ENDING THE TOBACCO EPIDEMIC

PROGRESS TOWARD A HEALTHIER NATION



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INTRODUCTION

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. Because of this, many mistakenly assume that future advances will be assured. In 2009, recognizing that declines in smoking prevalence had stalled, Secretary of Health and Human Services (HHS) Kathleen Sebelius directed HHS to develop a Department-wide strategic action plan for tobacco control to accelerate progress in combating the tobacco epidemic. A working group of public health experts across HHS was convened to develop *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*, or the *Plan*) (U.S. Department of Health and Human Services, 2010a).

Published in November 2010, the *Strategic Action Plan* mobilizes HHS tobacco control resources toward the bold vision of a society free from tobacco-related death and disease and provides a framework for coordinating tobacco control efforts across the Department and the nation. The *Strategic Action Plan* prescribes proven, practical, achievable actions that can be implemented at the federal, state, and community levels. It sets forth the most effective evidence-based and evidence-informed approaches that will enable HHS to build on recent legislative milestones, respond to the changing market for tobacco products, and promote robust tobacco control programs at the federal, state, and community levels.

The Strategic Action Plan charts a framework designed to achieve four central tobacco-related objectives of Healthy People 2020 (U.S. Department of Health and Human Services, 2010b):

- Reduce tobacco use by adults and adolescents
- Reduce the initiation of tobacco use among children, adolescents, and young adults
- Increase smoking cessation success by adult smokers
- Reduce the proportion of nonsmokers exposed to secondhand smoke

The *Plan* also directs that future activities focus on accomplishing specific objectives in four major action areas:

- Leading by example
- Improving the public's health
- Engaging the public
- Advancing knowledge

In 2011, a newly established HHS Tobacco Control Implementation Steering Committee comprising senior HHS leaders and tobacco control experts and chaired by Assistant Secretary for Health Howard K. Koh, MD, MPH, began monitoring the overall implementation of the *Strategic Action Plan* to ensure effective coordination and collaboration across the Department and with other federal agencies and to provide support to the Food and Drug Administration's role of regulating tobacco products. The Steering Committee meets regularly to set priorities, develop plans for cross-agency implementation of strategic actions, and promote information exchange and collaboration.

This report, *Ending the Tobacco Epidemic: Progress Toward a Healthier Nation*, fulfills the recommendation put forth by the *Strategic Action Plan* for periodic reports that document progress in implementing the specific actions in the *Plan* and ultimately achieving the *Healthy People 2020* objectives.

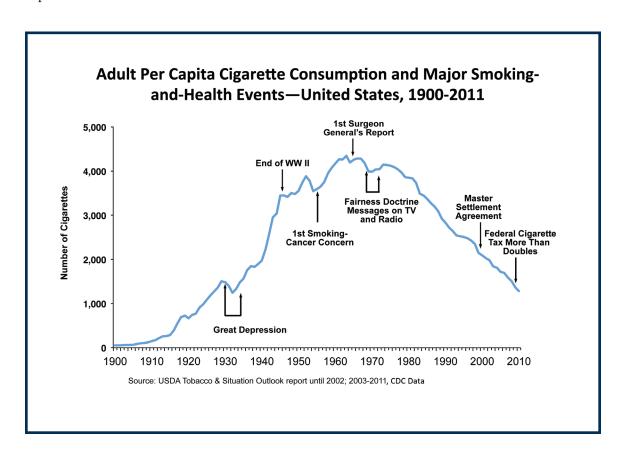
Tobacco Control High-Priority Performance Goal

In 2011, the Office of Management and Budget asked federal Departments to commit to ambitious goals that stimulate innovation. These priority goals would be attained within an 18- to 24-month time frame.

The following tobacco control objective was selected as one of HHS's priority goals:

By December 31, 2013, reduce annual adults' cigarette consumption in the United States from 1,281 cigarettes per capita to 1,062 cigarettes per capita. This would represent a 17.1% decrease from the 2010 baseline of 1,281 cigarettes per capita.

In the United States, per-capita cigarette consumption data, which reflect cigarettes legally purchased for domestic consumption, are available as far back as the late 1800s. Per-capita cigarette consumption is a key measure that has been used by researchers in the United States and other countries to objectively measure cigarette use and the impact of tobacco control over time. The Steering Committee is coordinating the actions necessary to achieve this goal, and data confirm that the priority goal intermediate target for 2011—1,232 cigarettes per capita—was achieved.



CHALLENGES: THE BURDEN OF TOBACCO USE AND BARRIERS TO PROGRESS

One hundred years ago, tobacco use was not a significant cause of illness or death in the United States. In fact, lung cancer was almost nonexistent a century ago; it now ranks as the leading cause of cancer death in the United States for both men and women, with more than 80% caused by smoking (Centers for Disease Control and Prevention, 2008).

Smoking kills an estimated 443,000 Americans each year, with 50,000 of these deaths from exposure to secondhand smoke (Centers for Disease Control and Prevention, 2008). Almost one in five adults smoke—45 million altogether—along with one in five high school seniors (U.S. Department of Health and Human Services, 2012a). Their prognosis is grim. Half of the adults who continue to smoke will die from smoking-related causes (Centers for Disease Control and Prevention, 2008). Many who comprise the other half will suffer from cancer, stroke, heart attack, and other serious tobacco-related diseases. Users of other tobacco products, such as smokeless tobacco and cigars, also suffer from significant adverse health consequences, such as cancer and heart disease.

Nonsmoking Americans are also affected by tobacco use. Approximately 88 million non-smokers, or 40% of the nonsmoking U.S. public, continue to be exposed to secondhand smoke (Centers for Disease Control and Prevention, 2010a). Because even brief exposure to secondhand smoke can be harmful, many nonsmokers are at risk of developing smoking-related illnesses, and many will get sick or die prematurely from cancer or heart disease as a result (Centers for Disease Control and Prevention, 2008).

Moreover, the financial burden imposed by cigarette smoking is enormous. Smoking-related illness in the United States costs \$96 billion each year in medical costs and \$97 billion in lost productivity due to premature mortality (Centers for Disease Control and Prevention, 2008), and the human toll on survivors and caregivers of individuals affected by tobacco-related illness is incalculable.

In addition, there is a growing concern about new tobacco products being marketed to smokers and nonsmokers as alternatives for use in smoke-free environments. Dual use of cigarettes and smokeless tobacco can sustain tobacco addiction, encouraging continued tobacco use among smokers who might otherwise quit. And the marketing of smokeless tobacco and new purported reduced-risk products may increase overall tobacco use. Consumer misperceptions regarding the "safety" of the use of these products, independently and concurrently with smoking, pose an ongoing challenge to tobacco prevention and control efforts.

The tobacco industry continues to aggressively promote tobacco use and fuel addiction among consumers. Cigarette manufacturers spend \$9.94 billion each year, or \$27 million each day, on advertising and promotions to attract new youthful users, retain current users, increase consumption, and generate favorable attitudes toward tobacco use and tobacco manufacturers. Of this amount, 72% is spent on providing discounts to make cigarettes more affordable, increasing initiation and consumption. Data also demonstrate that the depiction of cigarette smoking in movies continues to glamorize its use for young people and substantially increases smoking initiation by youth (U.S. Department of Health and Human Services, 2012a).

In response, the U.S. government, along with states and localities, has worked hard to reduce tobacco use over the last 50 years. The federal government has a) documented the lethal and addictive nature of tobacco products, b) supported state and community tobacco control efforts, c) required cigarette and smokeless tobacco products to carry warning labels, d) banned certain tobacco advertisements from television and radio, e) banned smoking from air travel, f) worked to educate the public about the lethal nature of secondhand smoke exposure, and g) supported education and research initiatives to prevent tobacco use and facilitate quitting.

The United States has made historic progress in combatting tobacco-related death and disease. Since the release of the first Surgeon General's Report on tobacco use in 1964, adult smoking rates in the United States have been cut in half (from 42.4% in 1965 to 20.9% in 2005). Despite this progress, tobacco use remains the leading cause of premature and preventable death in our society. The prevalence of current cigarette smoking among U.S. adults aged 18 years and older declined only slightly between 2005 and 2010—from 20.9% to 19.3%; however, even this small reduction in the smoking rate resulted in approximately 3 million fewer smokers, which over time will avert as many as 1.5 million premature deaths (Centers for Disease Control and Prevention, 2011a). These efforts need to be expanded and sustained if we are to achieve our *Healthy People 2020* objectives for tobacco use.

