Center for Tobacco Products

HHS Tribal Budget and Policy Consultation Session

March 4, 2011

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Center Director

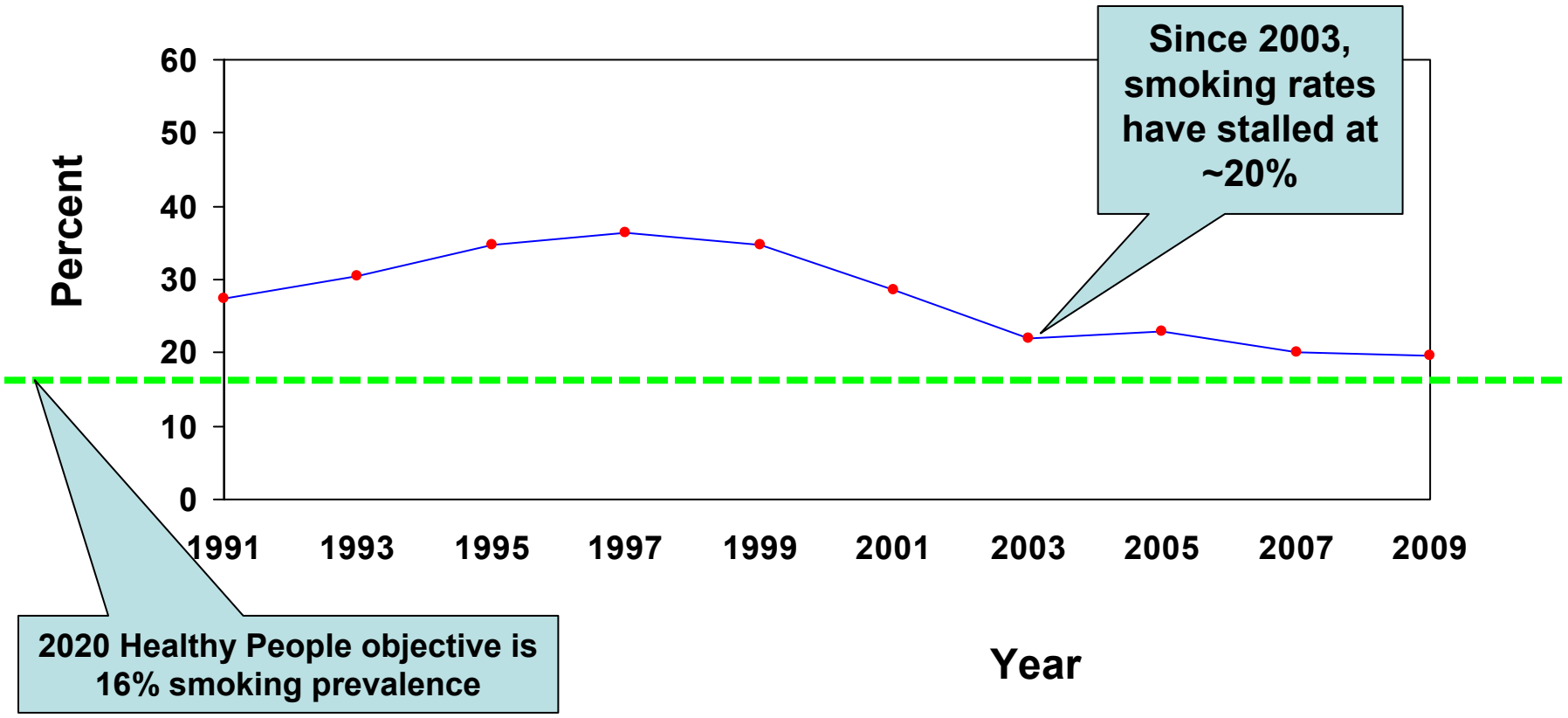
Agenda

- Overview of the Food and Drug Administration (FDA)
- Overview of the Family Smoking Prevention and Tobacco Control Act and the Center for Tobacco Products
- The Public Health Imperative and FDA Tobacco Control Goals
- Tobacco Control and Tobacco Product Regulation
- CTP Outreach and Engagement
- How to Contact Us

