RESEARCH THAT INFORMS FDA'S CENTER FOR TOBACCO PRODUCTS

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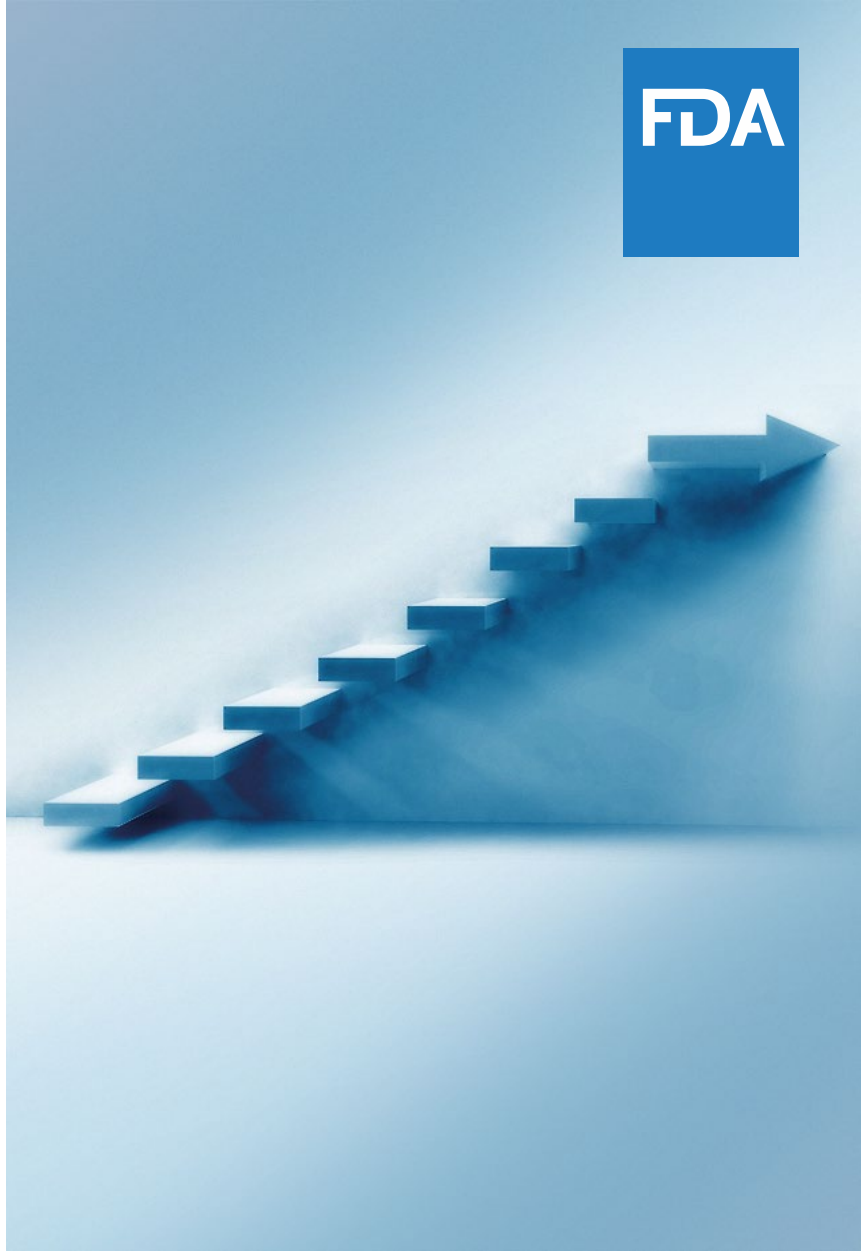

