



Center for Tobacco Products

Briefing for the Senate Committee on Health, Education, Labor & Pensions

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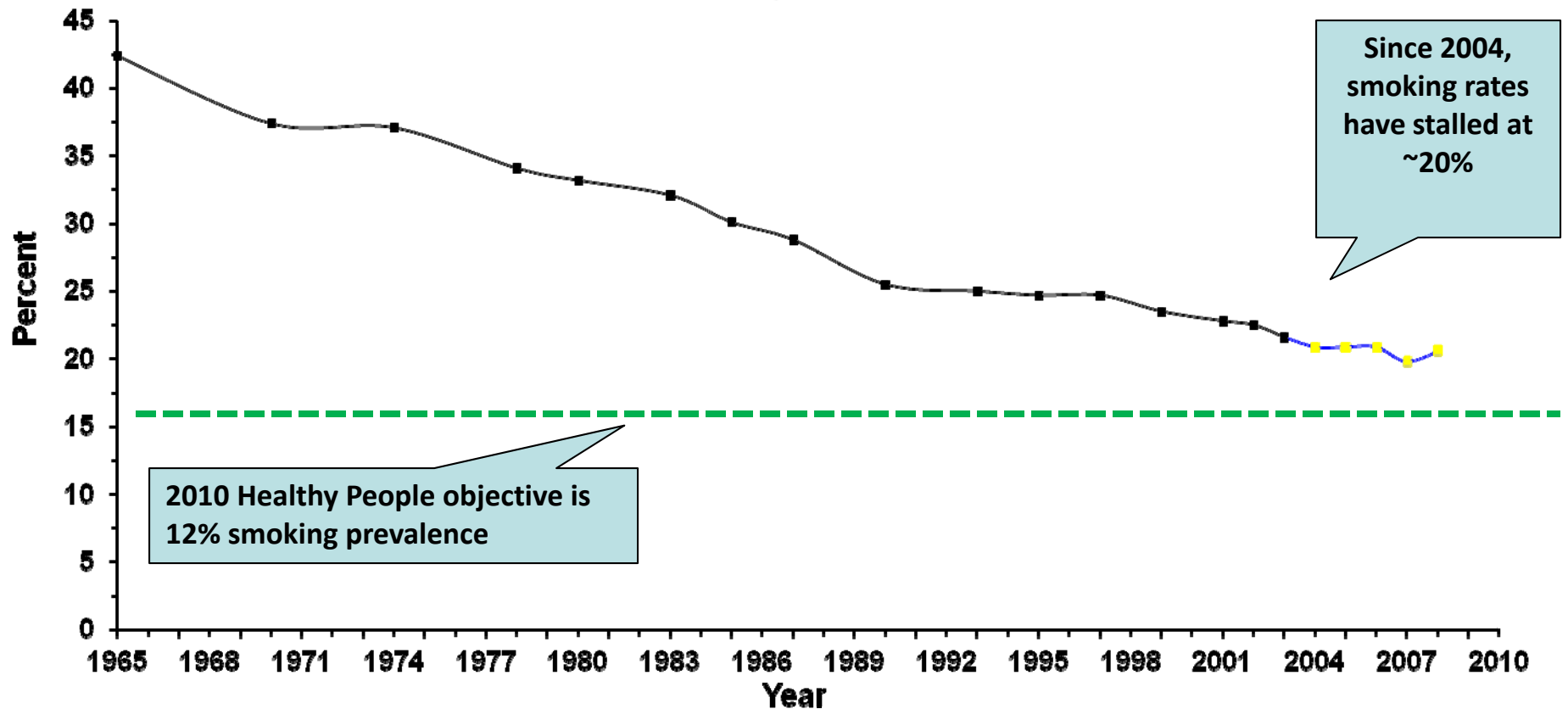
Overview of Presentation

- Tobacco Use in U.S. and Trends
- FDA Goals
- FDA Authorities
- FDA Accomplishments
- Upcoming Activities

