own age as more willing to buy cigarettes for them. Klonoff et al.[11] recruited 15- to 17-year-old adolescents to approach adult strangers and ask them to purchase cigarettes. Adults appearing to be 18 to 30 years of age were 2.6 times more likely to purchase cigarettes than adults who appeared to be 60 years of age or older. Ribisl et al.[12] found that 42.5% of 18- to 19-year-old and 23.5% of 20- to 24-year-old California adults reported (in a telephone survey) being asked to purchase cigarettes for a minor.

These studies show that young adults are frequently approached by, and are willing to supply cigarettes to, adolescents. This indicates that adolescents might make more use of those near their own age to obtain cigarettes, but previous studies do not assess the extent to which adolescents themselves choose to utilize young adults as a cigarette source. We used adolescent response data from a large population-based survey (the 1999 California Tobacco Survey [CTS]) to examine usual adolescent cigarette sources (economic or social) and the age and identity of usual suppliers in both types of transactions.

METHODS

Design

This study employed data from the 1999 CTS, a large population-based random-digit–dialed telephone survey designed to monitor changes in tobacco use and attitudes in California.[13] Methods for the 1999 CTS are described in detail elsewhere.[14] Survey procedures were approved by the University of California, San Diego, Human Research Protections Program.

Sample

The 1999 CTS enumerated a total of 46,590 households; 11,071 adolescents between 12 and 17 years of age were identified in these households. If there were multiple adolescents in the household, only one was randomly selected for interview. After receiving adult permission, a call was scheduled several days later to conduct the interview with the selected adolescent. Altogether, 8069 adolescents were selected, and completed interviews were obtained for 6090 (75.5%) of these adolescents. Of those who completed interviews, 1239 (20.3%) reported smoking at least one whole cigarette in their lifetime, and these individuals were included in this analysis.

Measures

Those adolescents who reported ever having smoked (ever smokers) were asked "Which of the following *best* describes how you *usually* get/got *most* of the cigarettes that you smoke? Would you say: I buy/bought them myself; someone in my home buys/bought them for me; someone in my home gives/gave them to me; I take/took them from someone in my home without permission; other people buy/bought them for me; other people give/gave them to me; I take/took them from other people without permission; or I take/took them from a store without permission?" Adolescents who reported that someone else gave or bought them cigarettes ($n = 1014$) were then asked "Who was the person who *usually* bought/gave you cigarettes? Was it: a brother or sister; a parent or guardian; another family member; a boyfriend or girlfriend; another friend; or strangers?" The adolescent was also asked to estimate the age of this person.

Smoking experience was categorized as current established smokers vs. experimenters. A current established smoker was one who reported smoking at least 100 cigarettes in his lifetime and who reported having smoked in the last 30 days. Current established smokers were further divided into occasional smokers (those who had smoked less than 25 days in the previous 30 days) and daily smokers (those who smoked 25 or more days in the previous 30 days). All other adolescents with smoking experience were categorized as experimenters, regardless of whether or not they had smoked recently.

The majority of adolescent ever smokers were 16 to 17 years old (58.2% ± 3.0%, vs. 33.1% ± 3.3% who were 14 to 15 years old). Most were experimenters (77.4% ± 2.5%), with 12.7% ± 2.2% being occasional established smokers and 9.8% ± 1.8% daily established smokers.

Analysis

Respondents were assigned survey weights that reflected their probability of selection; the weights were further adjusted to population totals to account for nonresponse. These weights render the sample representative of the California adolescent population and allow for the computation of valid population estimates. Variance estimation for the computation of 95% confidence intervals was based on the jackknife procedure,[15] as implemented in SUDAAN,[16] which takes into account the survey design. Nonoverlapping 95% confidence intervals are a conservative indication of statistical significance.

