2015 Science Writers Symposium

The Social Science of Tobacco Use: Research at the Center for Tobacco Products

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September 18, 2015

Implementing the Tobacco Control Act

FDA's Center for Tobacco Products (CTP) has authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless

- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah
  - FDA issued the "Deeming" Proposed Rule, April 25, 2014




Acting to Improve Public Health

- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harms and addictiveness




FDA's Public Health Framework for Tobacco Product Regulation

FDA is using our regulatory authority to:

1. Understand the regulated products
2. Restrict product changes that affect public health
3. Prohibit modified risk claims that state/imply reduced risk without an order
4. Decrease harms of tobacco products
5. Expand the science base for regulatory action and evaluation
6. Restrict marketing and distribution to protect public health
7. Ensure industry compliance with FDA regulation through education, inspections, and enforcement
8. Educate the public about FDA's regulatory actions

Deeming Authority

The statute gave FDA direct authority to regulate cigarettes, roll-your own, and smokeless tobacco.

FDA has proposed a rule deeming authority over products that meet the statutory definition of a tobacco product (e.g., e-cigarettes, hookah (waterpipe), cigars).

Once final, FDA will have regulatory authority over those products, which could include:

- Premarket review
- Product standards
- Restrictions on marketing

Population Health Standards

We assess tobacco products and regulations using various standards we loosely call “population health standards”:

- Consider impacts of actions on users and non-users of tobacco products;

- In general, this includes an assessment of impacts on the likelihood of initiation of tobacco use among non-users, and likelihood of cessation among current users.

Regulatory Science

Product regulation may be strengthened by regulatory science to inform FDA's assessment of the likelihood that consumers will adopt a product, initiate use of tobacco products, or cease use of tobacco products:

- What are the impacts of various product characteristics on likelihood of initiation or cessation, and patterns of tobacco use?
- What are the impacts of various forms of marketing on tobacco use (particularly initiation)?
- What are the best methods for assessing the likely impacts on initiation, cessation and patterns of tobacco use?
- What are the relationships between perceptions and knowledge on tobacco products with future behavior and patterns of use?

FDA Research

With respect to product regulation, FDA has been conducting research to understand the impacts of marketing of tobacco products on consumer perceptions, beliefs and behaviors related tobacco use:

- New and emerging tobacco products
  - E-cigarettes, hookah
- Modified risk tobacco products
  - Impacts of claims
  - Methodology for assessing impacts
- Provision of information on the risks of tobacco products
  - Health warnings
  - Harmful and potentially harmful constituents

Funding Opportunities

https://prevention.nih.gov/tobacco-regulatory-science-program

THANK YOU