

IMPROVING PUBLIC HEALTH AND REDUCING THE CONSEQUENCES OF TOBACCO USE THROUGH NIH RESEARCH

STORY

Cigarette smoking remains the leading cause of preventable disease and death in the U.S., with smoking-attributable healthcare spending exceeding \$225 billion each year.^{1,2} Over several decades, a large body of scientific evidence, including research funded by NIH, has established that smoking is addictive. This research also demonstrated that smoking and exposure to secondhand tobacco smoke cause a wide range of adverse health outcomes, including lung and numerous other cancers, cardiovascular disease, pulmonary disease, and poor pregnancy outcomes. Beginning in the 1960s, the development of tobacco dependence treatments (e.g., medication-based and/or behavior-change therapies),

implementation of policies at the local, state, and federal levels, and coordination of prevention efforts ultimately helped to (1) reduce the prevalence of cigarette smoking in the U.S. and the incidence of lung cancer and other diseases caused by smoking; (2) ban television and radio-based cigarette advertising; (3) protect a majority of the U.S. population from exposure to secondhand tobacco smoke; and (4) increase support for people who want to quit cigarette smoking. NIH has played a critical role in training scientists, conducting and funding tobacco-related research, building collaborations, and disseminating research findings to inform tobacco control, communication interventions, cessation treatment, and policy development.



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A publication documented early evidence from multiple countries indicating an increase in lung cancer incidence. Tobacco smoke is mentioned as a potential lung irritant. Prior to this, lung cancer was observed only rarely.³

1912

Early epidemiological studies indicated a potential causal link between cigarette smoking and mortality.^{4,5,6,7,8,9}

1930–
1950s

NIH launched the Framingham Heart Study. Years later, findings from the study showed that cigarette smoking was associated with an increased incidence of nonfatal heart attacks and death from coronary heart disease in men.¹⁰

1948

The December issue of Reader's Digest, then a widely read magazine, featured an article entitled "Cancer by the Carton"¹¹ that cited data from early epidemiological studies suggesting a link between lung cancer and cigarette smoking. After this article was published, public awareness of the dangers of smoking grew and was followed by a decline in cigarette consumption.^{12,13}

1952

1956

At the suggestion of the American Cancer Society and the American Heart Association, NIH convened a group of scientists to review the health effects of cigarette smoking. The study group reviewed evidence and consulted with a diverse range of scientists before concluding that "the smoking of tobacco, particularly in the form of cigarettes, is an important health hazard," and recommending that "further research on smoking and health be vigorously pursued."¹⁴

Surgeon General Leroy E. Burney publicly declared that the evidence pointed to a causal relationship between smoking and lung cancer.¹⁵

The Surgeon General Luther Terry released *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*,¹⁶ which consolidated many years of evidence on the relationship between smoking and disease. The impacts of this report on policies and public attitudes toward smoking are still acknowledged today. Several NIH staff members were acknowledged for their contributions to the historic report and successive Surgeon General's Reports were regularly cited in testimony in support of state and federal tobacco control legislation.^{17,18,19}



Following the release of the first *Surgeon General Report on Smoking and Health*, Congress passed the *Federal Cigarette Labeling and Advertising Act of 1965* that required tobacco companies to place health warnings on all cigarette packaging and advertising.²⁰ Congress later strengthened requirements for warnings on cigarette packaging and expanded the requirement so that it also applied to packaging and advertising for smokeless tobacco products.²¹

1965

The Surgeon General issued *The Health Consequences of Smoking*, which identified secondhand tobacco smoke as a health risk.²² Following the release of this report, Arizona became the first state to have some smoke-free public spaces, with other states eventually enacting restrictions on smoking in a variety of public settings.²³ Surgeon General Reports in 1986 and 2006 focused on involuntary exposure to tobacco smoke and were influential in the development of indoor smoking bans as an effective measure to protect against exposures.^{24,25}

1972

NIH established the Cancer Information Service, which provided the first telephone-based smoking cessation service.²⁶ Studies later reported evidence on the cost-effectiveness of quit lines, particularly when used to supplement self-help, pharmacotherapy, or counseling-based services.^{27,28} Many public and private quit lines were launched after the creation of the Cancer Information Service. In 2024, the Centers for Disease Control and Prevention (CDC) and NIH continued to support the 1-800-QUIT-NOW toll-free number and quit lines for people who prefer speaking Spanish, Mandarin, Cantonese, Korean, or Vietnamese when seeking free tobacco cessation services.