SETTING THE STAGE FOR A NEW TOBACCO STRATEGIC ACTION PLAN

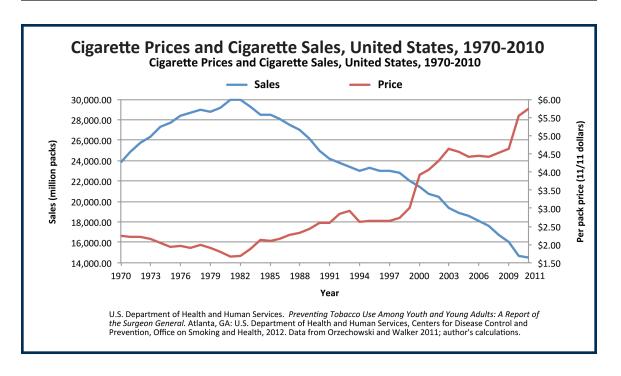
To strengthen and accelerate the nation's efforts to combat the tobacco epidemic, in 2009 and 2010, President Obama signed into law five new measures that provide critical tools for protecting Americans from the dangers of tobacco. These laws individually and collectively provide historic new opportunities to ameliorate the harm caused by tobacco. They also set the stage for a new national strategic planning effort for tobacco control. As described here, these new laws have given federal agencies more authority and funding to a) restrict the sale, distribution, and promotion of cigarettes and smokeless tobacco to make them less accessible and attractive to youth; b) deter people from smoking; c) help people quit; d) reduce exposure to secondhand smoke; and e) promote an overall culture of health and prevention. In short, these laws form an essential foundation for the successful launch and implementation of the *Strategic Action Plan*.

American Recovery and Reinvestment Act

In February 2009, President Obama signed into law the American Recovery and Reinvestment Act (ARRA), also known as the Stimulus or Recovery Act. ARRA, an economic recovery package, invested \$200 million to support local, state, and national tobacco prevention and control efforts, thus mitigating decreases in state tobacco control budgets. With this funding, HHS and the Centers for Disease Control and Prevention (CDC) launched the Communities Putting Prevention to Work (CPPW) program, which provided grants to help states, cities, counties, and tribes address the ongoing public health challenges; 22 grants addressed tobacco use specifically.

Children's Health Insurance Program Reauthorization Act

In February 2009, President Obama signed into law the Children's Health Insurance Program Reauthorization Act, which included an unprecedented 62-cent increase in the federal excise tax on cigarettes to \$1.01 per pack. For every 10% increase in the price of tobacco products, consumption falls by approximately 4% overall, with a greater reduction among youth. This single act by Congress—increasing the price of cigarettes—is projected to prevent more than 2 million children from initiating smoking, cause more than one million adult smokers to quit, avert nearly 900,000 smoking-attributed deaths, and avoid \$44.5 billion in long-term health care costs (Campaign for Tobacco-Free Kids, 2009).



Family Smoking Prevention and Tobacco Control Act

In June 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (hereafter referred to as the Tobacco Control Act), thereby granting the Food and Drug Administration (FDA) the authority to comprehensively regulate thousands of tobacco products for the first time in history. This law facilitated the creation of the Center for Tobacco Products (CTP) to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. Recognizing that most new users of tobacco products are younger than 18 years of age—the minimum legal age to purchase these products nationally and in most states—and that many new users will become addicted before they are old enough to understand the risks, parts of the act focus on reducing use by youth. The Tobacco Control Act also requires that as of September 2012, cigarette packages have larger and bolder health warnings, including graphic images (implementation of this provision is currently enjoined by a pending lawsuit brought by tobacco companies). In addition, the Tobacco Control Act mandates that tobacco companies disclose harmful or potentially harmful constituents in their products. Similarly, it prohibits false or misleading labeling and advertising for tobacco products and requires the tobacco industry to submit an application to CTP for new products or products with modified risk claims.

Importantly, the act gives CTP the authority to set standards for tobacco products that are appropriate for the protection of public health. Successful development of these standards will be informed by a strong science base. With support and guidance from FDA's Tobacco Products Scientific Advisory Committee as well as from the Office of the Assistant Secretary for Health, CDC, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, CTP is carefully researching what actions are appropriate for the protection of public health.

Prevent All Cigarette Trafficking Act

In March 2010, President Obama signed into law the Prevent All Cigarette Trafficking (PACT) Act to reduce the illegal sale and transport of cigarettes and other tobacco products. The PACT Act will reduce and prevent smoking by blocking access to underpriced and untaxed cigarettes and smokeless tobacco products. It will help curtail online and mail order sales to underage youth by requiring sellers to verify a customer's age prior to sale by checking databases. The delivery service must also check the age and identification of the person accepting a package containing cigarettes or smokeless tobacco products. This law will help the government collect more than \$5 billion a year in lost revenue from online and mail order cigarette sales (Quick, 2011). It also sets a new precedent by applying the same age verification and reporting requirements to online tobacco sellers in tribal lands, where 20% of all online tobacco sellers in the United States are located (Campaign for Tobacco-Free Kids, 2010).

The Affordable Care Act

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (hereafter referred to as the Affordable Care Act). As part of its emphasis on prevention and health promotion, the law a) requires private insurance plans to cover tobacco cessation treatments, including medications that help people quit smoking; b) expands smoking cessation coverage for pregnant women who receive Medicaid; and c) provides Medicare beneficiaries with an annual wellness visit that includes personalized prevention plan services that may include 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. Through this fund, the United States will invest mandated funds in prevention efforts every year (U.S. Department of Health and Human Services, 2012b). HHS distributed \$500 million from the fund in fiscal year (FY) 2010, \$750 million in FY 2011, and \$1 billion in FY 2012 to target four priorities: community prevention, clinical prevention, public health infrastructure, and research and tracking. In addition, the Affordable Care Act created the National Prevention, Health Promotion, and Public Health Council (National Prevention Council) and called for the development of the National Prevention Strategy to realize the benefits of prevention for all Americans' health. Tobacco control is one of the National Prevention Strategy's key priorities. The National Prevention Council has identified specific areas in which prevention can be accelerated through the combined efforts of all 17 National Prevention Council departments. One of these areas is a commitment to increase tobacco-free environments within National Prevention Council departments and encourage partners to do so voluntarily, as appropriate.

CONFRONTING THE EPIDEMIC: TRANSFORMING VISION INTO ACTION

In the year following publication of the *Strategic Action Plan*, HHS achieved measurable success in transforming goals into action. This section provides details about significant strides that have been made in all four major action areas.

Leading by Example: Leveraging HHS Systems and Resources to Create a Society Free From Tobacco-Related Death and Disease

One way for HHS to achieve its vision of change is to set a strong, clear example. HHS has now implemented its own model tobacco control policies to protect employees, contractors, and visitors against exposure to secondhand smoke; help employees quit tobacco use; and use federal programs to expand the delivery of tobacco control programs and cessation services to millions of Americans. HHS has also sought to create synergy by collaborating with other federal agencies, nongovernmental organizations, state and local leaders, business interests, and the international community in support of tobacco control and prevention initiatives.

HHS Establishes a Tobacco-Free Campus

In July 2011, HHS expanded its existing smoke-free policy to protect the health of its employees, contractors, and visitors by prohibiting the use of any tobacco products at all of its facilities under direct HHS control—within buildings as well as in outdoor spaces, parking lots, private vehicles on the premises, and government vehicles—regardless of location. The tobacco-free policy covers cigarettes, cigars, pipes, smokeless tobacco, e-cigarettes, and all other tobacco combustible and noncombustible products. As a key action step of the HHS *Strategic Action Plan*, this policy projects a positive, pro-health message and is intended to encourage similar policies in all workplaces.

In addition to implementing its comprehensive tobacco-free campus policy, HHS is working to ensure that its conferences take place only in states and localities that have laws making private workplaces and restaurants smoke-free. The National Cancer Institute (NCI), National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration (SAMHSA), and Centers for Disease Control and Prevention (CDC) have led the way, convening their events only in the 31 states and the many other cities and counties that currently have adopted laws making private workplaces and restaurants smoke-free (Centers for Disease Control and Prevention, 2011a).

