

Center for Tobacco Products Research

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FDA Authority Under the Tobacco Control Act

- Gives FDA direct authority over manufacture, marketing, and distribution of cigarettes, roll-your-own and smokeless tobacco products
- 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
- The Tobacco Control Act mandates its regulation using a population health standard taking into account both users and non-users of tobacco products



Research to Inform CTP's Regulatory Authorities

- Preventing youth access
- Advertising restrictions
- Information dissemination, e.g., health warnings, harmful and potentially harmful constituents
- Public education campaigns
- Product standards
- New and modified risk tobacco products



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



Tobacco Science Regulatory Decision Making



The science of tobacco products, individual health, and population health informs FDA's regulatory actions

- **Product**
 - Chemistry
 - Engineering
 - Microbiology
- **Tobacco User**
 - Toxicology, pharmacology
 - Environmental impact
 - Clinical medicine
 - Behavior, use, addiction
- **Population**
 - Epidemiology
 - Social science
 - Statistics, modeling



CTP Research and HINTS

- FDA Cycle – data collection in 2014
- Public Release – 4-6 months after end of data collection
- New questions to communications core:
 - Information seeking about tobacco products
 - Trust and credibility of sources of tobacco information
 - Awareness of different types of tobacco products
 - Perceptions of contents of tobacco products, including harmful chemicals and nicotine
 - Awareness of contents of tobacco products, exposure to communications emphasizing that information, interesting in seeing that information
 - Beliefs about cigarette claims



Funding Opportunities

- RFAs for R01 (research grants), R21 (exploratory/developmental), R03 (small)
 - Applications received twice a year
 - next due date – January 15, 2014
- Relevant topic areas –
 - Perceptions of tobacco products – cigars, smokeless tobacco, e-cigarettes, hookah, pipes, dissolvables
 - Perceptions of tobacco product labeling and marketing
 - Communications regarding harmful and potentially harmful constituents in tobacco products and risks of tobacco products



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Tobacco Regulatory

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Tobacco Regulatory Science Program (TRSP)

Located in the NIH Office of Disease Prevention (ODP), the Tobacco Regulatory Science Program (TRSP) coordinates the trans-NIH collaborative effort with the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) to conduct research to support its regulatory activities over tobacco products.

With the passage of the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the FDA acquired the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health. Within the framework of the Tobacco Control Act, the NIH and FDA formed an interagency partnership to foster tobacco regulatory research. The NIH has the infrastructure for the solicitation, review, and management of research, and several NIH Institutes and Centers have long supported tobacco-related research as part of their missions. The FDA has expertise in tobacco regulatory science and the authority and resources to support research responsive to FDA's regulatory authority. NIH biomedical, behavioral and social sciences research supported via funding from FDA will provide the scientific evidence needed to better inform FDA's regulatory authorities.

About the FSPTCA
Provisions of the Law and Center for Tobacco Products Information

Research Priorities
Research topic areas and projects

Research Portfolio
NIH-FDA Grants and contracts

Funding Opportunities
Current funding announcements and application instructions

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Publications, statistics, and other references

What's New

Tobacco Control Regulatory Research

- RFA-OD-13-013 (K08)
- RFA-OD-13-014 (K01)
- RFA-OD-13-015 (K22)
- RFA-OD-13-016 (K99/R00)
- Frequently Asked Questions (PDF - 205KB)

Tobacco Regulatory Research Mechanism Comparison Table (PDF - 87KB)

Tobacco Regulatory Science Career Awards Webinar – July 30, 2013

- RFA-OD-13-010 (R21)
- RFA-OD-13-011 (R01)
- RFA-OD-13-012 (R03)
- Frequently Asked Questions (PDF - 355KB)

FDA Invites Public Input on Menthol in Cigarettes – 07/23/2013

Questions?
Contact the TRSP

The Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act.

E-mail Updates from the