RESULTS

Table 1 shows the methods adolescents usually used to obtain cigarettes by demographics and level of smoking. Social transactions (being given cigarettes by someone in the home or by others) accounted for 60.6% ± 3.4% of the usual sources. Economic transactions (having someone in the home or others buy ciga-

Table 1

Usual Source of Cigarettes by Smoking Experience and Demographics of the Adolescent Smokers (CTS 1999)*

	N	Buy Them Myself	Someone Buys	Someone Gives	I Take	Refused/Don't Know
Overall	1239	9.1 ± 2.1	21.6 ± 2.5	60.6 ± 3.4	7.2 ± 1.8	1.5 ± 0.9
Smoking status						
Experimenter	949	3.7 ± 1.4	12.8 ± 2.1	73.2 ± 3.7	8.4 ± 2.0	1.9 ± 1.1
Occasional established smoker	162	22.6 ± 7.1	48.1 ± 9.4	25.5 ± 9.4	3.8 ± 3.8	0.0
Daily established smoker	128	34.1 ± 11.1	56.1 ± 10.1	7.3 ± 4.6	2.5 ± 3.5	0.0
Age (years)						
12–13	95	0.0	9.6 ± 7.3	65.3 ± 12.3	20.7 ± 10.2	4.3 ± 3.9
14–15	394	5.4 ± 3.0	18.5 ± 3.4	64.4 ± 5.4	9.8 ± 3.9	1.9 ± 1.6
16–17	750	12.6 ± 3.0	25.2 ± 3.9	57.7 ± 4.1	3.7 ± 1.6	0.8 ± 0.7

* Table entries are weighted percentages and 95% confidence intervals.

rettes) accounted for 21.6% ± 2.5% of the usual sources. Thus, 82.2% ± 2.6% of adolescent ever smokers usually obtained their cigarettes from others.

However, usual sources of cigarettes varied greatly according to smoking level. Social transactions were the usual source for 73.2% ± 3.7% of experimenters, 25.5% ± 9.4% of occasional established smokers, and only 7.3% ± 4.6% of daily established smokers. Conversely, economic transactions (either buying cigarettes oneself or having others buy) were the usual source for only 16.5% ± 2.7% of experimenters; 70.7% ± 9.2% of occasional established smokers and 90.2% ± 5.3% of daily smokers paid for their cigarettes. Acquisition by age group generally follows a similar pattern to smoking experience, reflecting the direct relationship between age and smoking experience. Taking cigarettes from stores or others was an important source only for 12- to 13-year-olds. Taking cigarettes from family members was more prevalent than taking from others, but this source also decreased with age and smoking experience. There were no significant differences in source of cigarettes between sexes or between racial/ethnic groups (data not shown).

Table 2 shows who supplied cigarettes to adolescents, by adolescent age, sex, smoking status, and relationship of supplier and by whether the cigarettes were obtained in a social or economic transaction. Cigarettes were supplied predominantly by friends in both economic and social transactions, but the overwhelming number (90.4% ± 2.0%) of social transactions were with friends. Family was an important source of cigarettes for 12- to 13-year-olds; these transactions primarily involved siblings. Family also became an im-

Table 2

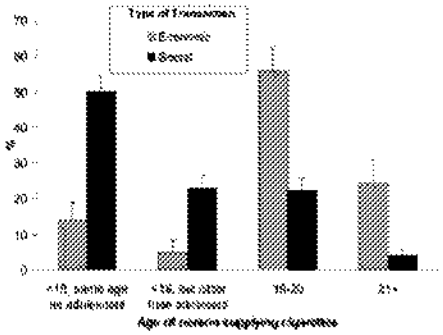
Identity of Person Who Usually Supplied Cigarettes to the Adolescent Smoker by Smoking Experience and Demographics of the Smoker and by Type of Transaction (CTS 1999)*

		Identity of Cigarette Supplier		
	N	Family Member	Friend	Stranger
Economic Transactions				
Overall	289	8.5 ± 4.3	65.0 ± 5.9	26.5 ± 6.3
Age (years)				
12–13	8	24.7 ± 52.3	64.0 ± 53.3	11.4 ± 25.1
14–15	81	6.5 ± 7.3	67.6 ± 12.0	25.9 ± 12.5
16–17	200	8.4 ± 4.4	64.0 ± 7.8	27.6 ± 8.1
Smoking status				
Experimenter	136	8.1 ± 7.2	64.9 ± 9.0	26.9 ± 8.2
Occasional established smoker	77	6.1 ± 7.4	62.4 ± 12.9	31.6 ± 12.9
Daily established smoker	76	11.8 ± 9.1	68.0 ± 12.4	20.1 ± 11.4
Social Transactions				
Overall	739	6.7 ± 1.9	90.4 ± 2.0	2.9 ± 1.6
Age (years)				
12–13	66	12.3 ± 9.9	87.7 ± 9.9	0.0
14–15	249	5.0 ± 2.4	89.8 ± 4.0	5.2 ± 3.3
16–17	423	6.9 ± 3.0	91.2 ± 3.2	1.9 ± 1.6
Smoking status				
Experimenter	689	6.0 ± 1.9	91.1 ± 2.1	2.9 ± 1.7
Occasional established smoker	40	13.8 ± 14.2	82.6 ± 14.6	3.6 ± 5.3
Daily established smoker	9	30.5 ± 37.5	69.5 ± 37.5	0.0

* Table entries are weighted percentages and 95% confidence intervals.