HHS Collaborates With the Office of Personnel Management to Help More Employees Become Tobacco-Free

In addition to strengthening its own workplace policies, HHS is collaborating with other federal departments on tobacco control activities across the federal government. One notable success is that the Office of Personnel Management (OPM) now ensures that all federal employees have access to robust cessation treatments consistent with the 2008 U.S. Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (Fiore et al., 2008). Specifically, with HHS support and technical guidance, OPM adopted a groundbreaking new policy: starting in 2011, it expanded tobacco cessation treatment coverage under the Federal Employee Health Benefits (FEHB) program for all current and retired full-time federal employees and their dependents. FEHB covers approximately 2 million federal employees, of whom an estimated 18% were smokers as of 2008–2009, as well as

6 million dependents and retirees whose smoking prevalence is unknown (U.S. Office of Personnel Management, 2012). As part of the new policy, FEHB plans now cover four annual telephone, group, or individual counseling sessions and access to all FDA-approved tobacco cessation medications. These services and medications require no copayments or coinsurance and are not subject to deductibles or annual or lifetime dollar limits. By providing these comprehensive tobacco cessation services without barriers, the federal government increases the productivity of its workers, protects both their health and that of their families, and also reduces the taxpayer dollars needed to treat tobacco-related illnesses in the future. Based on a recent survey of plans, OPM estimates that 100,000 tobacco users were prescribed cessation medications and/or had cessation counseling in the first year of the benefit.

HHS Launches Initiative to Support the Adoption of Tobacco-Free Policies by Colleges and Universities

In 2011, HHS created its Tobacco-Free College Campus Initiative to promote and support the adoption and implementation of tobacco-free policies at universities, colleges, and other institutions of higher learning across the United States. Advertising, marketing, and promotion of tobacco products have been strategically designed by the tobacco industry to attract young people. HHS has enlisted the participation of leaders at academic institutions with tobacco- or smoke-free campus policies to counter these efforts. Supported by HHS, these academic champions—themselves leading by example—planned multiple events for 2012, including education and training sessions at the National Conference on Tobacco or Health to take the tobacco-free academia message to their peers and prepare public health advocates and others to effectively promote tobacco- or smoke-free campus policies across the nation. Prior to the launch of this initiative, approximately 775 colleges and universities had implemented 100% smoke-free campus policies (American Nonsmokers' Rights Foundation, 2012). Collectively, these institutions are accelerating the momentum for increasing the number of tobacco- and smoke-free campuses and the number of students, faculty, and staff covered nationwide. Also of note, the City University of New York (CUNY) garnered widespread attention in early 2011 when it adopted a smoke-free campus policy that applies to almost half a million students and more than 20,000 faculty across CUNY's 23 campuses (City University of New York, 2011). Their comprehensive policy takes effect in September 2012.

Also, funds received from CDC's Communities Putting Prevention to Work (CPPW) program have helped a number of academic institutions develop comprehensive tobaccoand smoke-free policies, including seven community colleges in Chicago, eight community colleges in St. Louis, and the CUNY system.

HHS Partners With Employers to Launch a Smoke-Free Worksite Challenge

The benefits of employers going smoke-free are tremendous. The Task Force on Community Preventive Services concluded that smoke-free workplace policies are associated with a 6.4% increase in cessation and 3.4% decrease in tobacco use prevalence (Task Force on Community Preventive Services, 2012). Cessation has been shown to lead to reduced medical costs and increased worker productivity. Additionally, nonsmokers are no longer exposed to the hazards of secondhand smoke.

In September 2011, at the United Nations High-level Meeting on the Prevention and Control of Non-communicable Diseases, HHS's Assistant Secretary for Health introduced the Global Smoke-Free Worksite Challenge, a global multisector partnership comprising private-sector companies, nongovernmental organizations, and governments whose goal is to totally eliminate smoking and tobacco smoke at the worksite and ensure that every worker is protected from exposure to secondhand smoke.

The Global Smoke-Free Worksite Challenge represents a collaboration among HHS, the American Cancer Society, the Campaign for Tobacco-Free Kids, Edelman, the Global Business Coalition on Health, Johnson & Johnson, the World Heart Federation, and the Mayo Clinic with support from the World Health Organization. The Global Smoke-Free Worksite Challenge is a 2011 Clinton Global Initiative "Commitment to Action." The partnership has begun to work with governments, global corporations, hospitals, and nongovernmental organizations who are interested in committing to the challenge of becoming a 100% smoke-free worksite. HHS has set a goal of recruiting six partner countries to participate by the end of 2012.

Improving the Public's Health: Strengthening the Implementation of Evidence-Based Interventions and Policies in States and Communities

State and Local Initiatives Prevent Tobacco-Related Illness and Save Lives

Much of the burden of tobacco-related illness can be reduced with approaches that incorporate proven, evidence-based, and affordable population-wide measures.

Some of the most effective tobacco control programs start at a smaller scale as states and communities take action to reduce tobacco consumption and decrease health care costs. For example, in California, home to the nation's longest-running tobacco control program, the adult smoking rate has declined by nearly 50%, with the number of cigarettes smoked per person decreasing by 67% since the state began its tobacco control program in 1988. During the program's first 15 years, California saved \$86 billion in health care costs by spending \$1.8 billion on tobacco control, resulting in a 50:1 return on investment (Lightwood, Dinno, & Glantz, 2008). Additionally, as a result of program-related reductions in smoking, lung cancer incidence has declined four times faster in California compared with the rest of the nation (Centers for Disease Control and Prevention, 2007).

Based on this example and others, the federal government has supported state tobacco control programs for many years, with CDC recently also promoting grants for cities and counties to implement evidence-based tobacco control measures.

Through its National Tobacco Control Program (NTCP), CDC supports coordinated, evidence-based tobacco control efforts and interventions across the country to reduce tobacco use. CDC funds all 50 states, the District of Columbia, 8 U.S. territories, 8 tribal support centers, and 6 national networks. The funding leverages significant state investments to implement comprehensive, evidence-based tobacco control interventions and to reduce morbidity and mortality as well as tobacco-related disparities.

In the last 2 years, HHS has used both the American Recovery and Reinvestment Act (ARRA) and the Prevention and Public Health Fund, created through the Affordable Care Act, to make important strategic investments in promoting public health prevention. These new opportunities invest in effective strategies to prevent tobacco-related death and disease.

Federal Grants Build Healthier Communities: The HHS Communities Putting Prevention to Work and Community Transformation Grants Programs Combat Tobacco Use in Localities and States

Treating cancer, lung and heart disease, and other chronic illnesses resulting from tobacco use is responsible for 8% of total health care expenditures in the United States—approximately \$96 billion each year (Centers for Disease Control and Prevention, 2008). In contrast, studies have consistently demonstrated that relatively small investments in preventive health programs lead to enormous savings in future health care costs (Trust for America's Health, 2009). As previously noted, in 2009, HHS directed \$200 million from ARRA to launch CPPW. CPPW provides resources to local communities to reduce tobacco use and obesity; 22 cities and counties received funds to implement evidence-based strategies to reduce tobacco use. Each community developed its own specific approach, designed to produce documented results and to be replicable in other localities and states.

CPPW-funded tobacco control programs have provided tools, education, and information explaining the improvements in public health to be derived from the adoption of smoke-free and tobacco-free policies for multiunit housing settings, college campuses, local school districts, and outdoor spaces and for implementing health care system changes related to tobacco use screening, documentation, and cessation treatment.

CPPW Success Stories: Adoption of Tobacco-Free Policies in School Districts

CPPW funds have supported efforts to make schools tobacco-free

- Florence, SC Four public school districts passed comprehensive tobacco-free policies, protecting 18,700 students and 2,500 staff in 30 schools
- Archdiocese of Chicago The Chicago Catholic schools adopted a tobacco-free campus policy in 137 schools, protecting an estimated 40,000 students and 2,500 faculty and staff
- Cherokee Nation All schools and child care facilities now prohibit tobacco use at all times in school buildings, on school grounds, in school vehicles, at school functions, and at offsite school events
- St Louis, MO Rockwood School District, the largest in St Louis County (with more than 25 schools, 22,500 students, and 3,300 employees), adopted a comprehensive tobacco-free policy

CPPW SUCCESS STORIES: ADOPTION OF SMOKE-FREE MULTIUNIT HOUSING POLICIES

CPPW funds have supported efforts of communities to adopt smoke-free housing policies and helped people find smoke-free homes

- Boston, MA In May 2011, seven multifamily housing providers implemented smokefree policies, directly affecting more than 3,000 affordable and market-rate units
- Chicago, IL By March 2012, four Chicago Housing Authority sites had implemented smoke-free housing policies, affecting 367 public units The Chicago Tobacco Prevention Project has 211 private housing units that are committed to going smoke-free, with an ultimate goal of 1,000 units going smoke-free
- Santa Clara County, CA The county adopted a policy requiring that all multiunit housing be smoke-free, including public housing This policy covers unincorporated areas of the county, and after full implementation will impact 1,328 existing units occupied by more than 3,300 residents