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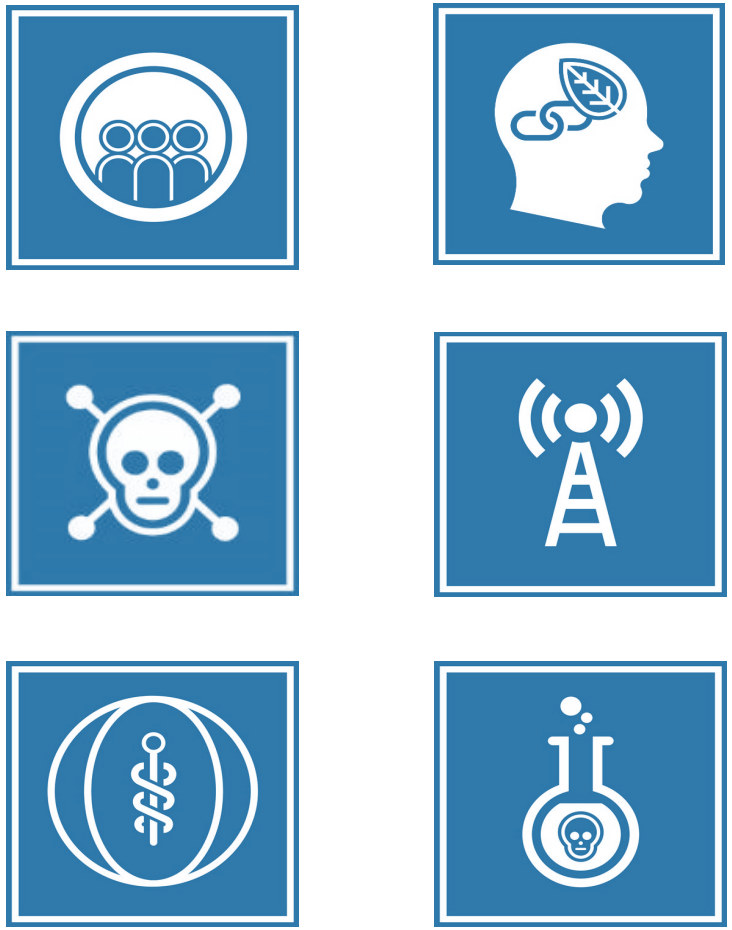
To conduct programs of multidisciplinary research that will inform the manufacture, distribution, and marketing of tobacco products related to the regulatory authority of FDA CTP.

SCIENTIFIC DOMAINS

- **TCORS Scientific Domains**
  - Addiction
  - Behavior
  - Product Composition and Design
  - Communications
  - Health Effects
  - Impact Analysis
  - Marketing Influences
  - Toxicity



https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-004.html

FOR THIS FUNDING OPPORTUNITY ANNOUNCEMENT

- The term "characteristic" encompasses materials, ingredients (including additives, nicotine formulations, and flavors), design, composition, heating source, and other features of a tobacco product, including harmful and potentially harmful constituents.

- Product characteristics can be incorporated into all the previous topics

FDA Center for Tobacco Products

CTP'S PUBLIC HEALTH GOALS

Our goal is to **reduce the harm from tobacco products across the entire population**, including:

- Reducing the number of people who start to use tobacco products
- Encouraging more people to stop using tobacco products
- Reducing the adverse health impact for those who continue to use tobacco products

VULNERABLE POPULATIONS

- FDA encourages research studies to include, where appropriate to the research question, vulnerable populations, including (but not limited to):
  - youth and young adults
  - those from lower socioeconomic backgrounds (e.g., those with lower household incomes or lower educational attainment)
  - racial or ethnic minorities
  - sexual and/or gender minorities
  - rural populations
  - those pregnant or trying to become pregnant
  - active-duty military or veterans
  - those who are or have been incarcerated
  - those with mental health conditions or substance use disorders

REGULATORY SCOPE

- Since June 2009, CTP has had authority to regulate tobacco products intended for human consumption to reduce harm across the population
  - Immediate authority to regulate the manufacture, marketing, and distribution of **cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco**

- Effective August 2016, an FDA rule "deemed" **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

EXPANDING THE DEFINITION

- An omnibus spending bill signed by the President on March 15, 2022, expanded the definition of an FDA-regulated tobacco product
- The bill includes language amending the Tobacco Control Act to bring synthetic nicotine under FDA's tobacco authorities
- This change becomes effective 30 days after the bill is signed into law

