FDA'S CENTER FOR TOBACCO PRODUCTS

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Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.





March 21, 2022

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





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





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

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RESEARCH PRIORITY AREAS

- CTP OS Research Priorities
 - Addiction
 - Behavior
 - Chemistry and Engineering
 - Communications
 - Health Effects
 - Impact Analysis
 - Marketing Influences
 - Toxicity

https://www.fda.gov/tobacco-products/research/research-priorities















Product Science N

SCIENTIFIC EXPERTISE

- Chemistry
- Engineering
- Microbiology

Health Science

- Medicine
- Behavioral Pharmacology
- Psychology
- Neuroscience
- Clinical Pharmacology

Nonclinical Science

- Toxicology
- Pharmacology
- Biology
- Environmental Science

Population Science

- Epidemiology
- Social science
- Statistics, modeling
- Evaluation



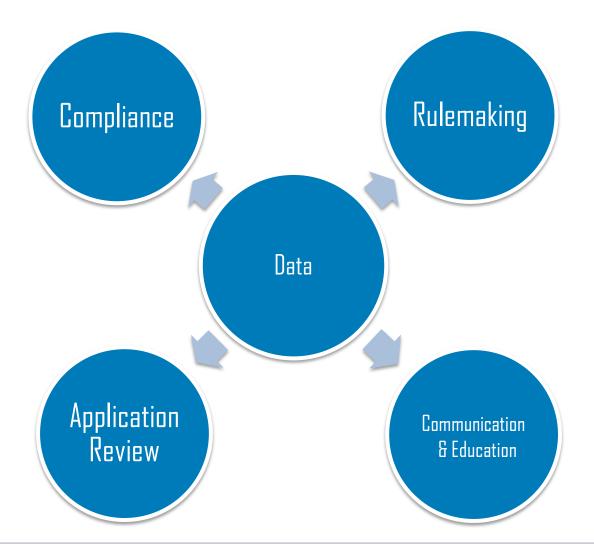






SCIENCE DRIVES DECISIONS





CENTER FOR TOBACCO PRODUCTS

CTP RESEARCH PROGRAM



CTP funds research through collaboration with federal agencies and contracts with non-HHS organizations that have particular expertise







CENTERS FOR DISEASE CONTROL AND PREVENTION





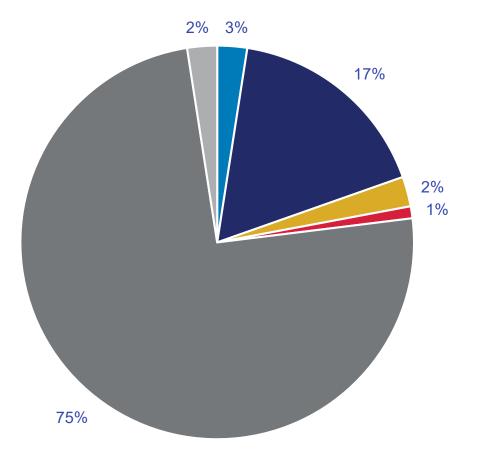




FY21 CTP-FUNDED RESEARCH PROJECTS ACROSS FUNDING MECHANISMS



FY21 CTP Funded Research Projects by Funding Mechanism



- Centers of Excellence in Regulatory Science and Innovation (CERSI)
- Contract
- Interagency Agreement (Non-PATH)
- Interagency Agreement (PATH)
- Intra-Departmental Delegation of Authority (IDDA)
- Performance Agreement

For more information: <u>CTP-Supported Tobacco Regulatory Research Projects</u>

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PROJECTS BY CTP RESEARCH DOMAINS (FY21)

Knowledge, Attitudes, and Behaviors 28 Toxicity & Carcinogenicity 14 Addiction 13 Health Disparities 12 Communication 10 Health Consequences Economics & Policy 8 Marketing Chemistry & Engineering 5 10 15 20 25 30 0 5 Number of CTP-funded projects

Number of CTP-funded Projects by Research Domain (FY21)

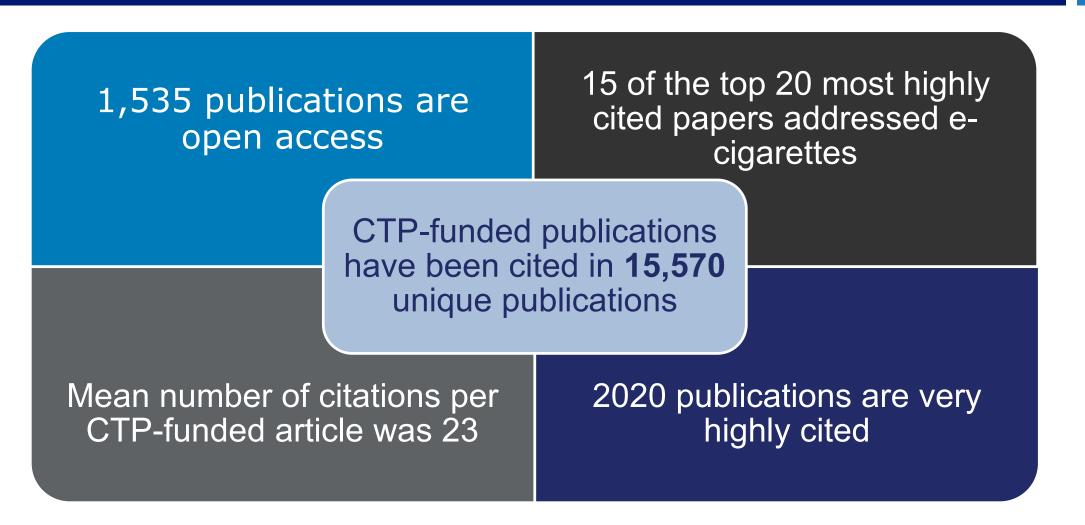
Projects could be classified as addressing multiple areas.

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CTP-FUNDED PUBLICATIONS ARE SHAPING THE TOBACCO REGULATORY SCIENCE FIELD



Source: FDA contract HHSF223201510002B/HHSF22318008 (RTI)

CENTER FOR TOBACCO PRODUCTS



Center for Coordination of Analysis, Science, Enhancement and Logistics (CASEL) in Tobacco Regulatory Science





Overall objective of CASEL is to support research programs that can inform the FDA CTP in tobacco product regulatory activities and actions.

- CASEL is expected to provide:
 - Scientific coordination for the broad CTP funded research portfolio
 - Provide leadership in fostering excellence in tobacco regulatory science
 - Support career enhancement effort

QUESTIONS?



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