Dissolvable Tobacco Products

Tobacco Control Network Webinar
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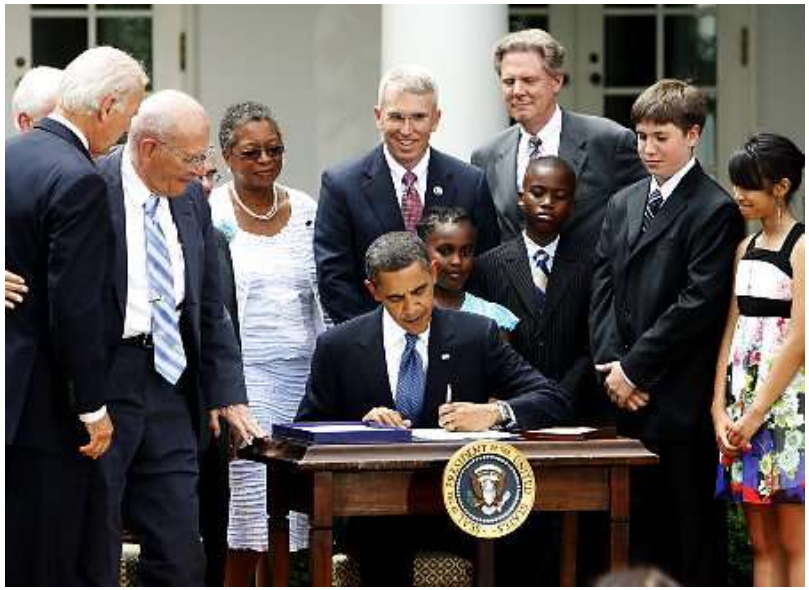
Sarah E. Evans, PhD
Office of Science
Center for Tobacco Products, FDA

Overview of the Family Smoking Prevention and Tobacco Control Act



The Family Smoking Prevention and Tobacco Control Act was signed into law on June 22, 2009 by President Barack Obama.

Scope of FDA's Authority Under the Tobacco Control Act

- The Act gives FDA authority to regulate tobacco products, which are products made or derived from tobacco intended for human consumption.
- Tobacco products do not include drugs or devices which are regulated under different provisions of the Food, Drug, and Cosmetic Act.
- The Act recognized FDA as the “primary Federal regulatory authority with respect to the manufacture, marketing and distribution of tobacco products.”

Tobacco Product

- "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." FD&C Act 201(rr)(1).
- "does not mean a product that is a drug, a device, or a drug-device combination product." FD&C Act 201(rr)(2).

Smokeless Tobacco

- “any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity” (FD&C Act 900(18)).

Dissolvable Tobacco Products

- There is no statutory definition of “dissolvable tobacco product.”
- We believe that many dissolvable tobacco products meet the current statutory definition of “smokeless tobacco.”
- It is possible that some dissolvable tobacco products are not currently regulated under Chapter IX of the Tobacco Control Act.

Charge to the Committee*

- The Tobacco Products Scientific Advisory Committee (TPSAC) is required to review and provide recommendations to FDA regarding the "the nature and the impact of the use of dissolvable tobacco products on the public health, including such use among children."

*Section 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Charge to the Committee*

- TPSAC is to consider:
  - The risks and benefits to the population as a whole, including users and non-users of tobacco products, of the proposed standard;
  - The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
  - The increased or decreased likelihood that those who do not use tobacco products will start using such products.
- TPSAC report and recommendations are due March 23, 2012.

*Sections 907(a)(3)(B) and 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Information Available to FDA

- Published Peer Reviewed Literature
- Submissions to Dockets

Literature search

- As of 7/01/2011, 22 peer reviewed articles regarding dissolvable tobacco products were found using PubMed, Science Citation Index, Social Sciences Citation Index, Google Scholar, PsychInfo and Business Source Corporate.

- Search terms included: dissolvable tobacco, novel, strip, stick, pellet, orb and brand names of products by manufacturers thought to market dissolvable tobacco products.

FDA Request for Public Information

- Impact of Dissolvable Tobacco Use on Public Health; Request for Comments
  - Submissions to Docket FDA-2010-N-0123
  - Published in Federal Register on March 22, 2010
    - http://edocket.access.gpo.gov/2010/pdf/2010-6216.pdf

- Responses Included:
  - Survey Data
  - Industry Comments
  - Health Association/State Government Comments
  - Individual Comments

Information Requested From Industry

- FDA issued letters to ~125 manufacturers on June 10, 2011.
  - http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm259009.htm
- Manufacturers are required to submit documents and information relating to research conducted, supported, or possessed by the manufacturer or its agents relating to specific topics.

Information Required From Industry

- All documents and underlying scientific information relating to research and research findings on the following topics:
  - Marketing research involving the use of dissolvable tobacco products
  - Marketing practices used by tobacco manufacturers and distributors for dissolvable tobacco products
  - The effectiveness of marketing practices used by tobacco manufacturers and distributors.
  - The health effects of dissolvable tobacco products
  - The toxicological effects of dissolvable tobacco products
  - The behavioral effects of dissolvable tobacco products
  - The physiologic effects of dissolvable tobacco products

Information Requested From Industry

- FDA requested voluntary submission of additional information, as applicable, to provide context and background for TPSAC.
  - A complete description of the composition and design of each dissolvable tobacco product.
  - A brief summary of the process, criteria, and considerations utilized in selecting the form (e.g. size, color, shape), flavoring, and sugar content of each dissolvable tobacco product.
  - Marketing research on the use of dissolvable tobacco products, e.g. by age, type of prior tobacco use (if any), and by interest in quitting cigarette smoking or traditional smokeless tobacco use. Includes consumer perceptions of taste, impact, nicotine strength, and product harm.
  - Marketing practices and the effectiveness of marketing practices (e.g. by age, type of prior tobacco use if any, and by interest in quitting cigarette smoking or traditional smokeless tobacco use)

Information Requested From Industry

- Additional information, continued:
  - FDA also requested manufacturers submit short summaries of:
    - Health effects of dissolvable tobacco products.
    - Toxicological effects of dissolvable tobacco products.
    - Behavioral effects of dissolvable tobacco products among users and non-users of other tobacco products regarding appeal, use, initiation, cessation, switching between cigarettes and dissolvable tobacco products, switching between traditional smokeless and dissolvable tobacco products, and dual use of cigarettes and dissolvable tobacco products. Summarize these results for users of different ages.
    - Physiological effects of dissolvable tobacco products on users and non-users of other tobacco products, including but not limited to chemosensory effects and abuse liability.

Information Requested From Industry

- FDA Information Request
  - Information due to FDA by August 1, 2011.
  - FDA plans to summarize this information and present it at a future TPSAC meeting

State Information of Interest

- The prevalence of dissolvable tobacco product use, including any survey data
- Poisonings or adverse events reports involving dissolvable tobacco products;
- Consumer perceptions of these products
- Marketing strategies used to promote dissolvable tobacco products;
- Educational or awareness campaigns that may have been carried out on a state or local level.

Clarifying Questions?