NOT WITHIN CTP AUTHORITY

- 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 (regulated by other parts of FDA)
  - Setting clean indoor air policies
  - Regulating tobacco growing
  - Requiring the reduction of nicotine yields to zero
  - Providing cessation services
  - Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products

CTP'S KEY STRATEGIC PRIORITIES

1. **Product Standards**
2. **Comprehensive FDA Nicotine Regulatory Policy**
3. **Pre & Post-Market Controls: Regulations & Product Reviews**
4. **Compliance and Enforcement**
5. **Public Education**

https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctps-key-strategic-priorities

PRODUCT STANDARDS

PRODUCT STANDARDS

- A product standard is a rule that sets requirements for how tobacco products are **manufactured, distributed, sold, or offered for distribution or sale in the United States**

- FDA is on track to issue **proposed product standards** next month that would:
  – prohibit menthol as a characterizing flavor in cigarettes
  – prohibit all characterizing flavors, except tobacco, in cigars

PROPOSED PRODUCT STANDARDS

- FDA may issue product standards addressing toxicity, appeal, and/or addiction
- FDA's must consider if a product standard is **appropriate for the protection of the public health**
- This means we have to assess the **risks and benefits to the population as a whole**, including:
  - Users and nonusers of the product under review
  - Whether people who currently use any tobacco product would stop
  - Whether nonusers would start

RESEARCH THAT MAY INFORM PRODUCT STANDARDS

- Studies conducted to estimate the range of potential impacts on behavior and health of potential FDA regulatory actions, for example:
  - Surveys
  - Behavioral economics experiments
  - Population-based modeling
  - State, local, or national policy evaluations
- Evaluations of the differential impact and/or possible unintended consequences of tobacco regulatory actions among specific populations
  - addressing how such actions may affect vulnerable populations

PRE & POST-MARKET CONTROLS: REGULATIONS & PRODUCT REVIEWS

PRODUCT REVIEW

- Includes:
  - Investigational tobacco products
  - New product review
  - Substantial equivalence (SE)
  - Exemption from SE
  - Modified risk tobacco products

- Applicant must provide adequate evidence for FDA to make a finding

- FDA uses scientific research to evaluate the evidence provided by the applicant

POSTMARKET

- Authority to market is contingent upon the conditions described in the respective order letters, including:
  - Postmarket recordkeeping and retention requirements
  - Annual postmarket reporting to FDA
  - Specific marketing restrictions related to advertising, sales, and product packaging/labeling

- FDA will **withdraw a marketing order** if it determines that the continued marketing of a product is no longer appropriate for the protection of the public health, for example, as a result of **significant uptake of the product by youth**

RESEARCH THAT MAY INFORM PRODUCT REVIEW

Research that informs product review supports FDA's assessment of the evidence provided in a product application

- Toxicity models that evaluated exposure based on how a product is intended to be used.
- Understanding how use of multiple tobacco products alter health risk
- Impact of flavors on product abuse liability
- Development of biomarkers to assess exposure across patterns of use behavior and route of exposure.
- Impact of tobacco product characteristics on disease risk and human health
- Product design impact on tobacco use preferences and behaviors among youth, young adults, and adults

COMPLIANCE AND ENFORCEMENT

COMPLIANCE AND ENFORCEMENT

FDA takes a 3-pronged approach to help ensure industry complies with the law by:

- Developing and providing compliance training and education
- Monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations
- Taking action when necessary, which may entail issuing warning letters, civil money penalty (CMP) complaints, or no-tobacco-sale order complaints; pursuing product seizures, injunctions, or criminal prosecution

RESEARCH THAT MAY INFORM ENFORCEMENT ACTIONS

- Monitoring tobacco industry marketing
- Post-market surveillance of authorized tobacco products
- Evaluations of the differential impact and/or possible unintended consequences of tobacco regulatory actions among specific populations

