FDA-NIH Partnership on Tobacco Regulatory Science

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Family Smoking Prevention and Tobacco Control Act, June 22, 2009
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
- “Tobacco product” is defined as any product made or derived from tobacco that is intended for human consumption, including any component part, or accessory of a tobacco product
- 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
- CTP funded solely via “user fees” from tobacco company assessments
FDA/CTP Public Health Goals

• Prevent American – especially youth – from starting to use tobacco

• Encourage current users to quit

• Decrease the harms of tobacco product use
CTP Uses a Public Health/Population Health Regulatory Standard

- Tobacco products cannot be regulated using FDA’s traditional “safe and effective” standard

- The Tobacco Control Act mandates its regulation using a population health standard taking into account both users and non-users of tobacco products
Specific Authorities Include:

- Premarket applications for new and modified risk tobacco products
- Testing and reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Tobacco product standards
- Health warnings on cigarettes and smokeless tobacco products & ads
- Advertising and promotion restrictions
- Industry registration and listing of ingredients
- FDA has authority to conduct research to support tobacco product regulation
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 CDER, FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine yields to zero
- Provision of cessation services
FDA’s Public Health Framework for Tobacco Product Regulation

FDA is using our regulatory authority to:

1. Understand the regulated products
2. Control product changes that affect public health
3. Prohibit false/misleading claims that state/imply reduced risk
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
8. Educate the public about FDA’s regulatory actions
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
• Science to ensure that scientifically valid techniques, tools, and models are available to evaluate products, and to inform regulatory actions

• Research to inform CTP’s regulatory authority with respect to the manufacture, marketing, and distribution 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
Established Joint NIH-FDA Leadership Council for Regulatory Science - February 2010

- Tobacco Regulatory Science Working Group
- Representatives from NIH intramural & extramural and CTP

Tobacco Regulatory Science Program (TRSP) -

- Established NIH-FDA coordination office within the NIH Office of Disease Prevention in January 2013
Tobacco Regulatory Science Program (TRSP)

- FDA has expertise in tobacco regulatory science, and the authority and resources to support research.
- NIH has expertise in tobacco research and the infrastructure for receipt, review, and administration.
- TRSP allows NIH to support FDA's mandate for research in regulatory science.
- TRSP provides new funding opportunities that complement existing NIH tobacco research activities.
TRSP Roles

- Located within the NIH OD, coordinates trans-NIH extramural and intramural collaborative activities with CTP
- Serves as resource for IC program, review, budget and grants management
- With input from FDA and NIH staff, prepare FOAs, screen applications for responsiveness, arrange for scientific review, ensure special terms met, monitor progress, schedule meetings
- With OD Budget Office, monitors CTP related expenditures
IC program, review and grants management staff function in same capacity as with other funding mechanisms, but with added CTP-specific requirements

- Serve as “face” of TRSP to extramural community
- Participate in FOA development and grantee meetings
- Respond directly to investigator inquiries and communicate with TRSP staff when clarification is needed
- Communicate with investigators about responsiveness, budget requests, and TRSP requests for more information
- Approve grantee progress reports and requests in collaboration with TRSP/CTP
• 44 projects funded by FY12
  • R01/U01 Competitive Revisions
  • P01/P50/P60 Administrative Supplements
  • Investigator-initiated research projects
• 8 Intramural Projects – FY13
• P30 NIH Revision Applications
  • Reviewed July 13, funding in early FY14
• Funding Opportunity Announcements - R01 (research grants), R21 (exploratory/developmental), R03 (small)
  • next due date – January 15, 2014
• Career Awards – K01, K08, K22, K99/R00 - Receipt date – October 2
• Tobacco Centers for Regulatory Science (TCORS)
  • Reviewed in May, funding by September
• Population Assessment of Tobacco and Health (PATH) Study - contract
The PATH Study is a large, national, longitudinal cohort study of tobacco use and health in the United States.

PATH Study will collect data from adults, youth, and parents and biospecimens (urine, buccal cells, blood) from adults.

PATH Study will inform FDA’s regulatory activities.

Specific Aims of the PATH Study

• Identify and explain between-person differences and within-person changes in tobacco use patterns, including use of new products, dual use, poly use and switching

• Identify between-person differences and within-person changes in risk perceptions of HPHCs, new and emerging products, design features, packaging and labeling

• Characterize the natural history of tobacco dependence, cessation and relapse

• Assess health conditions related to tobacco use
Specific Aims of the PATH Study

• Assess associations between CTP-specific actions and tobacco product use, risk perceptions, attitudes, use patterns, cessation outcomes
• Assess changes overtime in behaviors, exposure to products, and related biomarkers
• Compare former and never users for changes in relapse, uptake, risk perceptions, and indicators of tobacco exposure and disease processes
• Use data to launch small-scale research studies focusing on new and emerging tobacco-related behavior, attitudes, and health issues,
Baseline data collection (N ~ 59,000) began September 11, 2013 with a cohort of never, current, and former users of tobacco products in the U.S. ages 12 and over - followed annually for at least two additional waves of data collection

- Youth, 12-17 years old: ~16,900
- Young adults, 18-24 years old: ~10,700
- Adult current tobacco users: ~24,100 (daily users: ~19,200)
- Adult dual users of cigarettes and smokeless tobacco products: ~3,300
• NIH plans to award TCORS by September 19
• Multidisciplinary research, at least 3 research projects
• Opportunities for developmental and pilot research
• Research training component
• Collaboration across TCORS grantees
• Data harmonization to the extent possible
Research Portfolio

FDA-NIH Research Portfolio

This list contains grants and contracts carried over from prior fiscal years and new projects awarded in the current fiscal year for Special Research Priority on U.S. Food and Drug Administration (FDA) Tobacco Product Regulation.

Investigator Initiated, FY12
Program Projects Administrative Supplements, FY12
R01 Competitive Revisions, PAR-12-010, FY12
U01 Competitive Revisions, PAR-12-011, FY12
Communication Administrative Supplements, FY12
Administrative Supplements, NOT-CA-10-007, FY10
Contracts supported by FDA Center for Tobacco Products

Investigator Initiated for Special Research Priority on U.S Food and Drug Administration (FDA) Tobacco Product Regulation funded in fiscal year 2012.

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<thead>
<tr>
<th>Principal Investigator Organization</th>
<th>Title</th>
<th>Grant Number</th>
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<tr>
<td>Blalock, J. Edwin University of Alabama at Birmingham</td>
<td>PGP, A Possible Biomarker for COPD Exacerbations and or Progression</td>
<td>1R01HL114439-01</td>
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<td>Clark, Pamela I. University of Maryland College Park Campus</td>
<td>Rapid response human testing of smokeless tobacco products</td>
<td>1R01DA031142-01A1</td>
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<td>Crystal, Ronald G Weill Medical College of Cornell University</td>
<td>COPD Metabolome, Smoking Oxidants and Aberrant Ciliated Cell Function</td>
<td>1P20HL113443-01</td>
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<td>Cummings, K. Michael Medical University of South</td>
<td>Effectiveness of tobacco control policies in high vs. low income countries</td>
<td>3PO1CA138389-05S1 (Admin Supplement)</td>
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