CPPW SUCCESS STORIES: INTEGRATION OF TOBACCO USE SCREENING, DOCUMENTATION, AND CESSATION TREATMENT REFERRAL INTO MENTAL HEALTH AND SUBSTANCE ABUSE TREATMENT FACILITIES

CPPW funds have supported efforts to enhance tobacco prevention and cessation efforts in mental health treatment settings

- Austin, TX The Seton Family of Hospitals, Central Health, and CommUnityCare
 Clinics implemented a screening protocol for assessing tobacco use and referring patients
 to cessation services and integrated this protocol into their electronic medical record
 systems This new policy reaches 1 8 million patients in 11 counties
- State of Utah The State Department of Health is facilitating staff training, resource development, and tobacco-free policies to reduce tobacco use among patients and staff at treatment centers
- New York, NY The New York Health Department provided training to help 44 Assertive Community Treatment teams and staff at 160 Supportive Housing units integrate tobacco dependence treatment into care given to clients with severe mental illness

As part of CPPW, the Office of the Assistant Secretary for Health awarded grants to 10 national organizations to support CPPW community outcomes. Included in these grants were three national organizations to support tobacco prevention and control outcomes in 18 CPPW communities: the American Academy of Pediatrics, American Lung Association, and Society for Public Health Education. In the first year of the grant, these organizations provided more than 170 sessions of peer-to-peer technical assistance and 64 products, including issue briefs, Webinars, and roundtables.

To build on the successful CPPW effort, in September 2011, CDC awarded more than \$100 million in prevention funding through a new program called Community Transformation Grants (CTGs), funded by the Prevention and Public Health Fund. CTGs are now helping states, communities, and tribes across the nation implement tobacco control programs and other wellness initiatives that promote healthy lifestyles and reduce the incidence of preventable disease. Again, by financing proven prevention programs, the CTG program is improving not only public health but also the nation's economic well-being (Centers for Disease Control and Prevention, 2011b).

FDA Implements Regulations to Reduce Youth Access to Tobacco Products

FDA contracts with states to conduct federal compliance check inspections of tobacco retailers. These retail inspections focus on ensuring compliance with the Tobacco Control Act and FDA regulations at retail locations. FDA awarded contracts to 15 states in 2010 and to 37 states as well as the District of Columbia in 2011, infusing \$33 million into these communities. These contracts enable FDA to conduct compliance check inspections at retail locations to ensure compliance with the law, including a) age and ID verification, b) requirements for labeling and advertising of smokeless tobacco products, c) restrictions on the sale of single cigarettes, d) a ban on certain candy- and fruit-flavored cigarettes, and e) prohibition of the use of self-service displays and vending machines in retail establishments where minors are present or permitted to enter. As of June 1, 2012, FDA has conducted almost 70,000 retail inspections and issued nearly 3,000 warning letters to retailers, the majority of which include violations relating to selling tobacco to minors. Awarding additional contracts in 2012, including contracts with territories, will facilitate FDA's progress on its goal to contract with every state and U.S. territory to assist FDA with tobacco retail inspection efforts and ultimately reduce tobacco use among all Americans and particularly youth (Food and Drug Administration, 2012).



SAMHSA's Synar Program Works to Reduce Youth Access to Tobacco

SAMHSA implements the Synar program; the Synar amendment and its implementing regulation require the 50 states, District of Columbia, and 8 U.S. territories (as a condition of receipt of their full Substance Abuse Prevention and Treatment Block Grant awards) to enact and enforce state laws prohibiting tobacco sales to youth. FDA works closely with SAMHSA to ensure that these regulations work together with SAMHSA's efforts to reduce youth access to tobacco under the Synar program to help reach the shared goal of reducing youth access to, and use of, tobacco products. In 2011, the average national retailer violation rate of tobacco sales to youth was 8.5%, the lowest level in the history of the program (Substance Abuse and Mental Health Services Administration, 2012).

HHS Strategic Action Plan Helps People Quit

HHS has implemented a coordinated Department-wide tobacco-use cessation strategy. This strategy includes increasing insurance coverage for cessation services, media and education on the benefits of quitting, and support for the national quitline network.

Insurance coverage of services to treat tobacco use significantly reduces use of tobacco products. For example, in 2006, Massachusetts provided comprehensive tobacco cessation coverage for all Medicaid beneficiaries. Smoking prevalence among Medicaid enrollees dropped from 38% to 28%, reducing

QUITLINE FACTS (MCKAY & KESMODEL, 2011)

- In 2010, quitlines served approximately 478,000 smokers, including 170,000 Medicaid beneficiaries
- State and federal quitline program funding totaled \$114 million in 2011

hospitalizations for cardiovascular events by nearly 50% (Land et al., 2010). Within 2 years, Massachusetts realized an estimated total savings of more than \$10 million, representing a return on investment of \$3 for every \$1 spent. If this program were implemented in every state, it is estimated that the Medicaid program would save \$2.4 billion within 5 years (Richard, West, & Ku, 2012).

By making key modifications to agency policies, HHS has significantly increased direct assistance to consumers who want to quit using tobacco.

The Health Resources and Services Administration (HRSA) is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. As a result of the HHS *Strategic Action Plan*, HRSA has designated tobacco control as an agency priority. In 2011, HRSA began requiring all of its 1,100 Health Center Program grantees to report on measures for tobacco screening and cessation counseling. In order to improve clinical performance on these measures, HRSA has implemented several programs to support clinicians. The Center for Integrated Health Solutions, a joint SAMHSA-HRSA cooperative agreement to integrate behavioral health and primary care, offered two national Webinars on tobacco cessation for health centers and community behavioral health centers. Area Health Education Centers that partner academic institutions with community-based health care organizations provided educational activities addressing tobacco cessation and prevention services. The 340B Drug Pricing Program continues to provide discounted medications for tobacco cessation.

Medicare and Medicaid Expand Tobacco Cessation Coverage

In August 2010, the Centers for Medicare & Medicaid Services, the federal agency that administers Medicare, Medicaid, and the Children's Health Insurance Program, expanded its coverage of tobacco cessation counseling to include Medicare beneficiaries who use tobacco but who did not have signs or symptoms of tobacco-related disease. As a result of these changes and prior Medicare Part D legislation covering FDA-approved cessation pharmacotherapies, all Medicare patients now have coverage for tobacco cessation.

Similarly, Medicaid coverage has been expanded to include full cessation support for pregnant women (pregnancy may be a period of high motivation for maternal smoking cessation), and it reimburses states for 50% of the cost of providing telephone quitline support to callers covered by Medicaid. As a result of the latter policy, over the next 10 years, approximately 2.5 million additional smokers are expected to use quitlines and related services (North American Quitline Consortium, 2010). Since this policy went into effect in June, 2011, six states (Maryland, Massachusetts, Louisiana, Montana, North Carolina, and Oklahoma) have executed a memorandum of understanding (MOU) with their state Medicaid agencies to obtain the federal match. Another four states (Arizona, California, Colorado, and Delaware) are close to having such MOUs in place.

Quitlines Improve Access to Cessation

Quitlines are an important cessation resource for lowering the burden of tobacco use in the United States. Quitlines provide telephone-based support to help tobacco users quit. This support includes counseling, medications, Web-based information, referral to community resources, and self-help materials. Research has found that quitlines are effective with diverse populations and have broad reach (Fiore et al., 2008).

The National Network of Tobacco Cessation Quitlines, which is a collaborative effort between CDC, NCI, and states and which is funded through NTCP and states, makes free telephone cessation counseling available in the United States. Every state has its own quitline. CDC, through additional funds provided by the Affordable Care Act, provides funds to states to expand or enhance existing services. These enhanced services may include expanding hours of operation, offering services in additional languages, and providing callers with additional counseling sessions and free nicotine replacement therapy. Funding has also been used to promote state quitlines to increase the number of smokers reached, often with a focus on underserved populations with higher smoking rates. Most significantly, the 1-800-QUIT-NOW number was included in CDC's national tobacco education campaign, *Tips From Former Smokers*. This provided a direct point of support for people to quit tobacco use.

Innovative Mobile and Social Media Initiatives Make Quitting Easier

HHS cessation promotion efforts include new innovations designed to reach larger audiences. Using a multiplatform strategy that includes mobile, Internet, and social media components, HHS is harnessing technology to deliver smoking cessation interventions broadly and inexpensively to both teens and adults. Participating in conversations and building a community is a way that social media tools, like Facebook and Twitter, can help HHS integrate social support into our interventions and remove barriers associated with traditional smoking cessation treatments.