1975

1975

NIH established the Tobacco Control Monograph Series to provide clinicians, researchers, and public health practitioners with scientific reviews of tobacco use, treatment, and prevention topics.³⁸ Monograph 19 of the series was cited in the final rule issued by the Food and Drug Administration (FDA) in 2020 to establish new required warnings for cigarette packages and advertisements.^{39,40} Done in collaboration with the World Health Organization (WHO), Monograph 21 of the series presented evidence on the effectiveness of using tax and price increases as a tobacco control measure, in which it is estimated that a 10% increase in the price of cigarettes could result in a 4% decrease in tobacco consumption in high income countries and a 5% decrease in tobacco consumption in low and middle income countries.^{41,42}

1991

NIH launched the Community Intervention Trial for Smoking Cessation (COMMIT) to test existing methods for helping people who want to quit cigarette smoking.³⁶ Modest decreases in smoking prevalence were observed among people who were light to moderate smokers in COMMIT's treatment communities. The trial paved the way for the launch of the American Stop Smoking Intervention Study (ASSIST) in 1991, a large-scale community-based smoking prevention and control intervention focused on the social and policy environment. The Community-Based Interventions for Smokers: The COMMIT Field Experience describes the methods used, resources and training required, and potential barriers to implementing community-based approaches to smoking cessation.³⁷

1986

NIH launched the Smoking, Tobacco, and Cancer Program to support clinical trials aimed at developing and testing prevention and smoking cessation interventions in schools, and medical and home settings.³³ At the time, the program was the largest effort on applied smoking research and served as the basis for published intervention guidelines.^{34,35}

1982

The NIH-supported Monitoring the Future (MTF) survey was launched to measure youth behaviors and attitudes around substance use, including those regarding tobacco products.²⁹ Later survey results would show that youth favored using cartridge-based nicotine electronic cigarettes (e-cigarettes) with flavors such as fruit and mint, and these results informed FDA's 2020 regulatory actions regarding flavored e-cigarette products.^{30,31,32}

1975

NIH launched the [Smokefree.gov](https://www.smokefree.gov) initiative to provide free website-based support to people who smoke and are interested in quitting. In the years following the launch of the site, [Smokefree.gov](https://www.smokefree.gov) expanded to include text message programs, smartphone applications, quit plans, and social media channels.⁴⁸

The National Toxicology Program, an interagency program comprised of representatives from the FDA, CDC, and NIH, released the Report on Carcinogens, in which environmental tobacco smoke was listed as a known human carcinogen.⁴⁵ The report was cited in numerous publicly available booklets and reports, including the World Health Organization's *Protection From Exposure To Second-hand Tobacco Smoke: Policy Recommendations* and CDC-developed guidance for multi-unit housing.^{46,47}

The NIH-sponsored Tobacco Use Supplement is administered as part of the U.S. Census Bureau's Current Population Survey, which became a key source of national, state, and sub-state data on tobacco use behavior, attitudes, and policies.⁴⁴

NIH, in partnership with the American Cancer Society and 17 state health departments, established ASSIST, the most comprehensive U.S.-based public health tobacco control project at the time.⁴³ ASSIST changed the focus from intervention services for individuals to a systems-level approach that focused on coalition building and policy interventions. ASSIST informed the development of the Robert Wood Johnson Foundation's SmokeLess States Program, the CDC's Initiatives to Mobilize for the Prevention and Control of Tobacco Use program, and other tobacco control programs implemented in several states. The project contributed to the increasing acceptance of using tax increases as a measure to reduce smoking and generate revenue that could be used to support smoking and tobacco use prevention programs, public health initiatives, and infrastructure projects.

