Tobacco Product Regulation at FDA: Regulatory Science and Programmatic Priorities

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FDA's Public Health Framework for Regulating Tobacco Products

- The Family Smoking Prevention and Tobacco Control Act created CTP to regulate tobacco products under a new standard "appropriate for the protection of the public health."
- The ultimate public health objective is to reduce the death and disease from the use of tobacco products.
- As regulators, we have to assess risks and benefits for the population as a whole, including among users and non-users of tobacco products.

FDA's Public Health Framework for Tobacco Product Regulation

FDA is using our regulatory authority to:

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

FDA and Regulatory Science

- Focuses on informing FDA's regulatory authority
- Recognizes that tobacco products cannot be regulated using FDA's traditional "safe and effective" standard
- Enables FDA to best assess the "net" population-level health impacts
- FDA-CTP cannot fund research on:
  - Diagnosis of disease
  - Treatment of disease or tobacco use
  - Clinical practice

NIH & FDA Collaboration

Established Joint NIH-FDA Leadership Council for Regulatory Science (Feb 2010)

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

Tobacco Regulatory Science Program (Jan 2013)

- Established NIH-FDA coordination office within the NIH Office of Disease Prevention

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

Tobacco Regulatory Research Funding Opportunities

Funding Opportunity	Fiscal Year	# of Awards	# of NCI
Administrative Supplements (R01 & P01)	2010	8	8
FSPTCA Longitudinal Study N01 (PATH)	2011	1	0
U01 Competitive Revisions	2012	3	1
R01 Competitive Revisions	2012	12	7
Administrative Supplements to (P01 & P50)	2012	7	2
Communication Administrative Supplements	2012	3	3
NIH Intramural	**2013**	**8**	**2**
Administrative Supplements	**2013**	**5**	**2**
Investigator-Initiated	**2013**	**7**	**5**
Tobacco Centers of Regulatory Science P50	**2013**	**14**	**7**
Tobacco Regulatory Research R01, R21, R03	**2013**	**19**	**5**
P30 Revision Applications	**2014**	**pending**	
Tobacco Control Regulatory Research Career Awards (K01, K08, K22, K99/R00)	**2014**	**pending**	
U54 Coordinating Center	**2014**	**pending**	
Tobacco Regulatory Research R01, R21, R03	**2014**	**pending**	

Population Assessment of Tobacco and Health (PATH) Study

- Large, national, longitudinal cohort study of tobacco use and health in the United States – began September 2013
- Collecting data from adults, youth, and parents and biospecimens (urine, buccal cells, blood) from adults
- Designed to monitor and assess between-person differences and within-person changes in behaviors, attitudes, biomarkers, and health outcomes associated with tobacco use
- Contract awarded to Westat funded via an IAA with NIDA
- NCI scientists have contributed to the study design and implementation including instrument development

Additional NIH-FDA Collaborative Research Activities

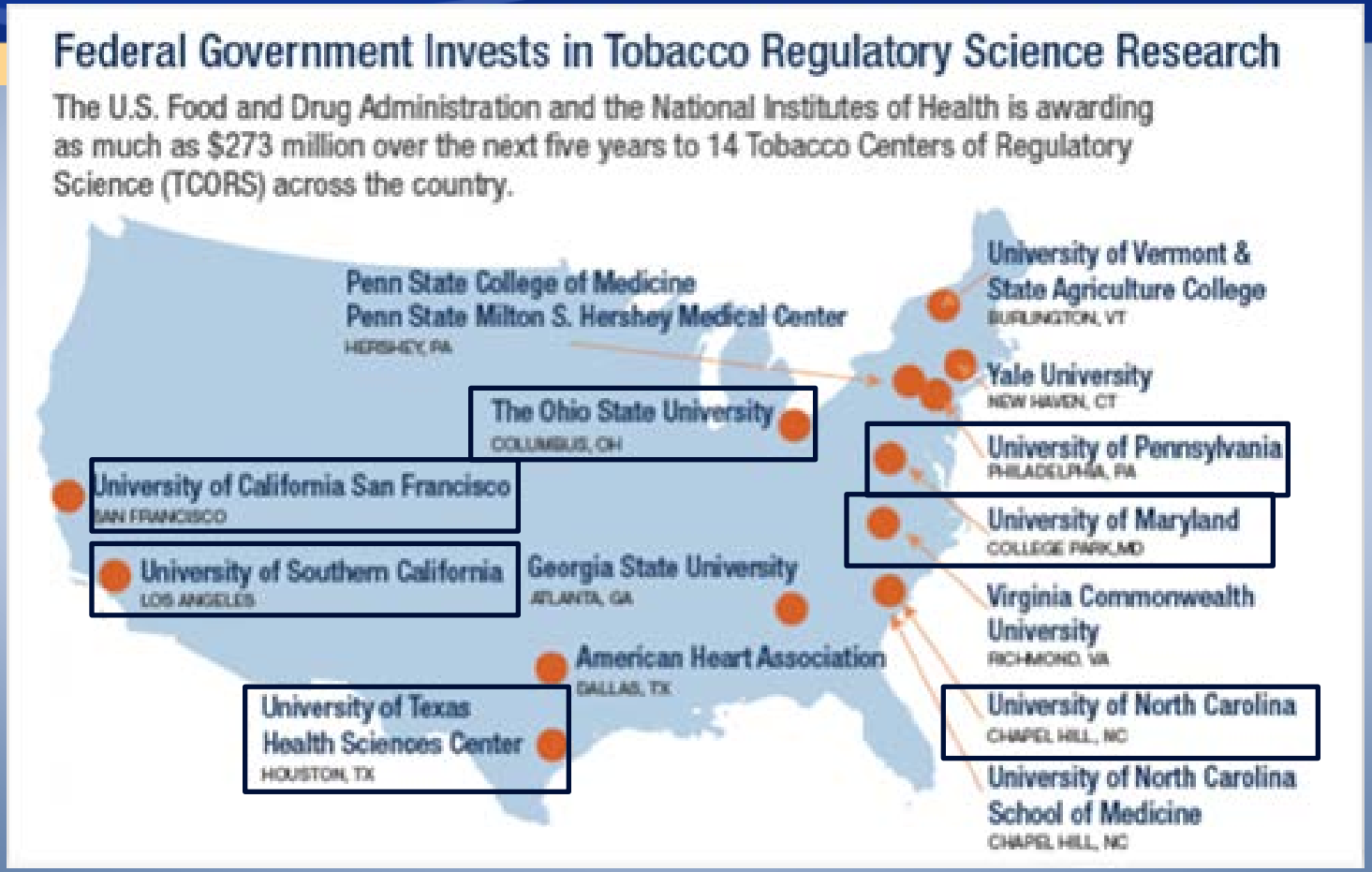
- Health Information National Trend Survey (HINTS)
  - FDA module in NCI's 2014 HINTS instrument
  - New questions to communications core such as: Information seeking about tobacco products; perceptions and awareness of contents of tobacco products, including harmful chemicals and nicotine; exposure to communications about and interest in seeing information about contents of tobacco products, beliefs about cigarette claims
- Tobacco Use Supplement to the Current Population Survey (TUS-CPS)
  - Collaboration with NCI on the 2014-2015 survey

