



# The FDA and Tobacco: Past, Present and Future

Presentation to the TCN Webinar

June 12, 2013

# Overview of Presentation

- Evolution and Components of FDA Regulation of Tobacco Products
- Immediate Priorities
- Looking Ahead
- Working Together to Make Change Happen

# Evolution of FDA Tobacco Product Regulation

**1996:**

FDA moves to regulate tobacco products.

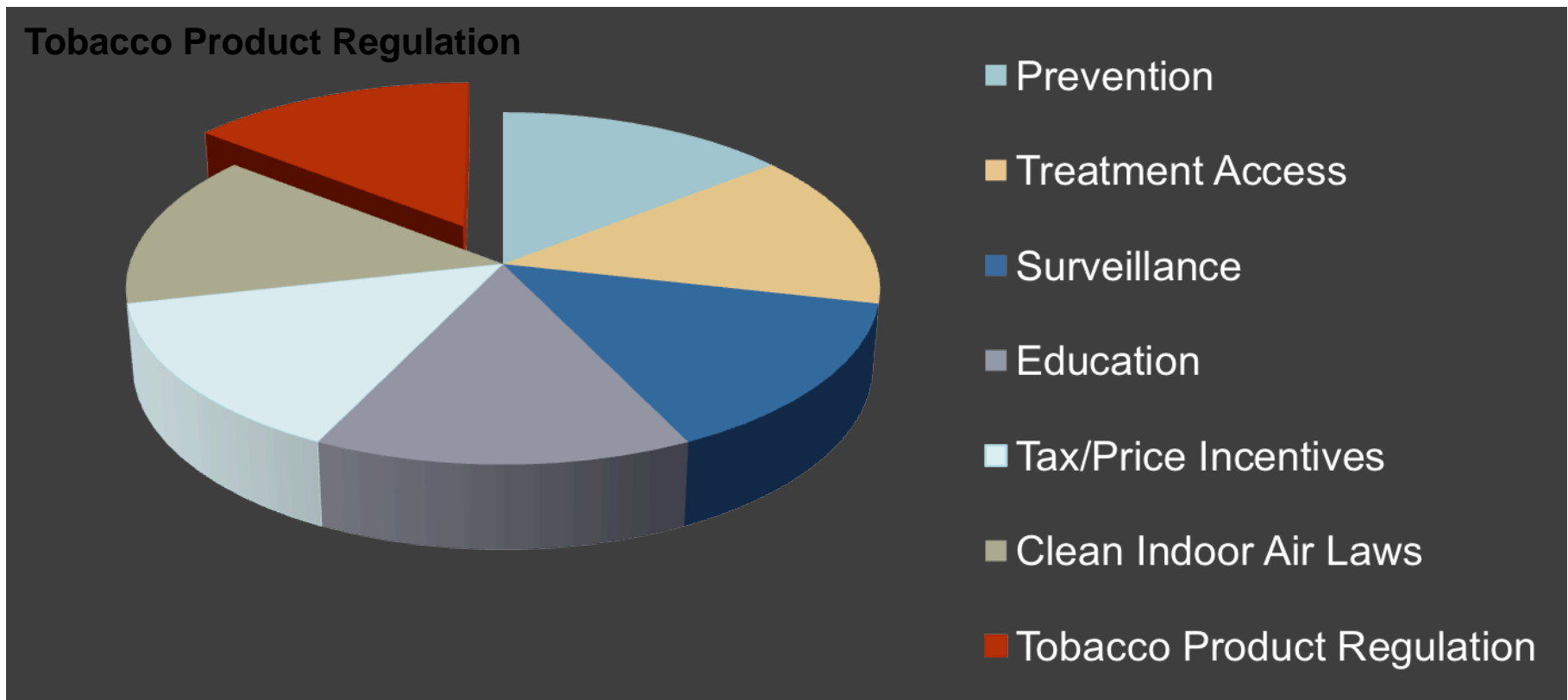


Using its existing authority under the FD&C Act, FDA asserted jurisdiction and began regulation of tobacco products. The effort was overturned by the Supreme Court in 2000.



**2009:**  
The Family Smoking Prevention and Tobacco Control Act, providing FDA with broad authority to regulate tobacco products, is signed into law by President Obama on June 22, 2009.

# Tobacco Product Regulation and Tobacco Control



# Tobacco Product Regulation

## Public Health Goals

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

# Tobacco Product Regulation Population Health Standard

- Tobacco products cannot be regulated using FDA's traditional "safe and effective" standard
- The Tobacco Control Act mandates tobacco product regulation using a population health standard that takes into account both users and non-users of tobacco products
  - It comes down to the "net" population-level health impacts

# Tobacco Product Regulation

## FDA Specific Authorities

- Tobacco manufacturer registration with FDA
- Listing of products and ingredients
- Reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Establishing tobacco product standards
- Premarket applications for new and modified risk tobacco products to protect the public health
- Health warnings on labels and in advertising
- Advertising and promotion restrictions
- Authority to conduct public health education and research to support tobacco product regulation

