FDA CENTER FOR TOBACCO PRODUCTS AND ITS TOBACCO REGULATORY SCIENCE PROGRAM

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Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.
• Since 2009, CTP had 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
• On August 8, 2016 regulation went into effect that “deems” all products meeting the statutory definition of tobacco product, including components or parts (but excluding accessories), to be subject to FDA’s tobacco product authorities, including:
  – ENDS (e-cigarettes, e-cigars, vape pens, etc.)
  – All cigars
  – Pipe tobacco
  – Nicotine gels
  – Waterpipe (hookah)
  – Dissolvables not already under the FDA’s authority
  – Future tobacco products
The Tobacco Control Act mandates tobacco product regulation using a population health standard that takes into account both users and non-users of tobacco products.
ELEMENTS OF THE FDA’S PUBLIC HEALTH FRAMEWORK FOR TOBACCO

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

**WHAT IS TOBACCO REGULATORY SCIENCE?**

*Scientific inquiry specifically to inform potential regulatory decisions and actions to protect the public’s health*

TOBACCO REGULATORY SCIENCE

- Tobacco regulatory science involves the application of the best available science to specific regulatory questions.

- Tobacco regulatory research translates general scientific knowledge into the specific scientific findings which serve as actionable information for regulatory decisions and actions.

- To do this, tobacco regulatory science evaluates distinct situations to determine the effect on public health.
THE SCIENCE OF TOBACCO REGULATION

- **Product**
  - Chemistry
  - Engineering
  - Microbiology

- **Tobacco Product User**
  - Toxicology
  - Pharmacology
  - Clinical medicine
  - Addiction
  - Product use behavior

- **Population as a Whole**
  - Environmental assessment
  - Epidemiology
  - Consumer perception
  - Statistical analysis
  - Evaluation
CTP FUNDED PROJECTS
CTP PRIORITY RESEARCH AREAS

- Addiction
- Chemistry and Engineering
- Knowledge, Attitudes, and Behaviors
- Toxicity and carcinogenicity
- Health consequences
- Communication
- Marketing
- Economics and policy
CTP RESEARCH PROGRAM

CTP funds research through collaboration with Federal agencies & contracts with non-HHS organizations that have particular expertise
ACTIVE CTP PROJECTS BY FISCAL YEAR

Note that a project maybe be active in multiple fiscal years.
CTP FUNDED PROJECTS BY RESEARCH CATEGORY
FISCAL YEARS 2010-2015

Research categories are not mutually exclusive
COMPANION FUNDING ANNOUNCEMENT
TOBACCO CENTERS OF REGULATORY SCIENCE (TCORS)

**Overall Objective**

Conduct multidisciplinary research that will inform FDA’s regulatory actions related to the manufacture, distribution, and marketing of tobacco products

**Essential Elements**

- Three hypothesis drive Research Projects with a scientific Integrated Theme
- Administrative Core that includes funds for Rapid Response Projects
- Career Enhancement Core to provide exposure and experience in tobacco regulatory science

Companion Funding Opportunity: RFA-OD-17-006, U54
THANK YOU