



Understanding the Tobacco Control Act

An Overview of
the Tobacco Control Act and
Center for Tobacco Products for the
National Native Network

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July 31, 2012

Presentation Overview

- The Tobacco Control Act and FDA
- Center for Tobacco Products (CTP)
- Outreach and Engagement
- Opportunities for Collaboration
- Questions

The Facts

- Tobacco use is the single greatest cause of preventable death in the United States - accounting for more than 440,000 deaths each year.
- Each day in the United States, over 3,800 youth under 18 years of age smoke their first cigarette.
- More than 80 percent of adult smokers begin before age 18.

The Disparities

AI/AN adults are, overall, more likely than any other racial/ethnic subgroup to be current smokers. (CDC 2011)

- 32.4% of AI/AN adults smoke. (CDC 2009)
- AI/AN have the highest prevalence of smoking adults who reported a single race (rates vary geographically). (CDC 2009)
 - lowest rates are in the Southwest (21.2%), and
 - highest rates are in the Northern Plains (44.1%) and Alaska (39.0%).

AI/AN youth are also adversely affected by tobacco abuse. (SAMHSA 2010)

- Prevalence of current smoking among Native youth, ages 12-17, is higher than any other single race at 11.6%.
- Smokeless tobacco abuse among adults and youth in the U.S. is highest among AI/AN.

Health Impacts

- Smoking causes lung cancer and lung cancer is one of the leading causes of AI/AN deaths. (Xu J, et. al. 2010)
- When examining the other causes of death among AI/AN, cardiovascular disease (i.e. heart disease, stroke, etc.) is at the top of the list. (Xu J, et. al. 2010) Commercial tobacco abuse is a major risk factor for cardiovascular disease in the U.S.

FDA gained the authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act, which was passed with bipartisan majorities in the House and Senate and signed into law by President Obama on June 22, 2009.



FDA Authority

Under the Tobacco Control Act

- Grants new authority to regulate tobacco products intended for human consumption (those marketed for use in smoking cessation are already regulated)
- Recognizes FDA as the “primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products”
- Gives FDA direct authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.
 - Enables FDA to deem other tobacco products subject to Chapter 9 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has announced its intent to do so.

Specific Authorities Include:

- Restrictions on youth access to tobacco products
- Advertising and promotion restrictions
- Health warnings on marketed product packages & ads
- Establishing tobacco product standards
- Registration and ingredient listing
- Testing and reporting levels of harmful and potentially harmful constituents
- Authority to conduct research to support tobacco product regulation
- Authority to take enforcement action for TCA violations

Tobacco Control Act

- The Tobacco Control Act does NOT authorize FDA to:
 - Ban certain specified classes of tobacco products
 - Require the reduction of nicotine levels to zero
- FDA is generally NOT involved with:
 - Taxing tobacco products at point of sale
 - Regulating the farming of tobacco leaf