Figure 1

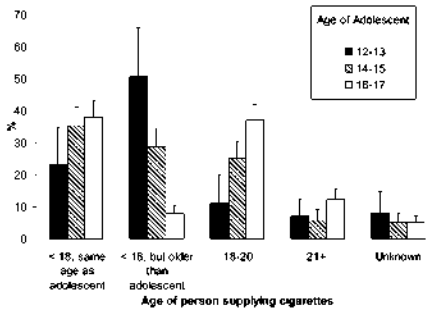
Social Source of Cigarettes to Adolescents by Age of Supplier, With 95% Confidence Intervals (CTS 1999)



The bars sum to 100% within type of transaction. Economic transactions include all cases in which the adolescent supplied money for the cigarettes; social transactions include all cases in which the adolescent reported they were given cigarettes.

Figure 2

Age of Cigarette Supplier as a Function of the Age of the Adolescent Smoker, With 95% Confidence Intervals (CTS 1999)



The bars sum to 100% within each adolescent age category.

portant source for daily established smokers. Strangers were rarely a source for social transactions, but they comprised about a quarter of the economic sources for older (14- to 17-year-old) adolescents.

Figure 1 shows the age of the supplier as a function of whether cigarettes were obtained by an economic transaction (money presumably supplied by the adolescent) or a social one (cigarettes given to the adolescent). The majority (73.3% ± 3.6%) of social transactions took place with someone under 18 years of age, with 50.1% ± 4.4% occurring with individuals who were the same age as the adolescent and 23.1% ± 3.4% occurring with individuals who were older than the adolescent (but still under 18 years of age). Another 22.5% ± 3.5% were given by young adults 18 to 20 years old, but only a few givers were 21 years of age or older. In contrast, over half (56.1% ± 6.6%) of those involved in economic transactions were young adults 18 to 20 years old; another 24.7% ± 6.3% were 21 years or older. Altogether, a substantial percentage (40.9% ± 3.4%) of suppliers (either givers or buyers) were adults, with most (31.3% ± 3.3%) suppliers being between the ages of 18 and 20 years.

Figure 2 shows the age of the person supplying cigarettes as a function of the age of the adolescent. Adolescents seemed most likely to get cigarettes from persons that were approximately their own age. In particular, 16- to 17-year-olds were more likely to obtain cigarettes from 18- to 20-year-olds than were younger adolescents. While social transactions might involve the adolescent either asking for or being offered a cigarette, the adolescent most likely asks the buyer to perform an economic transaction.

DISCUSSION

Our results confirm that the majority of adolescents who smoke, particularly those still in the experimentation phase, are primarily dependent on others for their cigarettes. Nearly three-quarters (73.2% ± 3.7%) of experimenters were given their cigarettes by others. Purchasing cigarettes generally occurred only among those who had progressed to established smoking, but even this group relied heavily on others to acquire cigarettes. A fifth (22.6% ± 7.1%) of occasional established smokers purchased cigarettes themselves; nearly half (48.1% ± 9.4%) had someone else buy cigarettes for them. Over a third (34.1% ± 11.1%) of daily established smokers purchased cigarettes directly, while over half (56.1% ± 10.1%) had others buy cigarettes for them. Altogether, a substantial percentage (40.9% ± 3.4%) of the people buying or giving these cigarettes were of legal age to purchase them, with most (31.3% ± 3.3%) being between 18 and 20 years of age. The majority (80.8% ± 5.8%) of people approached by adolescents to purchase cigarettes were of legal age to do so (18+ years). These results point out the importance of limiting acquisition through such sources.