PUBLIC EDUCATION

COMMUNICATION AND EDUCATION

- Research has shown public education campaigns are a proven strategy in preventing and reducing population-level tobacco use

- FDA's educational campaigns target discrete audiences:
  - *The Real Cost:* General market teens at risk of smoking (February 2014)
  - *Fresh Empire:* Multicultural teens at risk of smoking (October 2015)
  - *The Real Cost Smokeless:* Rural male teens at risk of using smokeless (April 2016)
  - *This Free Life*: Lesbian, Gay, Bisexual, Transgender (LGBT) young adults at risk of becoming regular smokers (May 2016)
  - *Every Try Counts*: Smokers who have tried to quit in the last year but were unsuccessful (January 2018)
  - *The Real Cost Youth E-Cigarette Prevention*: General market teens on the dangers of e-cigarette use (Digital Ads launched September 2018; TV Ads launched July 2019)
  - *Next Legends:* American Indian and Alaska Native youth, ages 13-17 at risk for using e-cigs and other ENDS (coming soon)

- FDA also has a voluntary retailer education campaign, *This is Our Watch,* which educates retailers, clerks & the public on how to comply with federal tobacco laws (November 2017)

RESEARCH THAT MAY INFORM HEALTH EDUCATION

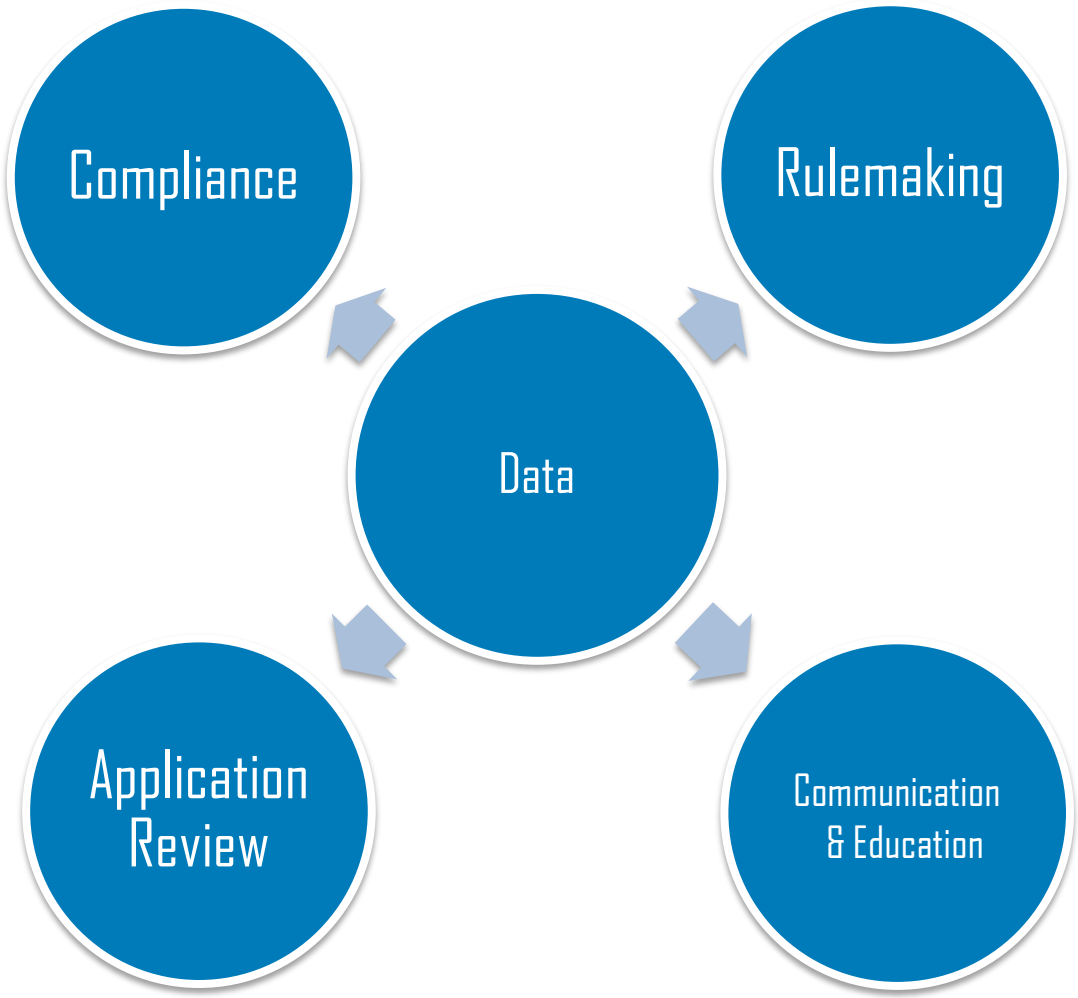
- Identifying effective tobacco education messages, message components, and communication channels to prevent initiation and to counter uptake of ENDS use and other novel product use by youth and young adults