# Tobacco Product Regulation

## FDA Specific Authorities

### **FDA is Using its Authority to:**

1. Understand the regulated products
2. Control product changes that affect public health
3. Ensure the validity of any product claims that state/imply reduced exposure or risk
4. Restrict marketing and distribution to protect public health
5. Decrease harms of tobacco products
6. Ensure industry compliance with FDA regulation
7. Educate the public about FDA's regulatory actions
8. Expand the science base for regulatory action and evaluation

# FDA's Federal Partners

- To carry out its mandate, FDA works closely with sister agencies throughout the Department of Health and Human Services and the federal government
- Our principal partners include CDC, SAMHSA, NCI, NIDA and other NIH institutes

# FDA and CDC

- Complementary missions
- CDC's unique TC coordinating role
- FDA's regulatory focus
- A 20-year history of collaboration



FDA Regulation of Tobacco Products:

# **IMMEDIATE PRIORITIES**

# FDA Immediate Priorities

- Substantial Equivalence
- Menthol
- Deeming
- Enforcement Contracts

# Substantial Equivalence

- Pending applications
  - Provisional
  - Regular
  
- Now close to announcing first science-based decisions

# Menthol

- Reviewed by TPSAC
- Getting closer to announcing what action we will take, but can't yet publicly discuss the details
- Any action we take will ensure an opportunity for the public health community and other stakeholders to provide input

# Deeming

- As enacted in 2009, the law gave FDA direct authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
- It enables FDA to assert jurisdiction over other products that meet the statutory definition of a tobacco product
- We can only do this through rulemaking
  - That's what the "deeming" rule will do
- FDA is currently drafting plans to broaden the scope of its regulatory program to encompass other products





FDA Regulation of Tobacco Products

# LOOKING AHEAD

# Future FDA Priorities

- Expand Youth Education Efforts via Mass Media Campaign
- Building FDA's Science Base for Tobacco Product Regulation
- Product Standards
- Comprehensive Nicotine Regulatory Policy

# Expanding Youth Education

- Media campaigns aimed at vulnerable, at risk 12 to 17 year olds
- Campaigns targeting general market, multi-cultural, LGBT and rural youth
- Alignment with TIPS campaign

# Building the Science Base for Tobacco Product Regulation

- Investing in laboratory science at FDA, NCTR and CDC
- Continued support for PATH
- Collaboration with CDC on NATS and NYTS
- Creating new research centers for regulatory science

# Product Standards

- The power of product standards
- Exploring potential product standards to reduce addictiveness, product toxicity and appeal
- Investing in research to support potential product standards

# Comprehensive Nicotine Regulatory Policy

- Hypothetical pack-a-day smoker
- Individual-level risk versus population-level harm
- Continuum of harm linked to different nicotine-delivering products
- Regulatory opportunity for FDA

# Modified Risk Tobacco Products (MRTP)

- The Family Smoking Prevention and Tobacco Control Act empowers FDA to issue orders for claims to reduce exposure and harm
- Issues related to MRTP are complex



FDA Regulation of Tobacco Products

# **WORKING TOGETHER TO MAKE CHANGE HAPPEN**

# Opportunities for Participation and Collaboration

- Actively engage in FDA rulemaking
- Support compliance and enforcement by reporting potential violations
  - Potential Tobacco Product Violations Report
- Evaluate opportunities for new policies at state/local level in aftermath of preemption being lifted in FSPTCA...you are the laboratories of tobacco control
- You are the eyes and ears of national TC...let us know about new tobacco product marketing initiatives

# Opportunities for Participation and Collaboration

- Listening sessions
  - Share your ideas; share your concerns
- Participate in TPSAC and other public gatherings
- Brainstorm other ways for FDA to work with you

## In Closing ...

- Product regulation is a recent addition to comprehensive tobacco control efforts
  - And we are still “standing up” CTP
- Regulation offers great promise to help reduce the death and disease toll from tobacco use
- We are a regulatory agency and operate under a different and sometimes more restrictive set of rules when it comes to sharing non-public information

## In Closing ...

- But even under those parameters we have an extraordinary opportunity to work together to tackle the leading, preventable cause of death and disease in our country
- A more personal observation in closing

# Resources for You

- Tools to Understand the Act
  - <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm>
- How to Comment
  - <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM314421.pdf>
- Comment Opportunities
  - <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm198169.htm>
- NIH Tobacco Regulatory Science Program (including CTP's Research Priorities)
  - <http://prevention.nih.gov/tobacco/>

# Resources for You (2)

- General CTP Information you can use and share
  - <http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm237760.htm>
- List of State Agencies awarded Tobacco Retailer Inspection Contracts
  - <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm228914.htm>
- Searchable Database of Compliance Check Inspections of Tobacco Retailers
  - [http://www.accessdata.fda.gov/scripts/oce/inspections/oce\\_insp\\_searching.cfm](http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm)
- How to Report Potential Violations
  - <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm>

# Resources for You (3)

- Public Health Liaison Branch:  
[ashley.ross@fda.hhs.gov](mailto:ashley.ross@fda.hhs.gov)
- Consumer Questions:  
[AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov) or 1-877-287-1373
- Formal correspondence, and speech and meeting requests:  
[ctpexecsec@fda.hhs.gov](mailto:ctpexecsec@fda.hhs.gov)
- CTP Ombudsman:  
[les.weinstein@fda.hhs.gov](mailto:les.weinstein@fda.hhs.gov)



## Center for Tobacco Products

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