Adolescents who are vulnerable to start smoking generally have friends who smoke, and those interested in experimenting can easily obtain cigarettes from these friends. Gilpin et al.[14] found that in 1999, 49.7% of susceptible never smokers were offered cigarettes and that 93.9% of established smokers had given cigarettes away to friends or acquaintances. Despite recent price increases, which have resulted from additional taxes and industry price hikes, a single premium cigarette in California still costs less than $0.25. Thus, giving away the occasional cigarette does not pose an economic burden. However, as an adolescent's smoking frequency increases, such 'borrowing' becomes untenable, either because it starts to impose a burden on friends or because the adolescent finds it necessary to have cigarettes reliably on hand. At this point, adolescents can either attempt to purchase cigarettes themselves or they can find someone who is willing to purchase cigarettes for them.

As access laws have been increasingly publicized and enforced, it has become more difficult for minors to purchase cigarettes themselves.[3,7,17] Data from the 1999 California Youth Tobacco Survey (CYTS, collected by the California Department of Health Services) showed that 40.2% of adolescents who had attempted to buy cigarettes in the previous month were refused at least once during that month. Although access laws are clearly not 100% effective, their presence may serve to deter adolescents from even attempting to make a purchase.[5] Only 6.8% of experimenters and 18.4% of occasional established smokers reported making such an attempt in the 1999 CYTS. If adolescents continue to smoke, they typical-

ly become more adept at making purchases.[9,18] They may learn which stores or clerks are most likely to sell to them, they may acquire false IDs, or they might learn to "flash" the ID, which seems to reduce the chance that the clerk will actually ascertain the adolescent's age.[19,20] However, even the most experienced adolescents were refused, at least part of the time.

A safer method for the adolescent is to find someone of legal age to make the purchase. Our 1999 CTS data showed that almost half of occasional established smokers and over half of daily established smokers relied on others to purchase their cigarettes. When an adolescent was given cigarettes by another (in particular, a friend), that person was usually about the same age; only 26.8% of adolescents reported being given a cigarette by a friend aged 18 years or older. When the adolescent needed to have others purchase cigarettes for them, they relied on older friends; 80.8% of adolescents who asked someone to purchase cigarettes for them asked a person 18 years of age or older. Adolescents who asked strangers to buy cigarettes for them relied exclusively on those who appeared to be at least 18 years of age and preferred those who appeared to be 21 years or older; however, only 29.4% of adolescents relied on strangers to either give or buy them cigarettes.

Smoking rates tend to increase with age, with adolescents generally becoming established smokers between 15 and 17 years of age. As these adolescents age, they will have more friends who are 18 years of age or older and who can legally purchase cigarettes, thus facilitating smoking in the younger individuals. These purchased cigarettes can then be shared with younger or less-experienced smokers, providing them with a source. It is therefore likely that the ultimate source of most cigarettes smoked by adolescents was a legal purchaser.

This study has several limitations. While the questions concerning smoking status have been used and validated in many previous surveys,[21–23] the questions on sources of cigarettes have been used less frequently,[1] and questions on the age of providers are new to the 1999 CTS. New CTS questions are field tested to make sure potential respondents appear to understand them, but they have not been subject to more rigorous validation procedures. Adolescent recall and perception of 'usual' may not be entirely accurate. Nevertheless, our results seem consistent with what would be expected from prior research,[10,11] and they provide important new information from the adolescent point of view.

Raising the minimum purchase age to 21 years would increase the age gap between adolescents taking up smoking and those who can legally provide them with cigarettes. Although this would not completely cut off the supply, it might restrict it enough to delay or deter regular smoking. Increasing the purchase age might also make it more difficult for younger adolescents to 'pass' for legal age and therefore reduce the frequency of illegal sales. While raising the legal purchase age has been proposed in California (Assembly Bill AB221) and other states, such proposals face strong opposition for reasons as varied as concerns about personal freedom and loss of tax revenue. It may be more effective to maintain or increase the stringency of enforcement of existing sales laws, including asking for and verifying identification. Clark et al.[18] reported that clerk failure to ask for ID was strongly associated with illegal sales. They also report that teenaged clerks, often employed in small stores to work evening hours, were more willing to sell cigarettes to contemporaries. If clerks do not rigorously ask for and inspect ID before selling cigarettes, increasing the legal age of purchase is unlikely to significantly reduce the supply of cigarettes to underage smokers. Of course, even more rigorous inspection may not overcome the problem of readily available fake IDs. Adolescents under age 18 years of age would have a more difficult time passing themselves off as 21-year-olds than they do in passing for 18 years of age, which is an argument for raising the legal purchase age. However, raising the minimum purchase age to 21 years will create a new group of 18- to 20-year-olds who are not of legal age to purchase but who might easily pass for 21 years old. It is difficult to predict whether increasing the purchase age would significantly curtail cigarette purchasing by members of this age group, who are the primary suppliers of cigarettes to adolescents.