Tobacco Use in the United States

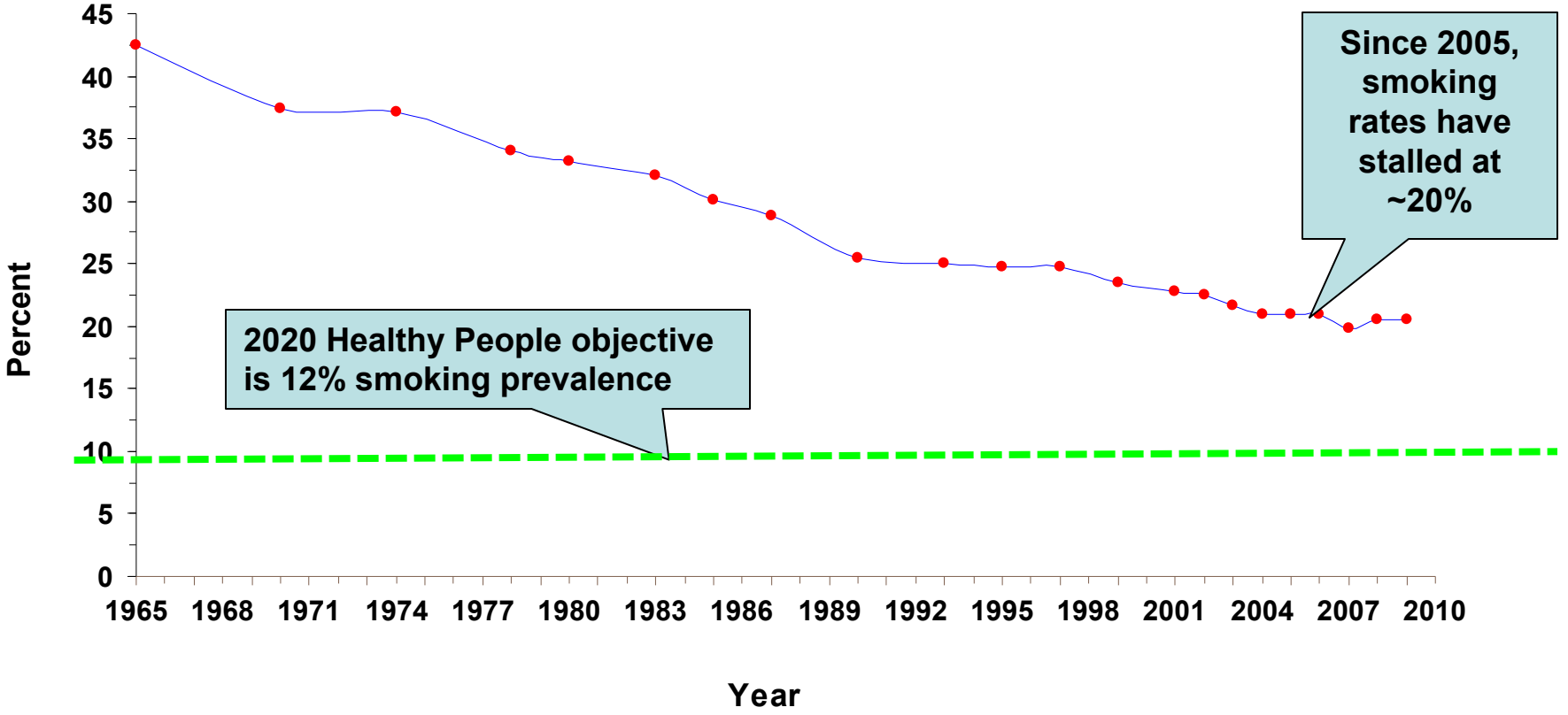
- Leading preventable cause of death in the United States
- Approximately 443,000 deaths yearly from cigarettes; 8.6 million smokers have at least one serious illness due to smoking
- $193 billion annual in lost productivity and medical costs attributed to tobacco use
- After decades of progress, adult smoking rates have stalled
  - Since 2005, smoking rates have stalled at ~ 20%
- More worrisome, the decline in youth tobacco use has slowed
  - 26% 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

Cigarette Smoking* Trends Among 9th-12th Graders, U.S., 1991-2009



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

Cigarette Smoking Trends Among Adults, U.S., 1965 -2009



Adults who were current cigarette smokers, National Health Interview Surveys, 1965-2009.