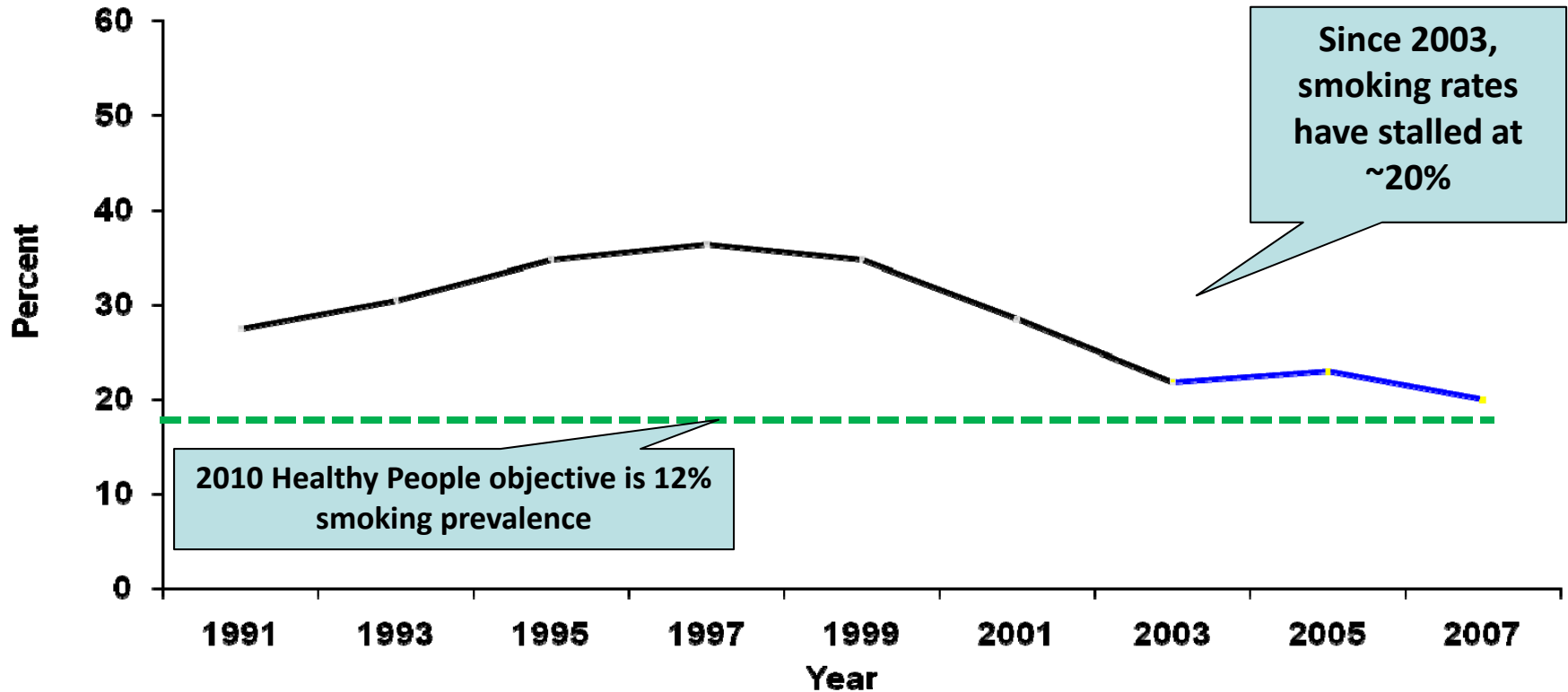
Tobacco Use in the United States

- Leading preventable cause of death in the United States
- Approximately 443,000 deaths yearly from cigarettes
- Approximately 50,000 deaths yearly in nonsmokers due to secondhand smoke exposure
- 8.6 million smokers have at least one serious illness due to smoking
- Smokers who die lose about 14 years of expected life
- For every death, another 20 Americans suffer from a tobacco-related disease or disability
- \$196 billion annual in lost productivity and medical costs attributed to tobacco use

After Decades of Progress, Decline in Adult Smoking Rates Has Stalled



Cigarette Smoking* Trends Among 9th-12th Graders, U.S., 1991-2007



* Smoking on 1 or more of the previous 30 days.
Source: Youth Risk Behavior Surveillance Survey

Youth Tobacco Use is *NOT* Decreasing

- 20-25% of high school students report current use
- 4,000 kids start smoking and 1,000 kids become regular smokers every day
- 90% of adult smokers start tobacco use as a teen
- Many of these kids will become addicted before they are old enough to understand the risks and will ultimately die too young of tobacco-related disease
- Scientists have found that tobacco promotion leads to adolescent tobacco use

FDA Tobacco Control Goals

- Prevent youth tobacco use
- Help adults who use tobacco to quit
- Promote public understanding of contents and consequences of use of tobacco products
- Develop science base and begin meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death

Scope of FDA's Authority Under the Tobacco Control Act

- The Act gives FDA authority to regulate tobacco products, which are products made or derived from tobacco intended for human consumption.
- Tobacco products do not include drugs or devices which are regulated under different provisions of the Food, Drug, and Cosmetic Act.
- The Act does not extend to tobacco warehouses and growers unless they also manufacture tobacco products.
- The Act recognized FDA as the “primary Federal regulatory authority with respect to the manufacture, marketing and distribution of tobacco products.”