THE ODDS OF QUITTING

- 68 8% of smokers say they want to quit (Centers for Disease Control and Prevention, 2011c)
- 52 4% of smokers had made a quit attempt in the past year (Centers for Disease Control and Prevention, 2011c)
- The average smoker makes multiple attempts before succeeding (Fiore et al , 2008)

Building on the success of its existing cessation Web sites (www.smokefree.gov and www.women.smokefree.gov), NCI recently launched Smokefree Teen, a suite of mobile and online resources to help teen smokers quit. Smokefree Teen features a youth-oriented cessation Web site (www. teen.smokefree.gov) as well as tools to connect teens with cessation support via their mobile phones. Also,

Smokefree TXT is a free text message cessation service that provides encouragement, advice, and actionable behavioral strategies to teens trying to quit smoking. Teens can sign up to receive text messages timed around their quit date and to continue receiving them for up to 6 weeks after they quit. Message content is targeted to the unique needs of teen smokers, and the bidirectional service allows teens to request real-time support when faced with common situational triggers, such as when they feel stressed and are tempted to smoke. Teens with iPhones can also download QuitStart, a mobile application that delivers cessation and mood management tips, tracks cravings, and monitors quit attempts. Along with the launch of these mobile tools, Smokefree Teen also unveiled a comprehensive social media strategy that includes an active presence on several social media pages: Twitter (@SmokefreeTeen), Facebook (www.facebook.com/SmokefreeTeen), and Tumblr (www.smokefreeteen.tumblr.com).

In addition, to reach adult smokers, NCI has introduced several new mobile and social media tools as well. SmokefreeTXT includes a second message library that targets young adult smokers. As part of a broader social media outreach strategy, NCI's Smokefree Women program created a Facebook group to connect women trying to quit smoking. More than 2,500 users are participating, some through their mobile phones. In addition to evidence-based cessation tips, this virtual community provides women with ready access to the social support vital for quitting.

NCI also launched an open-source library of smoking cessation messages that provides the foundation for an interactive text-based intervention for adult smokers called QuitNowTXT. The QuitNowTXT text messages, which offer tips, motivation, encouragement, and facts based on information tailored to the user's response, are available at www.smokefree.gov/hp.aspx. These mobile texting resources will be integrated into HHS's comprehensive tobacco control strategy to further address the burden of tobacco use across our nation.

At the United Nations High-level Meeting on the Prevention and Control of Non-communicable Diseases in September 2011, HHS launched a global public-private partnership to make the QuitNowTXT program available to other countries to reach adult tobacco users. Organizations committed to collaborating with HHS on this initiative include the mHealth Alliance (hosted by the United Nations Foundation), World Medical Association, Campaign for Tobacco-Free Kids, Johnson & Johnson, IBM, and the Center for Global Health at

George Washington University. This initiative brings interested governments and organizations together to support mHealth/text-based demonstration projects using this new text messaging resource. The QuitNowTXT library is also now freely available on the mHealth Alliance's HealthUnbound.org Web site.

Pioneers for Smoking Cessation Campaign Addresses High-Risk Groups

Those individuals suffering from mental illness or substance abuse disorders represent one of the most vulnerable and tobacco-dependent groups of people. Persons with mental illness are estimated to consume 44% of all cigarettes sold in the United States (Schroeder & Morris, 2010).

THE CONNECTION BETWEEN TOBACCO AND MENTAL ILLNESS AND SUBSTANCE ABUSE

- People attending substance abuse treatment show extremely high rates (77%) of smoking (Kelly et al , 2012)
- 75% of people with a severe or persistent mental illness are dependent on tobacco (American Psychiatric Association, 2006)

In 2009, SAMHSA partnered with the Smoking Cessation Leadership Center (SCLC) at the University of California, San Francisco (with support from the Robert Wood Johnson Foundation and the American Legacy Foundation) to help facilities treating mental illness or addiction provide tobacco screening and cessation support to their patients. A related goal was to estab-

lish smoke-free environments in these facilities. The program seeks to close a gap created 20 years ago when smoking was banned in hospitals but allowed to continue in psychiatric and drug treatment units.

The first phase of the program mobilized consumer groups, rehabilitation centers, health care providers, and other stakeholders at the local level to create smoke-free environments and provide smoking cessation services. One hundred organizations, named Pioneers for Smoking Cessation, received small grants and technical assistance for their proposed activities through Webinars, a toll-free number, a dedicated e-mail list, and a catalogue of tools.

Then, in 2010, SAMHSA launched the second phase of the program, awarding 25 Pioneers with additional funding to refine and expand their initiatives benefiting people with, or at elevated risk for, mental health or substance use disorders.

Results indicate that 20 of the 25 Pioneers reported a decrease in tobacco use among clients and staff (Smoking Cessation Leadership Center, 2011).

STATE LEADERSHIP ACADEMIES FOR WELLNESS AND SMOKING CESSATION

- Arizona
- Arkansas
- Maryland
- New York
- North Carolina
- Oklahoma
- Texas

The training and education at facilities has resulted in a more than doubling of the number of patients being counseled to quit—from just over 20% to just over 50% in the first 18 months of the program (Reyes, 2011).

In the fall of 2010, the collaboration of SAMHSA and SCLC continued with a new initiative, State Leadership Academies for Wellness and Smoking Cessation. The purpose of the Academies is to launch statewide partnerships among behavioral health providers, consumers, and other stakeholders to create and implement an action plan to reduce smoking prevalence among people with behavioral health conditions.

Engaging the Public: Changing Social Norms Around Tobacco Use

For the first time, the federal government is making substantial investments in national tobacco education campaigns. Both traditional media and new electronic media are increasing awareness of the dangers of tobacco use and promoting the resources available to help people quit.

CDC Spearheads a National Tobacco Education Campaign

In 2011, CDC launched a 12-week integrated advertising campaign pilot in several markets in the South and Southeast, where adult and youth smoking rates are among the highest in the country. Along with traditional media placement, the CDC campaign also included a substantial social media effort involving a Facebook fan page (www.facebook.com/cdctobaccofree), YouTube videos, sharable multimedia messages, and Twitter postings. The campaign achieved increases in smokers' and nonsmokers' awareness levels of the three television ads that ran during that period. It also yielded \$2.54 in earned media for every \$1.00 spent.

On March 15, 2012, CDC launched a hard-hitting national ad campaign that depicted the harsh reality of illness and damage suffered as a result of smoking and exposure to second-hand smoke. The *Tips From Former Smokers* campaign profiled people who are living with the significant adverse health effects due to smoking, such as paralysis from stroke, lung removal, heart attack, asthma, stomas, and limb amputations. The advertisements underscored the immediate damage that smoking can cause to the body and featured people who experienced smoking-related diseases at a relatively young age. These hard-hitting ads helped people quit, saving lives and decreasing the huge economic burden caused by tobacco use. The ads were tagged with 1-800-QUIT-NOW, a toll-free number to access quit support across the country, or the www.smokefree.gov Web site, which provides free quitting information.

The campaign's paid advertisements and public service announcements delivered a mix of high-impact advertising via television, radio, newspapers, magazines, movie theaters, bill-boards, and Web and social media such as Facebook and Twitter. The campaign has generated almost 200,000 additional calls to 1-800-QUIT-NOW and more than 400,000 additional unique visitors to www.smokefree.gov. These numbers provide a powerful early indication that the 12-week campaign, which ended on June 10, is on track to surpass the goal of generating at least 500,000 quit attempts and 50,000 successful long-term quits. Further data detailing the number of quit attempts will be available later this year. Throughout the 12-week campaign, more than 4,000 news stories with a total reach of 3.6 billion impressions and a publicity value exceeding \$10.5 million have been generated.

FDA Initiates the First of Multiple Public Education Campaigns

FDA plans to launch multiple campaigns to educate the public about the constituents in tobacco products and the harms of tobacco use, to reduce initiation, and to encourage cessation. Integrated campaigns, including advertising, digital marketing, social media, and event marketing, will reach and engage teen and young adult audiences. Special emphasis will be directed toward at-risk and underserved populations with high prevalence levels of tobacco use. Each distinct campaign will utilize formative research to ensure that the messages educate in ways that are relevant and motivating to unique audiences, with a goal of providing accurate information so youth can effectively resist pressure to initiate tobacco use and adults are encouraged to try to quit. Also, each campaign will undergo rigorous evaluation to demonstrate its effectiveness.