Tobacco Centers of Regulatory Science (TCORS)

- Conduct programs of multidisciplinary research to inform CTP's regulatory activities:
  - Opportunities for developmental and pilot research
  - Cores for administration and other components
  - Research training component
  - Collaboration across TCORS grantees
  - Data harmonization to the extent possible

- Each TCORS could budget up to $4 million total costs per year
- $53 million in FY13
- Total over 5 years of $273 million

TCORS Highlighting the 7 Funded through NCI



CTP Priorities

- Review Substantial Equivalence Reports
- Menthol
- Deeming Regulation
- Youth Tobacco Education Campaigns
- Product Standards
- Comprehensive Nicotine Regulatory Policy

Substantial Equivalence

FDA made history in June when it announced the first tobacco product review decisions via the Substantial Equivalence (SE) pathway

- SE is one review path a manufacturer may choose in order to receive authorization to sell a new tobacco product
- Must have the same characteristics as a predicate tobacco product (one that was on the market as of February 15, 2007), or have different characteristics but not raise different questions of public health
- If the new tobacco product raises different questions of public health, the product is not substantially equivalent and cannot be sold

Menthol

FDA announced an ANPRM pertaining to menthol and cigarettes

- Sought additional information to make informed decisions about potential regulatory options related to menthol in cigarettes
- Released preliminary scientific evaluation
- Currently analyzing comments received
- FDA is also supporting research efforts on menthol and non-menthol cigarettes
- Developing a youth education campaign focused on preventing and reducing tobacco use, including menthol cigarettes

Deeming

The law grants FDA direct authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco

- Enables FDA to assert jurisdiction over other products that meet the statutory definition of a tobacco product
- The proposed rule was submitted to OMB in October and is currently under review

Youth Tobacco Education Campaigns

A comprehensive initiative to reach at-risk youth with messages to prevent tobacco use initiation and experimentation

- Multiple paid media campaigns over several years
- Key messaging areas: addiction, health consequences, HPHCs
- Campaigns will target discrete audience segments

General Market At-Risk	Rural Smokeless	Multicultural	LGBT
			
Including youth already experimenting	Including male youth at risk of smokeless initiation	Including youth who are African American, Hispanic, Asian Pacific Islander, or American Indian / Alaskan Native	Including older LGBT youth

Product Standards

- Exploring potential for product standards to reduce product addictiveness, toxicity, and/or appeal
- Investing in research to support potential product standards

Comprehensive Nicotine Regulatory Policy

FDA has the opportunity to create a comprehensive nicotine regulatory policy:

- Different tobacco products deliver nicotine in different ways
- Certain products may pose more individual risk than others
- What can we do to help smokers, especially those unable or unwilling to quit?
- Legally, FDA must look at both individual level risk and population level harm
- Two key questions…who is using the products and how?
- It comes down to the “net” population effects

FDA

Center for Tobacco Products