1991

2003

NIH-funded research was cited in a U.S. District Court case focusing on the harmful effects of tobacco and secondhand smoke exposure, industry practices, and targeted marketing to teens.^{49,50,51}

2001

NIH, CDC, American Legacy Foundation, Robert Wood Johnson Foundation, the Agency for Healthcare Research and Quality, and the University of Wisconsin School of Medicine and Public Health co-sponsored an update to the *2000 Treating Tobacco Use and Dependence: Clinical Practice Guideline*.⁵² The updated Guideline included recommendations that emphasized the importance of (1) clinicians recommending tobacco dependence counseling and medication treatments to their patients and (2) healthcare delivery systems and insurers supporting clinicians and ensuring that treatments are accessible.

1992

Congress enacted the *Family Smoking Prevention and Tobacco Control Act*, which gave the FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products.⁵³ After the passage of this Act, a collaborative research effort between NIH and the FDA began, known as the Tobacco Regulatory Science Program (TRSP).^{54,55} Through TRSP, the FDA provides funding to support NIH research that can inform regulatory actions and media campaigns.

1992

The U.S. Department of Health and Human Services (HHS) published *Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services*.⁵⁶ To develop the Plan, scientists from NIH worked with experts from across HHS, focusing on tobacco control objectives of the Healthy People 2020 initiative, which were centered around reducing tobacco use and initiation, increasing cessation, and reducing secondhand smoke exposure. The Plan was also intended to support the FDA's ability to regulate the manufacture, marketing, and distribution of tobacco products.

2006

2008

2009

2010

2018

Several publications supported by the NIH/ FDA Tobacco Centers of Regulatory Science Program are referenced in FDA's advanced notice of proposed rulemaking to reduce nicotine in tobacco products.^{68,69,70,71,72,73}

2017

As part of the NCI Cancer Moonshot™ Program, NIH launched the Cancer Center Cessation Initiative to build and implement tobacco cessation programs for people with cancer and cancer survivors. Through 2024, more than 100,000 people with cancer received smoking cessation treatment as part of the program.⁶⁷

2016

NIH-supported publications are cited in the Deeming Rule that extended FDA's regulatory authority to all "tobacco products", including e-cigarettes, cigars, hookah (waterpipe) tobacco, and pipe tobacco.^{65,66} The rule prohibits the sale of covered products to individuals under the age of 18, limits vending machine sales to adult-only facilities, and requires the display of health warnings on product packages and in advertisements.

2011

In collaboration with the FDA, NIH launched the Population Assessment of Tobacco and Health (PATH) Study, a nationally representative longitudinal cohort study on tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes.⁵⁷ The PATH Study has made data and biospecimens available to researchers and informed FDA's regulatory actions under the *Family Smoking Prevention and Tobacco Control Act*.^{58,59} Findings from this study would be cited in FDA's 2020 guidance to prevent the sale of electronic nicotine delivery systems to minors and FDA's 2022 proposed rule prohibiting menthol as a characterizing flavor in cigarettes.^{60,61,62,63,64}



2022

Citing NIH-supported publications and ongoing collaborations with NIH,^{85,86,87,88,89,90,91,92,93} the FDA proposed rules to prohibit characterizing flavors (other than tobacco) in all cigars and prohibit menthol as a characterizing flavor in cigarettes.^{94,95,96} The proposed rules are intended to reduce the appeal of flavored products among youth and young adults.