Alternately, reducing the social acceptability of providing minors with cigarettes could be an important factor in limiting adolescents' access to cigarettes. Klonoff et al.[11] reported that 32.1% of adults approached by minors purchased cigarettes for them; some even provided cigarettes without taking the adolescent's money. A study investigating the frequency of asking for minor's identification noted that adults were present during 66% of the transactions but intervened only 0.6% of the time; half of these interventions were to help the minor acquire cigarettes.[24] To say the least, such behavior sets a poor example. Tobacco-control efforts should stress the message that it is not acceptable to provide minors with a product that may lead to a lifelong addiction and an early death. Future research will be required to evaluate any such tobacco-control efforts that may be undertaken, including raising the age of legal purchase.

SO WHAT? Implications for Health Promotion Practitioners and Researchers

The findings of this study indicate that most adolescent smokers who relied on economic transactions to obtain cigarettes used young adults of legal age (≥18 years) to purchase them. Since adolescent smokers frequently give cigarettes to friends, the ultimate source of most cigarettes smoked by adolescents may be a legal purchase. In order to reduce adolescents' access to cigarettes, it will be necessary to deter young adults (and older ones) from purchasing cigarettes for adolescents, and to reduce the acceptability among adolescents of sharing cigarettes.

Most adult smokers recognize that smoking is harming their own health and that it is difficult to quit. They should be reminded that when they provide adolescents with cigarettes, they are facilitating the adolescent's addiction and setting them on the path toward similar harm. Such a message may also help motivate clerks to be more conscientious in checking IDs and in refusing sales to minors. Finally, reducing such tacit social support for smoking may reduce the desirability of smoking in adolescents' eyes.

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Briefs

Which Adults Do Underaged Youth Ask for Cigarettes?

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A B S T R A C T

Objectives. This study identified adults' demographic and smoking behavior characteristics that are related to being asked to provide tobacco to a minor.

Methods. Telephone interviews were conducted with 6352 California adults. Predictors included age, sex, household income, and smoking status.

Results. Only 10.1% of California adults had been asked to provide tobacco to a minor in the previous year. Fewer than 3% of individuals 55 years and older had been asked to provide tobacco, but among younger smokers 59.0% of 18- and 19-year-olds and 39.3% of 20- to 24-year-olds had been approached.

Conclusions. Interventions to reduce the social availability of tobacco are needed. (*Am J Public Health.* 1999; 89:1561–1564)

Most smokers obtain their first cigarette from a nonretail or social source, usually a friend.[1,2] Although earlier studies indicated that most underaged youth purchase their cigarettes at stores,[3] more recent studies have shown that many youth now obtain their cigarettes from social sources, such as friends, relatives, or strangers.[4,5] Aside from being a prominent and increasing source of tobacco among youth, widespread social availability of tobacco can undermine activities to reduce retail sources of tobacco.[6] There are no published studies documenting effective strategies to reduce social availability of tobacco, and there is a pressing need to develop interventions.[7,8] A Minnesota study focused on youth who provided tobacco to their peers,[8] but no parallel studies have been conducted with adults. The purpose of the present study was to identify the demographic and smoking behavior characteristics of adults that are related to being asked to provide tobacco to a minor.

Methods

A representative sample of 6985 adults 18 years and older completed random-digit dialing telephone interviews as part of the statewide Independent Evaluation of the California Tobacco Control, Prevention and Education Program.[9] Approximately 388 adults per county were drawn from 18 representative counties that were nested within 4 strata based on county population density. Demographic information on the 6352 respondents, with complete data on all study variables (90.9% of the respondents), is shown in Table 1.

The outcome variable was a yes–no response to the question "During the past 12 months, have you been asked by someone under age 18 to buy or give them cigarettes or chewing tobacco?" The 6 predictor variables were sex, smoking status, age category, racial–ethnic group, annual household income category, and population density stratum.