Tobacco Use Among American Indians and Alaska Natives

- Although smoking rates can differ sharply from tribe to tribe, approximately 23% of American Indian and Alaska Native adults are smokers.
  - Second highest prevalence after adults who reported being of multiple races.
- In 2009, the prevalence of smoking among American Indian and Alaska Native youth, ages 12-17, was 21%; higher than rates among youth of all other races/ethnicities.*
- In 2008, a higher percentage of American Indians and Alaska Natives adults used smokeless tobacco (5.7%) compared with adults in all other races/ethnic groups.**
- In 2009, smokeless tobacco use prevalence among youth, ages 12-17, was higher for American Indian and Alaska Native youth (5.5%) compared with youth of all other races/ethnicities.**
- Tobacco use causes heart disease and cancer, the two leading causes of death among American Indian and Alaska Native adults.

CDC MMWR 2010; 59(35);1135-1140; SAMHSA Survey on Drug Use and Health: Detailed Tables on Cigarette and Smokeless Use, 2010; and U.S. HHS The Health Consequences of Smoking: A Report of the Surgeon General 2004.
*Based on use in past year. / **Based on use in past month.

Tribal Tobacco Businesses

- Several tribes are involved in the manufacture, wholesale and retail of tobacco products.
  - For some tribes, growing and selling tobacco is part of tribal culture.
- Tobacco businesses often provide employment to tribal members and their relatives.
- Revenue from tobacco sales is often used to fund tribal health and benefit programs and services.

FDA - What We Do

- FDA is a public health regulatory agency that uses the best available science to promote health by taking appropriate action on the marketing of products regulated by FDA.
- Help the public get accurate, science-based information to protect and improve their health.
- Traditional FDA regulatory standard is ‘safety and effectiveness.’
- A new regulatory standard is used for tobacco products: public health/population health.

FDA's Regulatory Tools

FDA's authority is derived from a set of laws, and FDA routinely issues regulations and guidance documents to explain and enforce those laws:

- The Federal Food, Drug, and Cosmetic Act (FD&C Act) is the primary federal law that governs FDA's work.
- The Tobacco Control Act amends the FD&C Act to give FDA the authority to regulate tobacco products.

FDA's Regulatory Tools (Cont'd)

- FDA implements its authorities through regulations, which have the force of law, and explain what regulated industry must do to comply with the law.
  - FDA uses the best available scientific evidence to develop proposed regulations.
- FDA guidance describes the agency's current thinking on a regulatory issue. Guidance is a generally recommended approach for meeting a legal requirement, but it is *not legally binding* on the public or FDA.

Overview of Regulatory Process

- FDA issues regulations to:
  - Comply with a statutory requirement, sometimes with a specific deadline (e.g., graphic health warnings).
  - Fill in details or gaps where there is a need for legally binding requirements.
- Regulations are usually developed through a "notice and comment rulemaking" process, which is set out in the Administrative Procedure Act.

The Tobacco Control Act

- FDA was granted the authority to regulate the manufacture, distribution and marketing of tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which President Obama signed into law on June 22, 2009.
- Gives FDA authority to regulate tobacco products, which are products made from tobacco intended for human consumption, but not those used for medical treatment of nicotine addiction.
- Recognized FDA as the *"primary Federal regulatory authority with respect to the manufacture, marketing and distribution of tobacco products."*

Tobacco Control Act (Cont'd)

- Provides a broad set of restrictions to reduce youth access and attraction to cigarettes and smokeless tobacco.
- Gives FDA authority to set standards for new tobacco products and those marketed with claims of reduced risk.

Center for Tobacco Products (CTP)

- FDA established the Center for Tobacco Products in August 2009 to:
  - Implement this new regulatory authority; and
  - Work with other federal, state, tribal and territorial authorities to develop effective public health strategies to reduce tobacco-related illness and death nationwide.
- CTP's budget is funded entirely by user fees that are based on the percentage of a tobacco company's market share.