New Health Warning Labels Will Convey the Harms of Tobacco

In 2009, four new health warnings were required for smokeless tobacco products. These health warnings now cover 30% of the two main surfaces of smokeless tobacco packages, and these warnings must comprise at least 20% of smokeless tobacco advertisements. In June 2011, FDA promulgated the historic final rule requiring cigarette packaging and advertisements nationwide to feature new warning statements accompanied by graphic images depicting the negative health consequences of smoking. This rule marked the first change to cigarette warnings in 25 years. FDA has developed nine warning label designs that educate consumers about the health risks of smoking. These warnings are designed to cover the top 50% of the front and back of cigarette packages and will occupy 20% of each cigarette advertisement. As noted earlier, a lawsuit by the tobacco industry has halted implementation of the cigarette labels.



Studies in other countries have shown that exposure to larger health warnings and exposure to graphic health warnings increase awareness of the health risks of tobacco use. This increased awareness can also lead to an increased interest in quitting, prompting calls to quitlines and conversations with a doctor, and therefore increase the number of successful quit attempts. Such education also discourages nonsmokers from starting. Based on an extensive evidence base, FDA expects that the new cigarette warnings will decrease the number of smokers and result in lives saved, increased life expectancy, improved health, and reduced medical costs. Specifically, it is estimated that these warnings will result in 16,500 fewer smokers each year, both by encouraging smokers to quit and by deterring nonsmokers from starting to smoke. Importantly, the monetized benefit of the health warnings is estimated to be more than \$630 million per year over 20 years. Additional benefits of the rule, such as reduction in secondhand smoke exposure, will also occur but were not included in the monetized estimate.

Advancing Knowledge: Accelerating Research to Expand the Science Base and Monitor Progress

Scientists have known about the dangers of tobacco for decades, but the market for tobacco and nicotine-delivery products continues to evolve and diversify in unprecedented ways. To identify more effective methods to prevent youth and young adults from starting and to help addicted smokers quit, researchers continue to study the effects of tobacco use and the pathways to addiction. HHS also administers national surveys to monitor tobacco use and attitudes, understand emerging trends, and guide future efforts. In addition to this ongoing research, HHS has recently embarked on new efforts to advance knowledge, including updated reports from the Surgeon General, a new cohort study of tobacco users, and increased tobacco regulatory research.

Surgeon General Reports on Tobacco

The Surgeon General provides the public with information to help them lead healthier lives. For the last 50 years, a series of Surgeon General Reports on tobacco and health has raised national awareness about the harms of tobacco use and the measures necessary to address these harms.

The 30th Surgeon General's Report on tobacco and health, released in 2010, is entitled *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease* (U.S. Department of Health and Human Services, 2010c). It details the ways in which tobacco smoke damages the human body, with major findings including:

- There is no safe level of exposure to tobacco smoke. Any exposure to tobacco smoke—even an occasional cigarette or exposure to secondhand smoke—is harmful.
- Damage from tobacco smoke is immediate.
- Smoking longer means more damage.
- Cigarettes are designed for addiction.
- There is no safe cigarette.
- The only proven strategy for reducing the risk for tobacco-related disease and death is to never smoke, and if you do smoke, to quit.

The report has achieved significant coverage since it was released:

- Within 24 hours of its release, the report received media coverage in all parts of the country—in more than 2,000 television, radio, print, and online media outlets and amassing a publicity value of \$3 million.
- By year's end, the report had generated more than \$4.6 million in earned media and 42 million media impressions.

On March 8, 2012, Surgeon General Dr. Regina Benjamin released *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*—the 31st tobacco-related Surgeon General's Report issued since 1964. This report 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 tobacco use and interventions proven to prevent it (U.S. Department of Health and Human Services, 2012a). Major findings include:

- Far too many young people are still using tobacco. More than 600,000 middle school students and 3 million high school students smoke cigarettes. Rates of decline for youth cigarette smoking have slowed in the last decade, and rates of decline for smokeless tobacco use have stalled completely.
- Prevention efforts must include focus on young adults ages 18 through 25, too.
 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 become addicted.
- Youth are vulnerable to social and environmental influences to use tobacco; messages and images that make tobacco use appealing to them are everywhere.
- 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.
- Comprehensive, sustained, multicomponent programs can cut youth tobacco use in half in 6 years.

The report has achieved significant coverage since it was released:

- In the first 2 weeks, more than 2,000 media outlets and 2,300 social media and Web sites covered the report.
- Three months later, the report had generated approximately \$6.69 million in earned media and 2.9 billion media impressions.

On May 30th, Dr. Regina Benjamin, U.S. Surgeon General, announced the winners of a video contest she launched on March 15, 2012, in conjunction with the release of *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General.* At that time, she invited young Americans to develop original videos that featured one or more of the findings from the report.

The contest—*Tobacco: I'm Not Buying It*—was hosted by CDC's Office on Smoking and Health (OSH) and supported through Challenge.gov. Applicants were invited to submit videos in either English or Spanish in two age categories: youth (13–17 years) or young adult (18–25 years). This creative outlet encouraged applicants to express their views about this problem and share why they choose to be tobacco-free. To encourage participation in the contest, CDC/OSH announced the availability of up to four grand prizes (one for each category, both in English and in Spanish). Three runner-up prizes were also available for each category and language. Contestants were instructed to submit their content via the Challenge .gov Web site.

CDC also publicly announced the winners and runners-up and promoted their videos through a variety of digital media (Web sites, YouTube, Facebook, Twitter), providing them with broader recognition and further publicizing the Surgeon General's Report findings.

On June 14, 2012, Dr. Benjamin and other public health officials joined youth in Seattle, Washington, to participate in a youth and tobacco town hall sponsored by HHS and FDA, in partnership with CDC, state and local public health authorities, and tobacco prevention professionals throughout the Pacific Northwest. This town hall brought together public health professionals; tobacco use prevention specialists; educators; advocates; policy makers; and most importantly, young people from around the Pacific Northwest to share information, tools, and best practices in tobacco use prevention.

FDA and NIH Collaboration

In October 2011, FDA and the National Institutes of Health (NIH) announced a joint national, prospective, longitudinal cohort study of tobacco users (and those at risk for tobacco product use) to monitor and assess their tobacco use and the health impacts of such use. The initiative, called the Population Assessment of Tobacco and Health (PATH) Study, represents the first large-scale FDA-NIH collaboration on tobacco regulatory research since Congress granted FDA the authority to regulate tobacco products under the Tobacco Control Act. Scientific experts at NIDA and FDA's Center for Tobacco Products (CTP) will coordinate this effort, which will prospectively follow at least 60,000 people who are users of tobacco products and those at risk for tobacco product use ages 12 and older in the United States. The study will a) examine what makes people susceptible to tobacco product use; b) evaluate initiation and use patterns; c) study patterns of tobacco product cessation and relapse; d) evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes; e) assess differences in attitudes, behaviors, and key health outcomes in racial/ethnic, gender, and age subgroups; and f) assess biomarkers of exposure and disease outcomes.

By measuring and accurately reporting on behavioral and health effects associated with tobacco product use in the United States, this study will play an important role in the development, implementation, and evaluation of tobacco product regulations by FDA.

NIH and FDA have established an unprecedented research partnership to increase tobacco regulatory science knowledge and capabilities.

THE PATH STUDY

"The launch of this study signals a major milestone in addressing one of the most significant public health burdens of the 21st century The results will strengthen FDA's ability to fulfill our mission to make tobacco-related death and disease part of America's past and will further guide us in targeting the most effective actions to decrease the huge toll of tobacco use on our nation's health"

- FDA Commissioner Margaret A Hamburg

This partnership has begun innovative research of the impact of how altering nicotine levels in tobacco products could affect the way people use tobacco products and become addicted. FDA and NIH are working to establish Tobacco Centers of Regulatory Science for research relevant to the Tobacco Control Act as well as funding research project grants and research training grants.

In a workshop in February 2012, FDA met with research organizations to communicate its tobacco regulatory research priorities. FDA's priorities for research include:

- Expanding understanding of the diversity of tobacco products
- Reducing addiction to tobacco products
- Reducing toxicity and carcinogenicity of tobacco products and smoke
- Continuing research of the adverse health consequences of tobacco use
- Broadening understanding of communications about tobacco products
- Increasing knowledge about tobacco product marketing
- Furthering understanding of how economics and policies affect tobacco product use

NIH Research

A number of key NIH agencies are accelerating tobacco research as part of the HHS *Strategic Action Plan*. NIDA has made the development of addiction-related medications, including new smoking cessation medications, a top priority through its Translational Medications Avant-Garde Award for Medications Development. One of the 2011 awardees is developing and testing a novel vaccine that induces a strong immune response against nicotine without the need for chemical enhancers, which could result in a less expensive vaccine with fewer side effects. In addition, NIDA is embarking on a novel product development partnership to leverage the strength and resources of public, nonprofit, and private-sector entities to accelerate the development and production of effective smoking cessation medications at reasonable costs.