Chi-square tests of independence were conducted to examine the bivariate relationship between each predictor and the outcome variable. SPSS CHAID Version 6.0[10] was then used to detect mutually exclusive and exhaustive subgroups of the sample that differed markedly in regard to rate of being asked to provide tobacco to minors. This approach is closely related to regression tree or signal detection methods.[11,12] The analysis selected the "best" predictor of the outcome and divided the sample into subgroups based on that variable while merging nonsignificant categories. This process was repeated within each subgroup until no further predictors could significantly contribute to the analysis or until one of several stopping rules was reached. Because segmentation analysis is an exploratory procedure, we investigated the replicability of the resulting subgroup categories by conducting the analysis on two thirds of the sample and by examining the replication with the remaining one third of the sample.

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Note. The analyses, interpretations, and conclusions presented in this brief are those of the authors, not the California Department of Health Services.

Results

Bivariate Analysis

Chi-square tests of independence between the outcome and each of the 6 predictors were statistically significant ($P<.001$), indicating that all of the predictors could potentially contribute to the segmentation analysis (see Table 1).

Segmentation Analysis

Figure 1 presents the results of the CHAID segmentation analysis of the two thirds sample. The top bar in Figure 1 indicates that, overall, 10.1% of adults had been asked by a minor to provide tobacco in the previous year. Age, smoking status, sex, and income all entered into the analysis, resulting in 11 subgroups. Age category was the predictor at the first level of the analysis, indicating that it had the strongest relationship with the outcome. At the second level of the analysis, 4 of the 5 age categories were split into smoking and nonsmoking subgroups. The first solid bar at the top of Figure 1 represents the subgroup of smokers aged 18 and 19 years, the group that had the highest rate of being asked to provide tobacco. Of these 39 individuals, who represented 0.94% of the total sample, 59.0% reported that they were asked to provide tobacco to a minor.

The bar at the bottom of Figure 1 indicates that respondents 55 years and older had the lowest rate of being asked to provide tobacco (2.6%). Subgroups consisting of smokers were between 1.5 and 6.6 times more likely to be asked to provide tobacco than were the nonsmoking subgroups within each age category. Two of the age categories were further divided by a third predictor. The subgroup of nonsmokers aged 20 to 24 years was divided into male and female subgroups, whereas the subgroup of smokers aged 35 to 54 years was divided into 2 income categories (less than $20000 and $20000 or more).

Replication Analysis

The one third holdout sample was categorized into the same 11 subgroup segments derived from the CHAID analysis of the two thirds sample. The differences between the 2 samples were less than 6% in all but 1 comparison, indicating excellent replication.

TABLE 1—Demographic Characteristics of the Sample and Rate's of Being Asked to Provide Tobacco to a Minor in the Previous Year: Independent Evaluation of the California Tobacco Control, Prevention and Education Program, 1996

Predictor	Sample (n = 6352), %	Asked to Provide Tobacco, %[a]
Sex		
Male	42.6	10.9
Female	57.4	8.7
Smoking status		
Smoker	21.2	20.5
Nonsmoker	78.8	6.7
Age, y		
18–19	3.5	42.5
20–24	7.8	23.5
25–34	22.7	11.4
35–54	43.3	7.4
≥55	22.6	2.4
Race–Ethnicity		
American Indian	2.2	16.3
African American	4.4	13.1
Hispanic	10.3	13.0
White	76.7	9.0
Asian–Pacific Islander	4.8	6.6
Other	1.5	9.2
Household income, $		
<10000	8.1	16.6
10000–14999	8.7	15.9
15000–19999	8.0	14.9
20000–24999	8.0	9.2
25000–34999	14.1	9.7
35000–49999	19.0	7.9
50000–74999	17.1	7.3
75000 or more	17.0	5.3
Stratum		
Media market (most urban)	27.5	8.5
High density	27.8	8.6
Medium density	22.5	11.7
Low density (most rural)	22.2	10.3