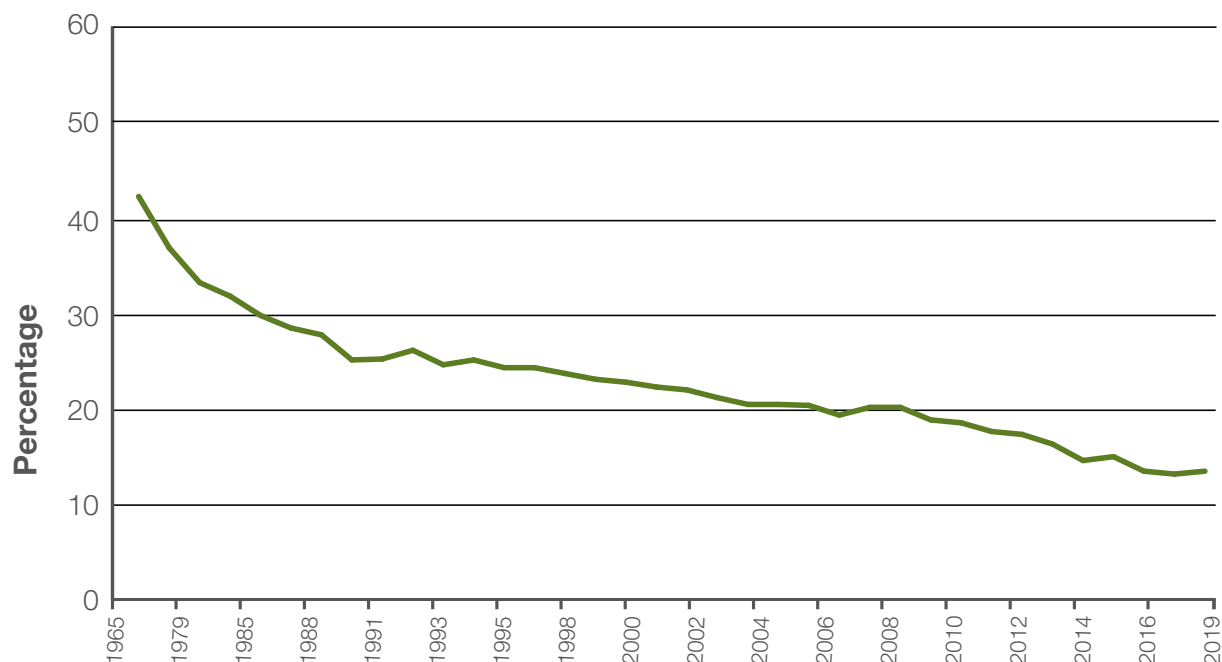
2021

Citing NIH websites and publications,^{76,77,78,79,80} the FDA issued a final rule to establish new warnings to be placed on cigarette packages and in cigarette advertisements. The new warnings included textual warning statements and graphics that depicted the negative consequences of cigarette smoking.^{81,82,83,84}

2019

While cigarette smoking prevalence continued to decline, results from the NIH-supported MTF Survey demonstrated a need for targeted prevention efforts and regulation enforcement in response to increased use of e-cigarettes among youth, with approximately 35% of 12th graders reporting use during the past 12 months.^{74,75}

FIGURE 1. Estimates of Cigarette Smoking Among Adults Aged 18 and Over: 1965–2019*