Center
for
Tobacco
Products

CTP – Office of Director

Office of Science

Office of Policy

Office of Health Communication & Education

Office of Compliance and Enforcement

Office of Regulations

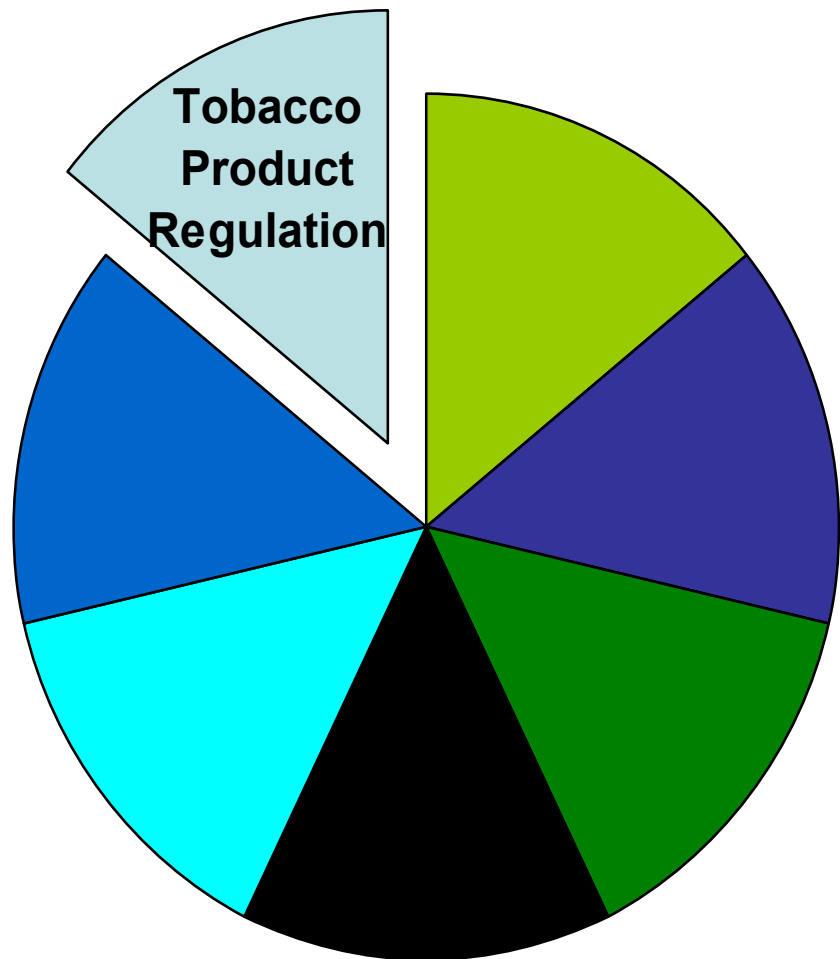
Office of Management





“How does FDA fit into existing Tobacco Control efforts?”

Tobacco Control Now Includes Tobacco Product Regulation



- Prevention
- Treatment Access
- Surveillance
- Education
- Tax/Price Incentives
- Clean Indoor Air Laws
- Tobacco Product Regulation

FDA's Regulatory Tools

FDA's authority is derived from a set of 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 routinely issues regulations and guidance documents to implement and explain these laws.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

- Prohibits sales to people younger than 18
- Prohibits sales of cigarette packs with fewer than 20 cigarettes
- Prohibits distribution of free samples of cigarettes and restricts free samples of smokeless tobacco products
- Prohibits tobacco brand name sponsorship of athletic, musical, or other social events and of teams and entries in those events
- Prohibits the sale or distribution of items, such as hats and tee shirts, that have tobacco brand names, logos, or selling messages
- Prohibits sale of tobacco products in vending machines, self-service displays or other impersonal modes of sale except in very limited circumstances

FDA's Regulatory Tools (Cont'd)

- FDA regulations have the force and effect of law, and create requirements that regulated industry must comply with.
- 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.
- FDA uses the best available scientific evidence in developing its regulations.
- FDA has the authority to issue enforcement actions for violations of the FD&C Act.

CTP's Public Health Goals

- Prevent youth tobacco use
- Reduce product harms
- Encourage those who use tobacco to quit
- Develop a science base and continue meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death

Public Education

- Raise public awareness about FDA regulatory actions
 - Smokeless warnings
 - Graphic health warnings on cigarettes: under litigation
 - List of harmful and potentially harmful constituents
- Educate youth and young adult audiences about the dangers of tobacco products to prevent initiation and encourage cessation
 - Paid media campaigns
 - Cooperative Agreement Program

Outreach and Engagement

- CTP is actively engaging stakeholders in communities interested in and affected by tobacco product regulation through the Stakeholder Discussion Series and other targeted outreach. CTP endeavors to respect the numerous distinct traditions among different tribes.
 - **Stakeholder Discussion Series**
 - State and Local Tobacco Control Officials, Oct. 3, 2010
 - Tobacco Manufacturers and Growers, Dec. 8, 2010
 - Minority Communities and Groups Affected by Tobacco-related Health Disparities, Feb. 8, 2011
 - Public Health Advocates, Jun. 9, 2011
 - **American Indians and Alaska Natives, Jun. 28, 2011**
 - Distributors, Importers, Retailers, and Wholesalers, Aug. 24, 2011
 - Youth, Sep. 13, 2011
 - **HHS Tribal Budget Formulation and Consultation Session, Mar. 4, 2011**

Outreach and Engagement (Cont' d)

- **State, Local, Tribal, and Territorial Governments page**
 - www.fda.gov/TobaccoProducts/ResourcesforYou/StateLocalTribalandTerritorialGovernments/default.htm
- **Utilize Available Resources**
 - National Native Network (NNN)
 - National Indian Health Board
 - National Congress of American Indians
 - Native American public health experts
- **Attendance at conferences hosted by Native American organizations**
 - A Promise National Conference, Inter-Tribal Council of Michigan
 - National Tribal Public Health Summit, National Indian Health Board

Feedback

CTP appreciates and seriously considers the feedback received from all stakeholders. Below are a few of our efforts to address suggestions while we continue to work toward new and improved means to address these issues.