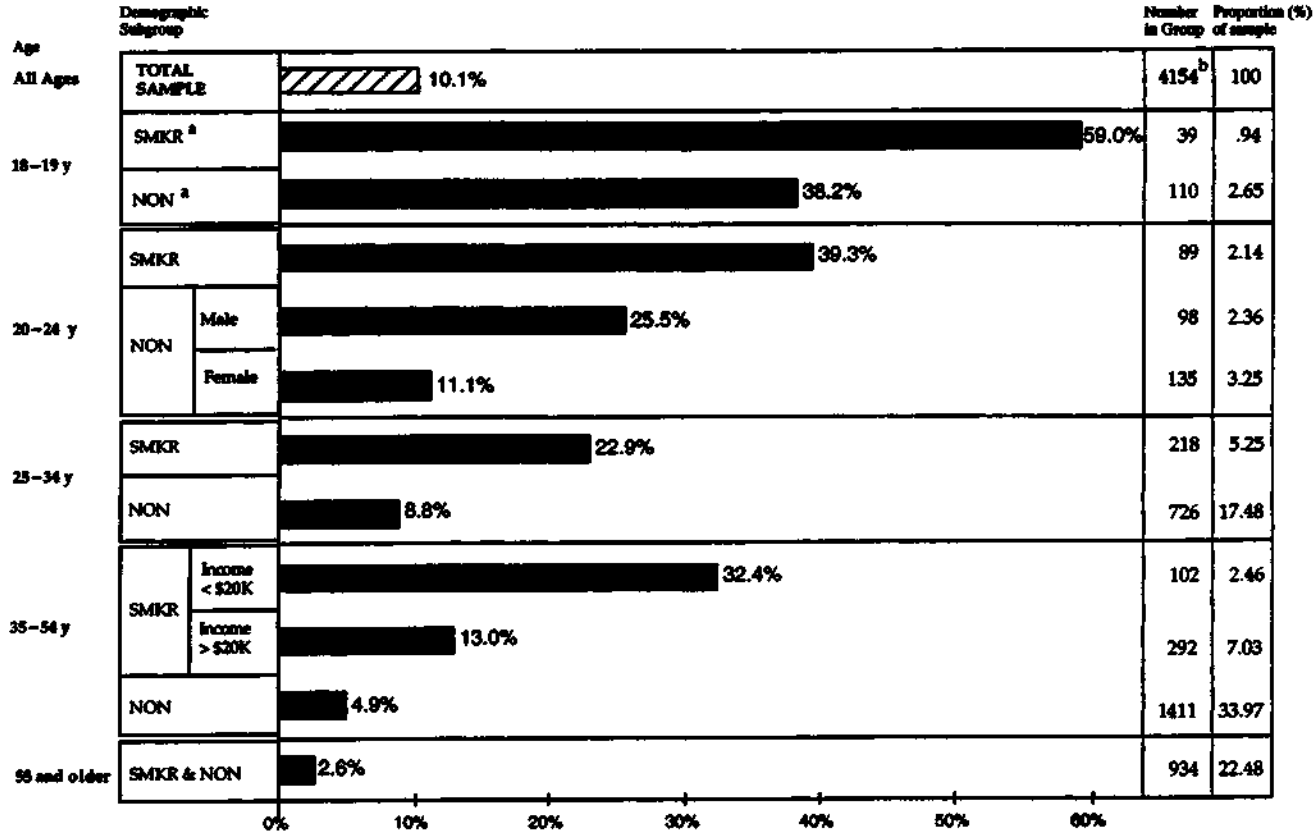
[a]All χ^2 tests of independence between the predictors and the outcome were statistically significant ($P<0.001$).

Discussion

The goal of this study was to identify the profile of adults who are at highest risk of being asked to provide tobacco to minors. Approximately 10% of the California adults in this study had been asked to provide tobacco to a minor at least once in the previous year. However, the rate was far greater among certain demographic subgroups. The most important predictors, in descending order, were age, smoking status, and sex or income. The 3 subgroups with the highest rates of being asked to provide tobacco to minors were smokers aged 18 and 19 years, smokers aged 20 to 24 years, and nonsmokers aged 18 and 19 years. The rate was approximately 4 to 6 times higher in these subgroups than it was in the overall sample. The rate for nonsmokers 25 years and older was below the overall 10% rate, and rates were especially low for adults 55 years and older.

In most communities, there are far more social than retail providers of tobacco. For example, in a small community of 25000 adults, there would be an estimated 30 to 40 tobacco retailers and approximately 2525 (10.1% of 25000) adults who are asked by young people to provide tobacco in a given year. Even if only a small fraction of these adults actually provides tobacco, a community has far more social than retail sources. Designing effective interventions to reduce social availability is a significant challenge. Social source providers are more diffuse and prevalent than retail sources of tobacco, and adult providers often have a personal relationship with the young person. Nevertheless, the results of this study provide a starting place for future efforts.