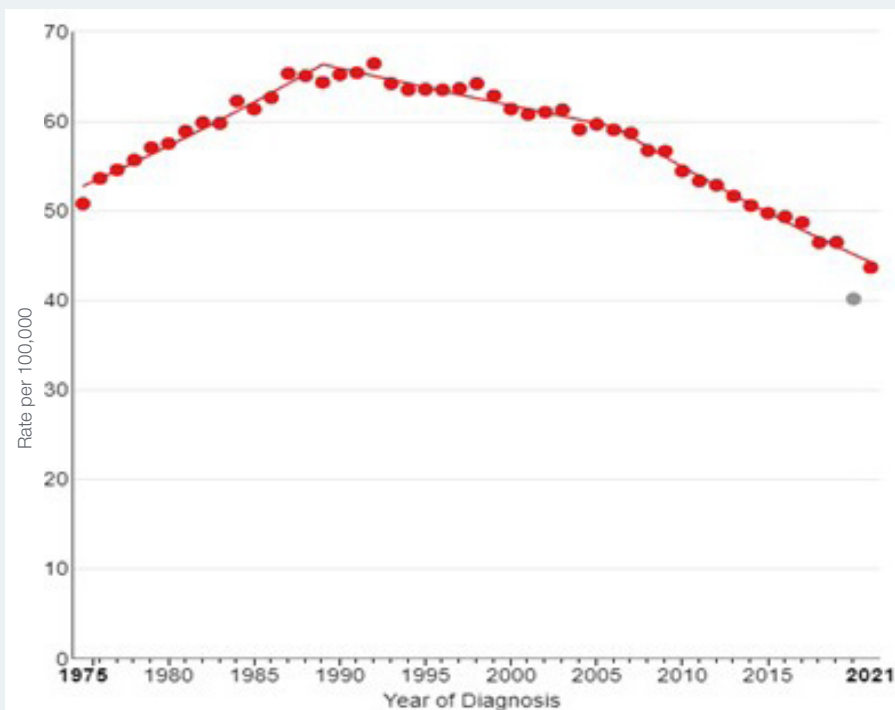


Source: National Center for Health Statistics, National Health Interview Survey⁹⁷

* From 1965–1991, an adult who reported smoking 100 cigarettes in his or her lifetime and who smoked cigarettes at the time they participated in a survey about this topic was defined as a “current” smoker. Beginning in 1991, an adult who reported smoking ≥ 100 cigarettes during their lifetime and specified that they smoked every day or on some days at the time they participated in a survey about the topic was defined as a “current” smoker.⁹⁸

FIGURE 2. Lung and Bronchus Cancers—Long Term Trends from the Surveillance, Epidemiology, and End Results (SEER) Program: 1975–2021 Observed SEER Incidence Rate, All Races/Ethnicities, All Ages⁹⁹

Note: The 2020 incidence rate was not used in the fit of the trend line and is displayed on the graph below as a gray data point. <https://seer.cancer.gov/data/covid-impact.html> for information on the impact of COVID on SEER Cancer Incidence Data



Data Source:

- SEER Incidence Data, November 2023 Submission (1975–2021), SEER 8 registries [<https://seer.cancer.gov/registries/terms.html>].

Methodology:

- Rates are per 100,000 and are age-adjusted to the 2000 U.S. Std Population (19 age groups—Census P25-1130).
- The Annual Percent Change (APC) and Average Annual Percent Change (AAPC) estimates were calculated from the underlying rates using the Joinpoint Trend Analysis Software [<https://surveillance.cancer.gov/joinpoint>]. Version 5.1, April 2024, National Cancer Institute using the default settings.
- The APC's/AAPC's direction is “Rising” (↑) when the entire 95% confidence interval (C.I.) is above 0, “Falling” (↓) when the entire 95% C.I. is lower than 0, otherwise, the trend is considered “Not Significant.”
- The 2020 incidence rate(s) was not used in the fit of the trend line(s) and is displayed on the graph as a gray data point. Impact of COVID on SEER Cancer Incidence 2020 data [<https://seer.cancer.gov/data/covid-impact.html>].

Race/Ethnicity Coding:

- For years prior to 1990, the Census Bureau has only provided county-level population estimates for White, Black, and Other races.

Cancer Site Coding:

- See SEER*Explorer Cancer Site Definitions [<https://seer.cancer.gov/statistics-network/explorer/cancer-sites.html>] for details about the cancer site coding used for SEER Incidence data.
- Created by <https://seer.cancer.gov/statistics-network/explorer> on Thu Jun 27 2024.