- Developing strategies to increase attention to and engagement with tobacco education messages delivered on digital channels

- Identifying messages to effectively communicate about the risks associated with nicotine use and the potential relative harms of tobacco products other than conventional cigarettes use

SCIENCE LEADS THE WAY ACROSS CTP

SCIENCE DRIVES DECISIONS



NON-RESPONSIVE RESEARCH TOPICS

Although the following research topics may be within FDA CTP's regulatory authorities to fund, they are not to be included in the FOA and will be deemed nonresponsive

- Studies of short-term health effects and/or acute topography/clinical pharmacology testing of early generation ENDS products
- Mechanistic studies (i.e., basic science of disease development) unless biomarkers of harm with predictive value for disease development associated with tobacco product use is an outcome
- Studies developing or testing graphic health warnings for cigarette packages and advertisements
- Communicating harmful and potentially harmful constituents to the public
- Impacts of marketing restrictions on adults except for studies on newly authorized products
- Descriptive studies of demographics and/or risk perceptions that describe only exposure to advertising without linking exposure to tobacco use behaviors
- Studies of retailer compliance to the tobacco product regulations not associated with user behaviors or marketing strategies
- Studies of physician or other health professional knowledge, attitudes, perception, and behaviors toward the use of ENDS or other tobacco products

COMMON NON-RESPONSIVE AREAS OF RESEARCH

- Cannabis or Marijuana Research
  - A study with marijuana as the primary outcomes is not responsive because FDA CTP does not regulate marijuana under its tobacco product authorities
  - Vape devices that deliver something other than nicotine (e.g., melatonin, vitamins) are also non-responsive
- Tobacco Cessation Treatment
  - FDA CTP's regulatory authority does not extend to regulating therapeutic uses of tobacco products as this authority rests with other Centers within the FDA.
- Diagnosis and Treatment
  - FDA CTP does not regulate products or support development of clinical interventions intended for the treatment of disease

SCIENTIFIC EXPERTISE

Product Science
- Chemistry
- Engineering
- Microbiology

Nonclinical Science
- Toxicology
- Pharmacology
- Biology
- Environmental Science

Health Science
- Medicine
- Behavioral Pharmacology
- Psychology
- Neuroscience
- Clinical Pharmacology

Population Science
- Epidemiology
- Social science
- Statistics, modeling
- Evaluation

MOVING FORWARD

- In addition to stated research examples

- Consider:
  - Commissioner's announcements
  - Announcements of ANPRMs, NPRMs, RFIs
  - MRTPA & PMTA submissions
  - Recent decisions including MDO and MGO

- What will be the specific rule or other regulatory decision that could potentially be made based on your research?

QUESTIONS?

- Report adverse experiences with tobacco products at: https://www.safetyreporting.hhs.gov
- Report Potential Tobacco Product Violation: https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation
- Call us: (877) CTP-1373
- Email us: AskCTP@fda.hhs.gov
- Follow us on Twitter: @FDATobacco