NCI leads and collaborates on research related to the prevention, treatment, and control of tobacco use and tobacco-related cancers, employing basic and applied research in the biological, behavioral, social, and population sciences. Two fiscal year (FY) 2009 NCI funding initiatives include "Measures and Determinants of Smokeless Tobacco Use, Prevention, and Cessation" and "Improving Effectiveness of Smoking Cessation Interventions and Programs in Low-Income Adult Populations." The goal of the smokeless tobacco initiative is to develop an evidence base to inform smokeless tobacco control efforts and develop effective ways to limit the spread and promote cessation of smokeless tobacco use. The long-term goal of the initiative is to facilitate a significant reduction in smoking prevalence among low-income adults, thereby reducing the excess disease burden of tobacco use within these groups and decreasing the prevalence of smoking the United States as a whole.

Historically, states and communities have played an important role in implementing tobacco prevention and control policies and programs and in designing and implementing mass media campaigns. In FY 2012, NCI funded the State and Community Tobacco Control Research Initiative to support innovative research that will yield actionable findings for state and community tobacco control programs and practitioners. Research funded by this initiative is aimed at addressing understudied aspects of tobacco control policy and media interventions by targeting four high-priority research areas at the state and community levels in the United States: 1) secondhand smoke policies, 2) tobacco pricing policies, 3) mass media countermeasures and community social norms, and 4) tobacco industry practices as they relate to the preceding three items. This research initiative includes seven research project sites around the country and one coordinating center site.

CDC Research

CDC has established a partnership with FDA to enhance tobacco-related surveys in the United States, including the recently conducted 2012 National Youth Tobacco Survey, which will provide the first round of data to evaluate the impact of CTP's regulatory efforts on youth, and the companion National Adult Tobacco Survey, which will be conducted in the fall of 2012 and aid in evaluating the impact of CTP's regulatory efforts on tobacco use among adults.

CDC is currently expanding the Smoking-Attributable Mortality, Morbidity, and Economic Costs online application, which contains two distinct Internet-based computational programs to estimate the economic and disease impact of smoking on adults and infants, to include estimates for the international tobacco control community. In addition, CDC is updating it to include current smoking-attributable factors.

In addition, FDA is funding CDC's Tobacco Laboratory to conduct a number of specific analyses related to the Tobacco Control Act. CDC will develop and validate new, more robust methods for analyzing harmful and potentially harmful constituents (HPHC) in tobacco products and tobacco smoke. CDC will use its expertise to train staff in FDA's Office of Regulatory Affairs Southeast Regional Laboratory to carry out analytical methods for compliance and enforcement testing. CDC's laboratory is establishing baseline levels of HPHC in selected tobacco products and smoke in order to assess the overall risk and overall trends in delivery of HPHC. The laboratory is building off of its decades-long experience in developing new biomarkers of exposure to HPHC in order to more fully assess the exposure of users of tobacco products. In order to better understand the relationship of tobacco product design, additives, ingredients, HPHC, and exposure, the laboratory is measuring biomarkers of exposure in smoking participants of the National Health Examination and Nutrition Examination Survey. The laboratory will serve as the primary biomarker analysis laboratory for the PATH study in order to help develop the most effective regulatory actions and to evaluate the impact of FDA regulatory actions on exposure of users and nonusers of tobacco products. CDC also conducts quick-turnaround projects to address specific questions related to FDA regulations.

SAMHSA Surveillance

SAMHSA'S National Survey on Drug Use and Health collects data on tobacco use and its association with both the use of other substances and mental health disorders. Additionally, beginning in 2011, SAMHSA's National Survey of Substance Abuse Treatment Services, which collects data from all private and public substance abuse treatment facilities in the United States, began collecting data on the extent of a facility's smoking policy and whether the facility provides nicotine replacement and/or non-nicotine smoking cessation medications to its clients.

TOWARD A SOCIETY FREE FROM TOBACCO-RELATED DEATH AND DISEASE

For more than a century, tobacco use has been a burden on American public health, causing decreased quality of life for tens of millions of Americans, almost half a million lost lives annually, and billions of dollars each year in medical expenses and lost productivity.

Despite these challenges, the resolve among HHS and other public health authorities to end the tobacco epidemic is strong, and the potential to do so unprecedented. More than ever before, public attitudes, political will, and scientific evidence are converging to support this goal.

A growing body of successful evidence-based tobacco control measures has added powerful new tools to stem tobacco use. HHS's *Strategic Action Plan* to end the tobacco epidemic provides a critical framework to guide and coordinate this work. Already, as described in this publication, federal and state agencies, together with local communities, are hard at work on many fronts applying proven methods for reducing the burden of tobacco dependence in the United States.

HHS has led the way by implementing the proven tobacco prevention and treatment interventions recommended in the *Strategic Action Plan*. The *Plan* demonstrates that HHS is making good on this historic opportunity to rekindle the momentum of previous decades and achieve the vision of a society free from tobacco-related death and disease.

To sustain the recent progress, robust action by HHS and other stakeholders must continue. With a committed and concerted effort, HHS and other public and private-sector partners across the country can achieve the *Healthy People* objectives of preventing youth initiation and reducing the adult smoking rate, resulting in millions of fewer smokers in the United States. The path charted by that achievement will then set a powerful stage for continued progress and success toward the ultimate goal of eliminating tobacco-related illness and death.

APPENDIX A: TRACKING PROGRESS TOWARD THE *HEALTHY PEOPLE* OBJECTIVES

The Strategic Action Plan is framed around Healthy People goals and objectives. Released by HHS each decade since 1980, Healthy People establishes 10-year targets to guide national health promotion and disease prevention efforts. In December 2010, HHS launched Healthy People 2020 (U.S. Department of Health and Human Services, 2010b), the fourth generation of this initiative, building on a foundation of three decades of work.

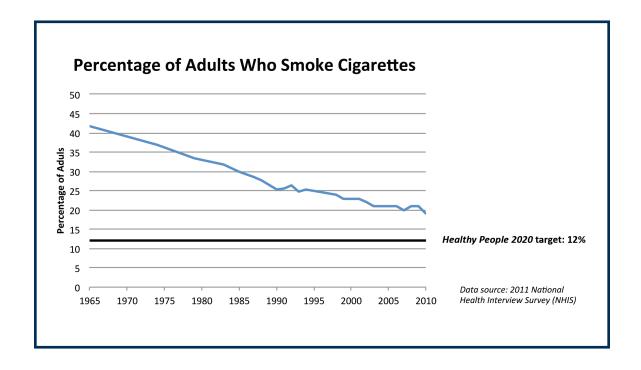
HHS adopted four *Healthy People 2020* objectives as the key goals for its *Strategic Action Plan* (U.S. Department of Health and Human Services, 2010b):

- Reduce tobacco use by adults and adolescents
- Reduce the initiation of tobacco use among children, adolescents, and young adults
- Increase smoking cessation success by adult smokers
- Reduce the proportion of nonsmokers exposed to secondhand smoke

HHS commits to tracking key outcomes noted below as part of these four objectives.

Adult Smoking Prevalence

Current overall smoking prevalence falls short of the *Healthy People 2020* target of 12%.



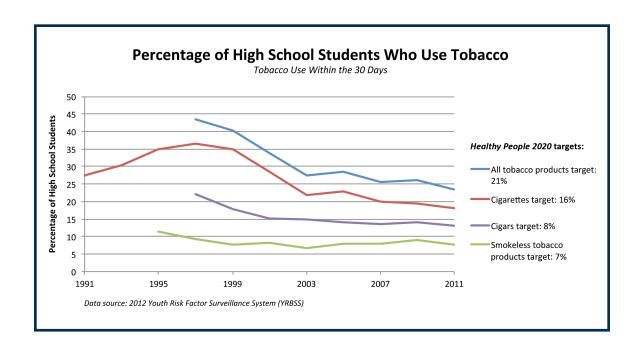
- As of 2010, nearly one-fifth of American adults smoke (Centers for Disease Control and Prevention, 2011a).
- The percentage of adults who smoke has been declining for many years, with today's smoking rate being less than half of what it was in the 1960s. However, the rate of decline has slowed in recent years (Centers for Disease Control and Prevention, 2011a).