THEN

- In 1964, when the first report of the Surgeon General on smoking and health was released, **40% of Americans were regular smokers of cigarettes**, with more than 50% of men and over 30% of women being regular smokers.¹⁰⁰
- Cigarette smoking was widely accepted and rarely restricted in public settings.¹⁰¹ Adults and children who did not smoke cigarettes were commonly exposed to secondhand tobacco smoke in schools, government buildings, airplanes, buses and trains, hospitals and physician offices, workplaces, and public places such as restaurants.
- Cigarettes were heavily marketed consumer products in the U.S.¹⁰² Cigarette advertising was commonly done through radio, television, magazines, newspapers, billboards, stores, and other venues. An estimated **2.4 billion dollars** was spent on cigarette promotions and advertising in 1986 alone.¹⁰³



NOW

- Americans' behaviors, perceptions, attitudes, and beliefs toward cigarettes have changed dramatically. Between 1974 and 2019, cigarette smoking among persons **aged 25 and over decreased** from **36.9% to 15.1%**.¹⁰⁴
- In 2023, at least 29 states prohibited smoking in bars and over 35 states and territories prohibited indoor workplace smoking.¹⁰⁵ Of the total U.S. population in 2023, **approximately 82%** was covered by some type of smoke-free indoor air policy.¹⁰⁶
- The incidence of lung and bronchus cancer has steadily decreased during the past 30 years, correlating with increased public health initiatives and tobacco control legislation.¹⁰⁷

IMPROVING HEALTH

- Research funded by NIH's Cancer Intervention and Surveillance Modeling Network (CISNET; <http://cisnet.cancer.gov/>) found that a reduction in smoking following publication of the 1964 Surgeon General's Report is estimated to have prevented approximately 795,000 deaths from lung cancer between the years 1975 and 2000.¹⁰⁸ Additionally, the study suggests that if all people in the U.S. who smoked had quit, and no youth had started smoking after 1965, 1.7 million more lung cancer deaths would have been prevented in this period.
- The contributions of NIH, its partner federal agencies, and state and local health departments have helped to mitigate the detrimental impact of wide-spread tobacco use. Robust research and surveillance programs, smoke-free policies, advertising restrictions, pricing and tax increases, and prevention and cessation interventions have been shown to be essential components of comprehensive tobacco control programs.¹⁰⁹



REVOLUTIONIZING SCIENCE

- Interagency partnerships such as the NIH–FDA Tobacco Regulatory Science Program supported biomedical, behavioral, and social science research that has been used to inform the regulation of tobacco products.
- Epidemiological data from the NIH-supported Monitoring the Future survey, the tobacco-related section of the Current Population Survey, and the PATH Study are freely available to researchers and the public.



SERVING SOCIETY

- For every dollar all U.S. states spend on providing tobacco cessation treatments, there is an average potential return on investment of \$1.26 from saved healthcare costs and avoidance of workplace productivity losses.¹¹⁰
- Created and sponsored by NIH to support the quit attempts of people who smoke, Smokefree.gov was accessed by 7–8 million people in 2018.¹¹¹
- Smoking cessation treatments have the potential to save over \$275 million in direct healthcare expenditures every year.¹¹²



FUTURE RESEARCH DIRECTIONS

- Despite dramatic decreases in cigarette smoking prevalence, there is now a rapidly evolving tobacco product landscape that includes e-cigarettes, heated tobacco products, and oral nicotine pouches, which pose new threats of nicotine addiction and dependence and unique challenges to public health officials and policymakers.
- While cigarette use among youth has steadily decreased over the past few decades, the increase in nicotine e-cigarette use reported in 2018 was the largest for any substance tracked since the launch of the Monitoring the Future survey in 1975. In 2022, nicotine e-cigarette use remained one of the most common types of substance use among teenagers, warranting continued epidemiological surveillance, medical research, and concerted public health interventions.¹¹³
- The prevalence of cigarette smoking in the U.S. has steadily declined, but disparities between subpopulations defined by various sociodemographic characteristics continue. Research to better understand the factors impacting risk and access to treatment could inform the development of policies, prevention and surveillance initiatives, and treatment interventions in support of eliminating tobacco-related health disparities and advancing overall health equity.
- NIH continues to support resources and research to address gaps in tobacco prevention intervention, research, measurement, and methodology and creates opportunities for collaborations and sharing of research results in tobacco control and tobacco regulatory science.¹¹⁴

