Tobacco Control Regulatory Science: Understanding the Family Smoking Prevention and Tobacco Control Act

NIH Council of Councils
September 5, 2012

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FDA/CTP Public Health Goals

- Prevent Americans—especially youth—from starting to use tobacco
- Encourage current users to quit
- Decrease the harms of tobacco product use

CTP Uses a Public Health/Population Health Regulatory Standard

- Tobacco products cannot be regulated using FDA's traditional "safe and effective" standard
- The Tobacco Control Act mandates its regulation using a population health standard taking into account both users and non-users of tobacco products

FDA Authority Under the Tobacco Control Act

- Gives FDA direct authority over cigarettes, roll-your-own and smokeless tobacco products
- "Tobacco product" is defined any product made or derived from tobacco that is intended for human consumption, including any component part, or accessory of a tobacco product
- FDA announced that it will propose a rule deeming products that meets the definition of a "tobacco product" to be subject to FDA's jurisdiction
- CTP funded solely via "user fees" from tobacco company assessments - $505 million for FY13
  - caps at $712 million in FY19

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
- Tobacco product standards
- Health warnings on cigarettes and smokeless tobacco products & ads
- Advertising and promotion restrictions
- Industry registration and listing of ingredients
- FDA has authority to conduct research to support tobacco product regulation

Tobacco Control Act -- Limitations

In general, CTP's regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine levels to zero

Key Accomplishments to Date

- Banned flavored cigarettes
- Required industry registration and product listing
- Required industry submission of ingredient listing
- Restricted access and marketing of cigarettes and smokeless tobacco products to youth
- Prohibited misleading marketing terms (“Light,” “Low,” and “Mild”) for tobacco

Key Accomplishments (cont'd)

- Required larger warning labels for smokeless tobacco products
- Issued guidance for new product applications and for new products that are substantially equivalent based on the public health standard
- Requiring graphic cigarette health warnings on cigarette packages and advertisements
  - Under litigation

Pathways to Market

New Products: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm273388.htm

Would permitting such a product to be marketed be appropriate for the protection of public health?

- **Full reports of investigations of health risks**
- **All components, ingredients, additives, properties, and principles of operation**
- **Methods of manufacturing and processing**
- **Compliance with tobacco product standards**
- **Product samples and components**
- **Proposed labeling**
- **Product chemistry**
- **Nonclinical studies**
- **Studies in adult human subjects**

Pathways to Market

Substantial Equivalence: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf

Does the new product have the same characteristics as a predicate or do the changes raise new questions of public health?

- Design Features
- Ingredients
- Materials
- Heating Source
- Composition
- Other Features: Harmful/Potentially Harmful Constituents

- Additional Data
  - Consumer perception
  - Abuse liability
  - Toxicology

Pathways to Market

Modified Risk Tobacco Products:

Would marketing of such a product significantly reduce harm and the risk of tobacco-related disease and benefit the health of the population as a whole?

Statutory Requirements:

- **Description of the product and any proposed labeling and advertising**
- **Conditions for using the product**
- **Formulation of the product**
- **Sample product labels and labeling**
- **All documents related to research findings**
- **Data and information on how consumers actually use the product**

Tobacco Product Standards

Through rulemaking, the Tobacco Control Act allows adoption of "…tobacco product standards… appropriate for the protection of public health." Sec 907.

Tobacco Product Standards apply to any regulated product on the market under regulatory authority of FDA and can include provisions for:

- **Nicotine yields**
- **Reduction or elimination of constituents, including smoke constituents**
- **Construction, components, ingredients, additives, constituents, and properties of the tobacco product**
- **Provisions for testing or measuring product characteristics**
- **Restricting sale and distribution**
- **Form and content of labeling for the proper use of the product**

CTP Research Priorities

- Diversity of Tobacco Products
- Reducing Addiction
- Reducing Toxicity and Carcinogenicity
- Adverse Health Consequences
- Communications
- Marketing of Tobacco Products
- Economics and Policies

Research

- FDA/CTP collaborating with Federal agencies:
  - National Institutes of Health
  - Centers for Disease Control and Prevention
  - FDA National Center for Toxicological Research
- FDA/CTP contracting with non-HHS organizations that have particular expertise

NIH-FDA Tobacco Science Workgroup

- Co-Chairs: Bob Croyle, National Cancer Institute and Bopper Deyton, Center for Tobacco Products
- NIH coordination to be within the Office of Disease Prevention
- IDDA – Interdepartmental Delegation of Authority – support grants
- Interagency Agreements, e.g., Population Assessment of Tobacco and Health (PATH) study contract via NIDA

NIH-FDA Tobacco Research Collaborations

- NIH Competitive Revision Applications for Research Relevant to tobacco product regulation (closed Feb. 17)
- Administrative Supplements to NIH-funded Program Projects/Center Grants: Research and Pilot Projects Relevant to tobacco product regulation (closed April 6)
- TCORS - Tobacco Centers of Regulatory Science (P50); (published July 10, 2012)

http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-13-003.html

NIH-FDA Tobacco Research Collaborations

- Tobacco Control Regulatory Research
  - R01, http://grants.nih.gov/grants/guide/pa-files/PAR-12-267.html
  - R03, http://grants.nih.gov/grants/guide/pa-files/PAR-12-268.html
  - R21, http://grants.nih.gov/grants/guide/pa-files/PAR-12-266.html
    (published August 23, 2012)
- Review Criteria for tobacco regulatory science
- Center for Scientific Review – peer review

http://dccps.nci.nih.gov/nih-fda/