CTP Vision and Mission

Vision:

- To make tobacco-related death and disease part of America's past, not America's future and, by doing so, ensure a healthier life for every family.

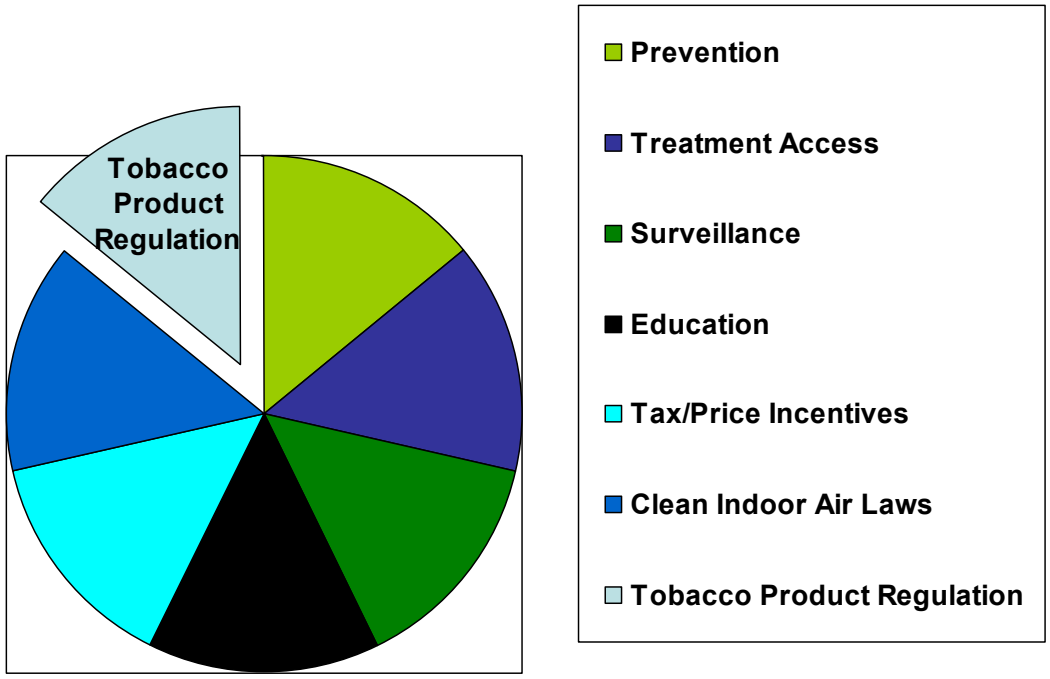
Mission:

- To protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

FDA/CTP Tobacco Control Goals

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

Tobacco Control



Tobacco *Control* Now Includes Tobacco Product *Regulation*

- **Tobacco Control.** Includes many well-established activities in the US: prevention, treatment access, surveillance, education, tax and price incentives, clean indoor air laws.

- **Tobacco Product Regulation.** FDA can now provide new tools to overall tobacco control activities:

  - Advertising of Products
  - Marketing of Products
  - Distribution of Products
  - Manufacturing of Products (setting standards)
  - Public Education and Communication around FDA Product Regulation
  - Training and Enforcement

Compliance and Enforcement

FDA must enforce the provisions of the Tobacco Control Act, including those related to the retail sale of tobacco products, with respect to the United States and Indian tribes. [§102(a)(5)]

"Indian Tribe" has meaning given in the Indian Self Determination and Education Assistance Act.

Compliance and Enforcement – Retail Inspection Program

- FDA issues Request for Proposals (RFPs) to assist with the inspection of retail establishments and other enforcement activities.
  - In fiscal year (FY) 2010, FDA contracted with 15 U.S. States.
  - The FY 2011 RFP solicitation closed on March 1st
    - Still available for informational purposes.
    - A link to the RFP is on our website.

- FDA intends to contract with Indian Tribes and/or tribal organizations, but would first like to work toward establishing relationships with the Tribes and tribal entities.

