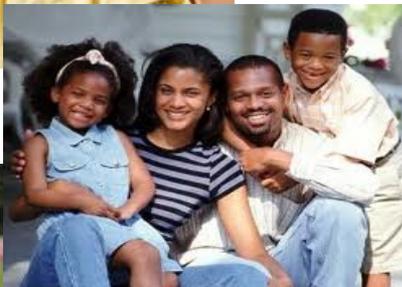




FDA's Action Agenda to Reduce Tobacco Related-Cancer Incidence and Mortality

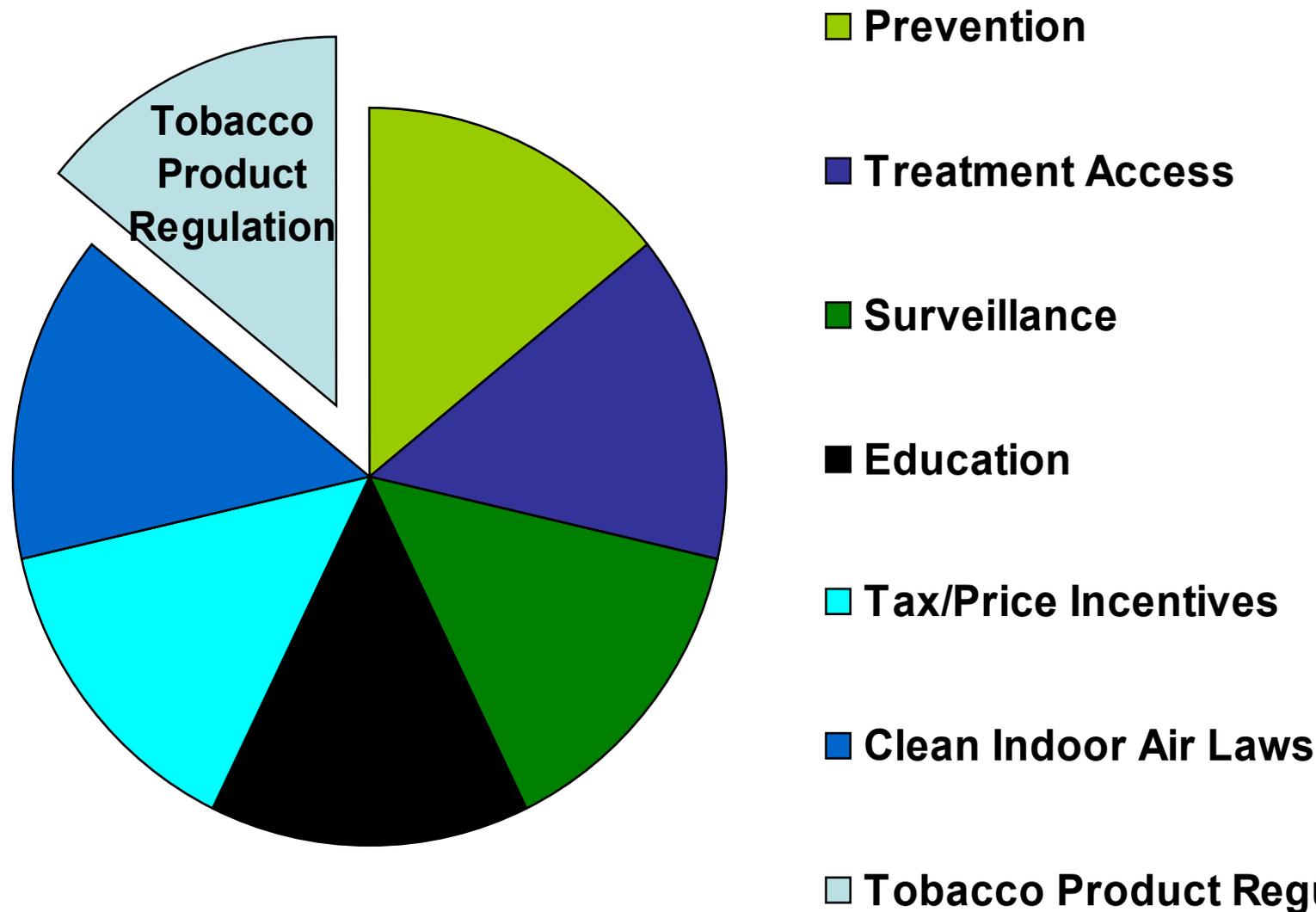
Lawrence Deyton, M.S.P.H., M.D.
Director, FDA Center for Tobacco Products
June 11, 2012



FDA's 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.