- **CTP should hire someone to support tribal issues**
 - A Tribal Liaison, Gail Cherry-Peppers, was hired this year and CTP continues to seek candidates with experience related to working with American Indians and Alaskan Natives.
- **Provide clear information on the Tobacco Control Act**
 - CTP has had informal discussions with federal entities and tribal organizations on how best to communicate with tribes about the TCA.
 - CTP recently awarded a contract to a tribally owned company to assist in developing protocols and collaborative communication pathways with tribal governments.

Feedback (Cont' d)

- **Improve communications with tribal nations**
 - CTP has been reaching out to tribal organizations for guidance and also attending conferences hosted by Native American organizations to gather and provide information.
- **Acquire and consider data and information regarding health disparities related to American Indian/Alaskan Native populations**
 - CTP held a Stakeholder Discussion Session in 2011 solely focused on American Indian/Alaskan Native tobacco control issues.
 - CTP conducted other Stakeholder Discussion Sessions and an additional Listening Session on disparities that included Native American participants.

Opportunities for Collaboration:

1. Active engagement in FDA rulemaking
2. Amplify CTP communications & education campaigns
3. Stay informed and connected with FDA activities
4. Support Compliance and Enforcement

1. Actively engage in FDA rulemaking

- Disseminate information about – and submit comments regarding:
 - Relevant dockets
 - Public meetings
 - Draft guidances and proposed regulations
- Collect and share evaluation and surveillance data
- Share policy direction and innovation with CTP

2. Amplify CTP Communications

- Visit www.fda.gov/tobacco to stay informed of latest CTP news and announcements
- Share CTP Web content on your website via content syndication – <http://tools.fda.gov>
- Share searchable Tobacco Control Act - www.fda.gov/TobaccoControlAct
- Promote Break the Chain of Tobacco Addiction Retailer Education Campaign materials – www.fda.gov/BreakTheChain
- Pledge to Protect Kids from Tobacco and support responsible retailing – www.fda.gov/BreakTheChain



3. Stay Informed and Connected

- *Connect with Us: This Week in CTP* and other email subscriptions, Twitter, text messages, Idea Forum, widgets – www.fda.gov/tobacco
- Monthly Compliance and Enforcement Webinars
- Mobile applications (*Coming Soon*)
- *Via Email:*
 - CTP Tribal Liaison: Gail.Cherry-Peppers@fda.hhs.gov
 - Consumer questions: AskCTP@fda.hhs.gov
 - Formal correspondence, speech, and meeting requests: ctpexecsec@fda.hhs.gov
- *Via our Call Center:* 1-877-287-1373
- *Via our Ombudsman:* les.weinstein@fda.hhs.gov

4. Support Compliance & Enforcement

- Provisions of the Tobacco Control Act, including those related to the retail sale of tobacco products, also apply to Indian tribes.*
- Tobacco Control Act directs FDA to contract with States, Territories, and Indian tribes, where feasible.
- FDA wants to collaborate with Indian tribes and tribal entities to provide education to their representatives to ensure they understand the provisions of the law.
- FDA hopes to contract with Indian tribes and tribal entities to help ensure compliance.

*“Indian Tribe” has meaning given in the Indian Self Determination and Education Assistance Act.

4. Support Compliance & Enforcement

Report Tobacco-Related Complaints/Violations

- 1.877.CTP.1373 (option #3)
- Email: CTPCompliance@fda.hhs.gov
- USPS Correspondence to CTP
Center for Tobacco Products
Office of Compliance and Enforcement
9200 Corporate Blvd.
Rockville, MD 20850
- Electronic tobacco violations reporting web form and mobile apps in development



“We are committed to protect public health and to make tobacco related disease and death part of America’s past and not its future.”

***-- Kathleen Sebelius
Secretary, Health and Human
Services***



Questions?