Some adults smoke at much higher rates than others. For example, in 2010:

- Non-Hispanic whites (21.0%) and blacks (20.6%) are far more likely to smoke than Hispanics (12.5%) and Asians (9.2%) (Centers for Disease Control and Prevention, 2011a).
- Among racial/ethnic groups, American Indians/Alaska Natives have the highest smoking rates (31.4%), but they have shown a large decrease in recent years (Centers for Disease Control and Prevention, 2011a).
- People who did not finish high school (25.1%) and those with only a high school diploma (23.8%) smoked at more than twice the rate of those with an undergraduate college education (9.9%) (Centers for Disease Control and Prevention, 2011a).
- Persons with chronic mental illness consume 44% of all cigarettes sold, reflecting both high prevalence and heavy smoking (Schroeder & Morris, 2010).
- Cigarette smoking also varies widely by geographic area. For example, 9.1% of adults in Utah and 12.1% of adults in California smoked cigarettes, compared with 26.8% in West Virginia and 24.8% in Kentucky. Overall, smoking rates were highest in the Midwest (21.8%) and South (21.0%) and lowest in the West (15.9%) and Northeast (17.4%) (Centers for Disease Control and Prevention, 2011a).

Adolescent Tobacco Use

In 2011, about 23% of high school students reported current use of some type of tobacco product, and 18% smoked cigarettes.



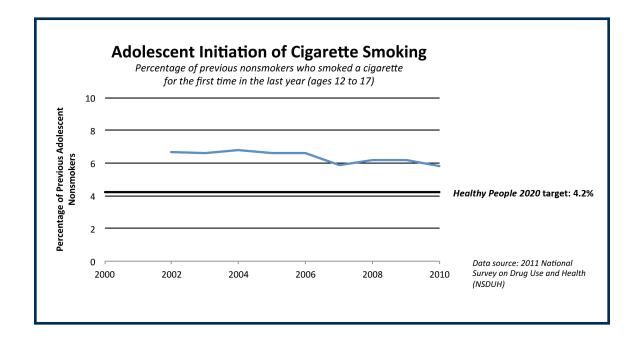
- The United States is not close to achieving the *Healthy People 2020* targets for adolescent tobacco use (Centers for Disease Control and Prevention, 2010b).
- Teen smoking rates increased dramatically through the mid-1990s, then dropped sharply. However, in recent years, the decline in prevalence has slowed (Centers for Disease Control and Prevention, 2010b).
- Since gradually falling in the preceding decade, smokeless tobacco use has risen slightly since 2003 (Centers for Disease Control and Prevention, 2010b).

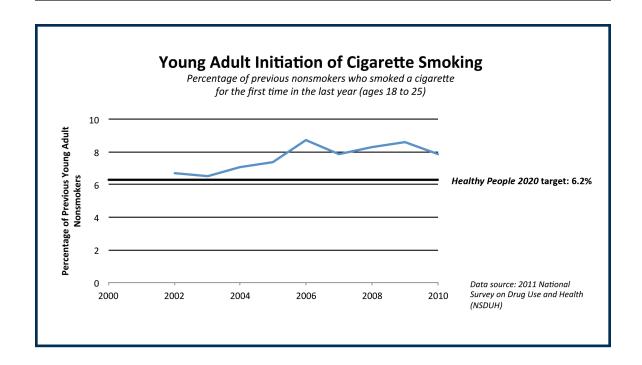
As with adults, patterns of tobacco use by high school students vary by demographic group. For example, in 2009:

- White high school students were more than twice as likely to smoke as black high school students. Hispanic high school students smoke more than black high school students (Centers for Disease Control and Prevention, 2010b).
- Smokeless tobacco remains a predominantly male problem; usage rates for high school students were 13.4% for males compared to 2.3% for females (Centers for Disease Control and Prevention, 2010b).

Smoking Initiation

The vast majority of smokers start when they are adolescents or young adults.

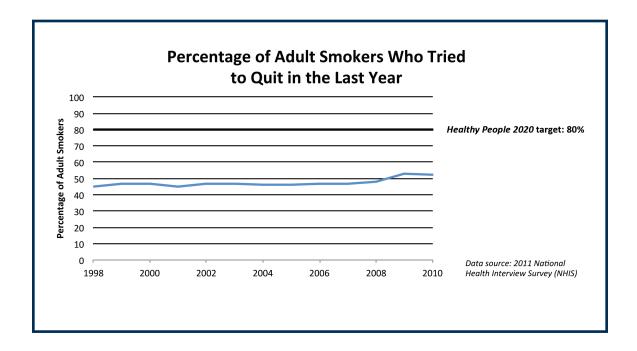




- The 2010 National Survey on Drug Use and Health estimated that 2.4 million people smoked a cigarette for the first time within the past 12 months (Substance Abuse and Mental Health Services Administration, 2011).
- The rate of adolescent initiation has held fairly steady for the last decade. In 2010, 5.8% of adolescents who had never smoked before smoked a cigarette for the first time (Substance Abuse and Mental Health Services Administration, 2011).
- Among 18- to 25-year-olds, the rate of initiation has increased since 2002. In 2010, 7.9% of the nonsmokers in this age group tried a cigarette for the first time (Substance Abuse and Mental Health Services Administration, 2011).

Attempts to Quit

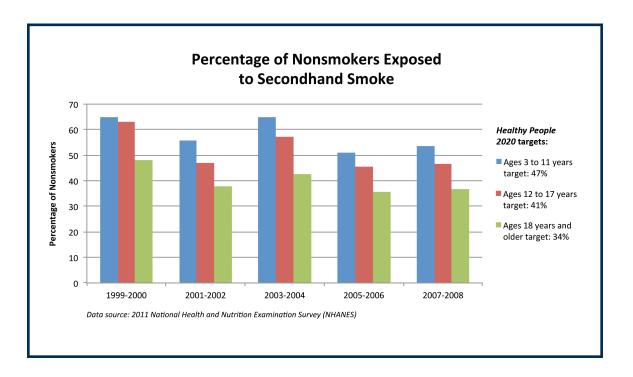
Every year, almost half of the adult smokers in the United States try to quit.



• The proportion of adult smokers who try to quit each year has increased slowly, at best, and the nation is far from the *Healthy People 2020* objectives of 80% of adult smokers trying to quit each year (U.S. Department of Health and Human Services, 2010b).

Exposure to Secondhand Smoke

The percentage of nonsmokers exposed to secondhand smoke has decreased dramatically since the early 1990s, owing to a combination of local, state, and federal smoke-free laws; workplace policies; and people deciding to make their homes smoke-free. The *Healthy People 2010* goal has been exceeded (U.S. Department of Health and Human Services, 2006).



Despite the overall progress at reducing nonsmokers' exposure to secondhand smoke, some groups remain disproportionally at risk. For example, in 2007–2008:

- Children aged 3-11 years (53.6%) were more likely to be exposed to secondhand smoke than adults aged 20 years and older (36.7%) (Centers for Disease Control and Prevention, 2010a).
- Black nonsmokers (55.9%) were exposed to secondhand smoke at much higher rates than whites (40.1%) or Hispanics (28.5%) (Centers for Disease Control and Prevention, 2010a).

APPENDIX B: LIST OF ACRONYMS

ARRA American Recovery and Reinvestment Act

CDC Centers for Disease Control and Prevention

CPPW Communities Putting Prevention to Work

CTG Community Transformation Grant

CTP Center for Tobacco Products

CUNY City University of New York

FDA Food and Drug Administration

FEHB Federal Employee Health Benefits

FY Fiscal year

HHS Department of Health and Human Services

HPHC Harmful and potentially harmful constituents

HRSA Health Resources and Services Administration

MOU Memorandum of understanding

NCI National Cancer Institute

NHANES National Health and Nutrition Examination Survey

NHIS National Health Interview Survey

NIDA National Institute on Drug Abuse

NIH National Institutes of Health

NSDUH National Survey on Drug Use and Health

NTCP National Tobacco Control Program

OPM Office of Personnel Management

OSH Office on Smoking and Health

PACT Prevent All Cigarette Trafficking

PATH Population Assessment of Tobacco and Health

SAMHSA Substance Abuse and Mental Health Services Administration

SCLC Smoking Cessation Leadership Center

YRBSS Youth Risk Behavior Surveillance System

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