Tobacco Control Now Includes Tobacco Product Regulation



FDA Authority

Under the Tobacco Control Act

- Grants authority to regulate tobacco products intended for human consumption (products marketed for use in smoking cessation regulated by another FDA Center)
- 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 assert jurisdiction over other tobacco products through rulemaking (cigars, pipe tobacco, hookah, e-cigarettes that do not contain drug claims, etc.). FDA has announced its intent to do that.

Specific Authorities Include:

- Premarket applications for new and modified risk tobacco products
- Testing and reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Establishing tobacco product standards
- Health warnings on marketed products & ads
- Advertising and promotion restrictions
- Registration and listing of ingredients
- Authority to conduct research to support tobacco product regulation

FDA TOBACCO PRODUCT REGULATION

September 2009



Banned flavored cigarettes making them less appealing to kids

March 2010



Restricted youth access to tobacco products

June 2010



Banned misleading advertising claims to communicate products are not safer

June 2010



Established new smokeless tobacco warnings to communicate health risks

June 2011



Issued new cigarette health warnings to highlight product dangers

March 2012



Established list of harmful and potentially harmful constituents

March 2012



Issued draft guidance on submitting a Modified Risk Tobacco Product Application

Tobacco Control Act -- Limitations

FDA is not authorized to:

- Set nicotine levels to zero
- Ban some classes of tobacco products
- Require prescriptions for tobacco products
- Tax tobacco products
- Regulate medications and products marketed to treat tobacco dependence through the Center for Tobacco Products [Note: FDA already regulates cessation medications and products through CDER]
- Regulate clean indoor air policies
- Regulate tobacco growing

Four Key Elements of FDA's Framework for Tobacco Product Regulation

1. Developing the science base for regulatory action & evaluation
2. Decreasing population harm from tobacco products
3. Ensuring industry compliance with regulations
4. Public education related to FDA authorities

Developing the Science Base for Regulatory Action & Evaluation

- Population Assessment of Tobacco and Health (PATH) study
 - National, longitudinal study of both users and those at risk of using tobacco products
- Development of more rugged methods for determining harmful and potentially harmful constituents
- Addiction research
- Research into toxicity and carcinogenicity of tobacco products

Decreasing Population Harm from Tobacco Products

- Cigarette flavor ban
 - Cigarettes cannot have characterizing flavors (except menthol).
- Deeming regulation
 - FDA has announced its intent to expand jurisdiction to include all tobacco products.
- Products standards
 - No statutory deadline
 - FDA can issue standards appropriate for the protection of public health including to make regulated products less addictive and/or less harmful.

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

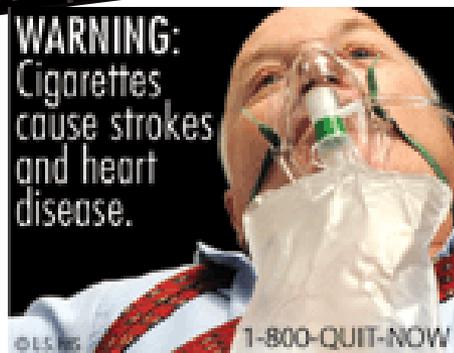
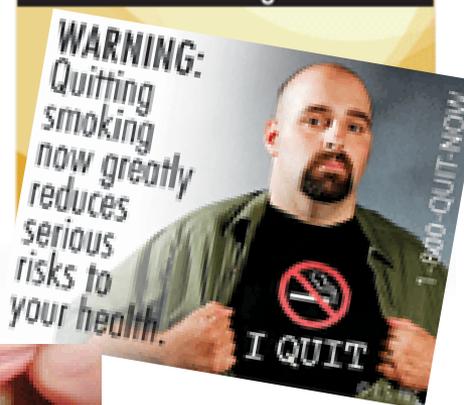
Ensuring Industry Compliance With Regulations

- Tobacco retailer inspection now in 37 states and DC; expanding to all states & territories
 - As of 5/15/12, over 63,000 inspections of tobacco product retailers conducted, resulting in more than 2,600 warning letters and more than 140 fines
- Manufacturer inspections every two years
- Tobacco Product Manufacturing Practices
 - Regulations will be developed
- Health document submission requirements

Public Education

- Public education campaigns related to statutory authorities and regulatory actions
 - 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

New Graphic Health Warnings



Connecting With CTP

- **Stay informed of FDA research and other activities:**
 - <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm>
- **Potential Violations of the Act:**
 - CTPCompliance@fda.hhs.gov
- **Consumer Questions:**
 - AskCTP@fda.hhs.gov
 - 1-877-287-1373
- **Formal correspondence, and speech and meeting requests:**
 - ctpexecsec@fda.hhs.gov
- **CTP Ombudsman:**
 - les.weinstein@fda.hhs.gov