Scope of FDA's Authority Under the Tobacco Control Act

- Statute modeled on device law and provides authority for:
 - Premarket applications for new and modified risk tobacco products
 - Post market surveillance
 - Performance standards
 - Testing and reporting of ingredients
 - Adverse event reporting
 - New warning labels
 - Advertising and promotion restrictions
 - User fees

Strong Support from Across the Federal Government

- HHS leading the effort -- Department-wide Working Group on Tobacco led by ASH
- Collaborating and coordinating with HHS sister agencies (e.g., CDC, NIH, SAMHSA) as well as other departments (e.g., FTC, USDA, TTB)

COMMUNICATIONS AND OUTREACH

- In collaboration with CDC, held listening session teleconference with State and local health departments
- Held listening sessions with public health advocates; tobacco industry representatives, and distributors
- Established a Small Business Assistance Office and Web page
- Launched a Call Center for consumers and stakeholders

COMMUNICATIONS AND OUTREACH

- Announced the Stakeholder Discussion Series
 - To leverage the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by tobacco product regulation
 - » Will hold moderated discussions across the U.S. during the next 12-18 months
 - » Discussions will be organized around the interests and perspectives of various stakeholder communities, including, but not limited to:
 - Public health and advocacy organizations;
 - State, local, Territorial, and Tribal governments;
 - Tobacco industry businesses and representatives;
 - Tobacco growers;
 - Retail establishments;
 - Minority health organizations; and
 - Academic and scientific organizations.
 - To enhance transparency, the FDA will publish summaries of the results of each session

COMMUNICATIONS AND OUTREACH

- Attend retailer and tobacco industry conferences
 - Society on Research of Nicotine and Tobacco (February 25, 2010)
 - Responsible Retailers Forum (April 22, 2010)
 - American Wholesale Marketers Association (May 13, 2010)
 - Tobacco Merchants Association (May 24, 2010)

- Attend other events
 - American Public Health Association (November 9, 2009)
 - CDC Grand Rounds (November 19, 2009)
 - Food and Drug Administration Alumni Association (January 21, 2010)
 - Society on Research of Nicotine and Tobacco (February 25, 2010)
 - Food Drug and Law Institute (April 22, 2010)
 - American Marketing Association (May 21, 2010)

PROTECTING KIDS

- Announced ban on cigarettes with characterizing fruit, candy or clove flavors and issued guidance on implementation
- Reissued final 1996 Rule: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents
 - Restrict sales to people younger than 18
 - Prohibits sale of cigarette packs with fewer than 20 cigarettes
 - Prohibits distribution of free samples of cigarettes and restricts distribution of free samples of smokeless tobacco products
 - Prohibits tobacco brand name sponsorship of athletic, musical, or other social event
 - Prohibits sale of tobacco products in vending machines except in limited adult only venues
- FDA plans to contract with States and Territories to help enforce the regulations; issued RFPs to states in March 2010

ESTABLISHING A SCIENCE BASE

- Tobacco Products Scientific Advisory Committee (TPSAC) formally established March 2010
 - Nine voting members and three non-voting members representing
 - » Tobacco manufacturers,
 - » Small tobacco manufacturers
 - » Growers
 - First meeting held on March 30-31, 2010
 - » Focus on the public health impact of the use of menthol in cigarettes
 - Subcommittee on Tobacco Constituents Created
 - Science Director Hired

Other Regulatory Actions

- Created the Tobacco User Fee Program
- Issued draft, and then final guidance on requirements for listing of ingredients and constituents in tobacco products
- Issued draft, and then final guidance on requirements for registration of establishments and product listings
- Issued draft, then final guidance on tobacco health document submission
- Issued warning letters to industry for possible violations of the flavor ban
- Issued letters to industry requesting information about perception and use of dissolvable tobacco products, especially among young people
- Began enforcing requirements with respect to registration of establishments and product listings (February 28, 2010)

Upcoming Activities & Regulatory Milestones

<p>June 2010</p>	<p>_____</p>	<p>Ban on the manufacture of tobacco products labeled or advertised with the terms "light," "low," or "mild"</p>
<p>June 2010</p>	<p>_____</p>	<p>Smokeless tobacco rotational warning labels</p>
<p>June 2010</p>	<p>_____</p>	<p>Effective date for enforcement of the reissued 1996 Rule</p>

Upcoming Activities & Regulatory Milestones

June 2010

TPSAC Tobacco Constituents Subcommittee meeting to be held on June 8 – 9, 2010

June -August 2010

Award of contracts to up to 25% of States and Territories to assist with enforcement

June 2011

Issue regulations on new graphic health warnings for cigarette packages