Regulatory Actions Ahead

March 2011

- TPSAC to issue menthol report/recommendations to FDA
- Manufacturers to submit either substantial equivalence report or pre-market application for all new products

June 2011

- Issue graphic health warnings final rule in *Federal Register*

April 2012

- Establish list of harmful/potentially harmful constituents

September 2012

- Regulations on graphic health warnings go into effect

Outreach and Engagement with American Indian Tribes and Tribal Organizations

- CTP is actively engaging stakeholders in communities interested in, and affected by, tobacco product regulation.
- To date, outreach to American Indian Tribes and Tribal Organizations has included:
  - Multiple meetings with the National Congress of American Indians and the National Native Commercial Tobacco Abuse Prevention Network.
  - Multiple conversations with key Native American public health experts.
  - Establishing a State, Local, Tribal and Territorial Governments Web page.
  - Establishing a Small Business Assistance Office and Web page.

Outreach and Engagement with American Indian Tribes and Tribal Organizations

March 4, 2011 – HHS Consultation

- June 28, 2011 – Gila River Indian Community (outside Phoenix, AZ) Stakeholder meeting

CTP Stakeholder Discussion Series

- CTP launched the Stakeholder Discussion Series to introduce itself and ensure an opportunity for meaningful engagement and dialogue with many of the audiences affected by tobacco product regulation.
- CTP also seeks to benefit from the knowledge, ideas, feedback, and suggestions of each stakeholder group.

State and Local Officials: Oct. 3, 2010 (Atlanta, GA)

Tobacco Manufacturers, Growers, and Warehousers: Dec. 8, 2010 (Raleigh, NC)*

Minority Communities: Feb. 8, 2011 (Oakland, CA)

Public Health Advocates: April 13, 2011 (Chicago, IL)

►American Indians/Alaska Natives: June 28, 2011 (Gila River Indian Community)

Distributors, Importers, Retailers, and Wholesalers: Aug. 24, 2011 (Dallas, TX)

Youth: Sept. 14, 2011 (Boston, MA)

**Included two American Indian Tribal-owned manufacturers*

CTP Stakeholder Discussion Series (Cont'd)

- Each session is moderated by an expert facilitator and focuses on key topics specific to the primary stakeholder community present.
- Invited stakeholders representing various interests participate in each session.
- Additional representatives as well as members of the public were able to observe the meeting at the site as space allowed.
- Those who could not attend in person were able to listen (only) to the meeting via a telephone conference line.

American Indian/Alaska Native Stakeholder Discussion Session

- Specifically, we would like your input on:
  - Possible topics of discussion at the meeting, such as
    - Sovereignty
    - Public health issues
    - Contracting with FDA/CTP for retail inspection
    - Issues related to enforcement and compliance
  - Invitees
    - i.e. Public health/regulatory officials

CTP Organization

Center Director:
Lawrence R. Deyton, M.S.P.H., M.D.

- **Office of Compliance and Enforcement**:
  Director, Ann Simoneau, J.D.
- **Office of Health Communication and Education**:
  Director, Kathleen Crosby
- **Office of Management:**
  Director, Brian Trent, M.P.A.
- **Office of Policy:**
  Director, Eric Lindblom, J.D.
- **Office of Regulations**:
  Director, Beverly Chernaik, J.D.
- **Office of Science**:
  Director, David Ashley, Ph.D.

Contact Us

Via Email:

- General questions and comments:
  - Michelle Jackson at AskCTP@fda.hhs.gov
- Formal correspondence, speech, and meeting requests: ctpexecsec@fda.hhs.gov
- Stakeholder Discussion Series: CTPstakeholderseries@fda.hhs.gov

Via our Call Center: 1-877-287-1373

Via our Ombudsman: les.weinstein@fda.hhs.gov

Contact Us (Cont'd)

To submit comments on proposed rules, dockets, and guidance documents through the public comment process at www.regulations.gov

For more information about the Center and our activities, please check our website –
http://www.fda.gov/TobaccoProducts/default.htm

Follow us on Twitter: @FDATobacco