One of the limitations of this study is that the sample was restricted to adults 18 years and older. A study comparing the rates at which adults and youth are asked to provide tobacco to minors would be a valuable contribution. Also, this study did not account for adult smokers who might act as unwitting social source providers by leaving their cigarettes accessible to minors. Finally, this study



[a]SMKR = current smokers; NON = nonsmokers and former smokers.
[b]This analysis was based on a randomly selected group representing two thirds of the total sample; one third of the sample was held back for replication purposes.

FIGURE 1—Rates at which California adults had been asked to provide tobacco to a minor in the previous year, by demographic subgroup: Independent Evaluation of the California Tobacco Control, Prevention and Education Program, 1996.

examined the proportion of adults who were asked to provide tobacco, but we were unable to examine whether they actually did so. The rate of being asked to provide tobacco was high among adult smokers aged 18 to 24 years (3% of the population); however, a greater number of adults 24 years and older had been approached by minors, because this older group is more prevalent in the population.

It is important for future studies to ask adults whether they provided the tobacco to the minor and how often they did so. Such knowledge can be used in estimating the amount of tobacco provided by different subgroups, and this information can be used for intervention planning. A strength of the present study is that it was based on a large representative sample, which allowed us to conduct a replication analysis that demonstrated the stability and generalizability of the findings to other similar samples.

Most states are making progress in reducing the rate of illegal tobacco sales to minors, but they may find that youth access still remains. As fewer minors are able to purchase tobacco for themselves, states need to address the willingness of friends, family members, and strangers to provide it to them. Effective intervention strategies are sorely needed to address this burgeoning problem. The findings from this study will be helpful in targeting much-needed interventions aimed at reducing the social availability of tobacco to minors. □

Contributors

K. M. Ribisl planned the study, supervised the data analysis, and wrote the paper. G. J. Norman analyzed the data and contributed to the writing of the paper. B. Howard-Pitney and K. A. Howard contributed to the writing of the paper.

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Retail Trade Incentives: How Tobacco Industry Practices Compare With Those of Other Industries

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ABSTRACT

Objectives. This study compared the incentive payments for premium shelf space and discounts on volume purchases paid to retailers by 5 types of companies.

Methods. Merchants were interviewed at 108 randomly selected small retail outlets that sell tobacco in Santa Clara County, California.

Results. Significantly more retailers reported receiving slotting/display allowances for tobacco (62.4%) than for any other product type. An average store participating in a retailer incentive program received approximately $3157 annually from all sampled product types, of which approximately $2462 (78%) came from tobacco companies.

Conclusions. Future research should assess the impact of tobacco industry incentive programs on the in-store marketing and sales practices of retailers. (*Am J Public Health*. 1999; 89:1564–1568)

The tobacco industry has shifted away from traditional forms of advertising toward focused retailer incentive programs. In 1996, traditional venues such as magazines, newspapers, and outdoor advertisements consumed only 11% of the tobacco industry's $5.1 billion advertising budget, while 47% of the budget ($2.4 billion) went into retailer incentive programs that included promotional allowances and point-of-sale marketing programs.[1]

Many industries, including tobacco companies, use dual strategies to maximize total sales by *pulling* or encouraging consumers to buy a product while using retailer strategies to *push* or sell a product through a distribution channel.[2] Consumer-based pull strategies include advertising, coupons, 2-for-1 sales, and gifts with purchase. Retailer-based push strategies include payments for prime shelf space, volume discounts, and in-store displays that are designed to motivate retailers to create in-store merchandising environments that maximize sales.[2]

Few systematic data are available on retailer incentive programs.[3] Two studies of tobacco advertising in stores revealed that about 50% to 60% received monetary incentives from tobacco companies to display advertisements, but neither the types nor the amounts of monetary incentives were identified.[4,5] We found no other studies that examined this issue. Given the magnitude of tobacco marketing expenditures in retail outlets, this study was designed to ascertain the types and amounts of incentives received by local tobacco retailers compared with those received for other commonly sold products.

Methods

Design

A cross-sectional survey was designed to investigate the types of retailer incentive programs offered in 5 product categories to

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