NIH-FDA Tobacco Regulatory Science Program

Advisory Committee to the NIH Director
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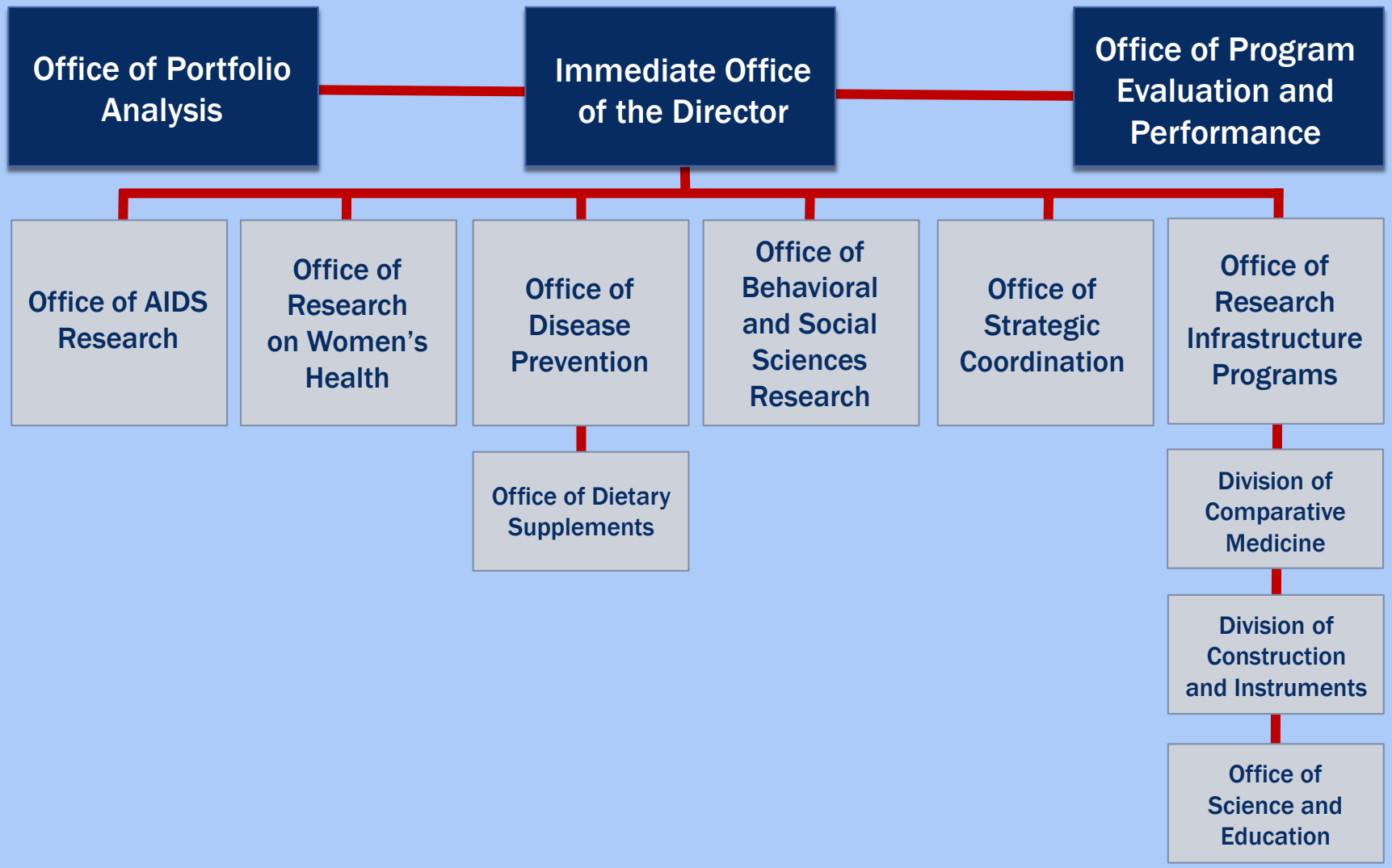
NIH Office of Disease Prevention

NIH-FDA Tobacco Regulatory Science Program (TRSP)

- FDA: expertise in tobacco regulatory science and authority and resources to support research
- NIH: 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
  - Approximately $66M in new funding in FY12

ODP and DPCPSI



Tobacco Use: Leading Preventable Cause of Disease & Death in the U.S.

- 440,000 (1 in 5) deaths each year from cigarette use and second hand smoke
- 8.6 million smokers have at least one serious illness
- More deaths each year than from HIV, illegal drug use, alcohol use, motor vehicle accidents, suicides, and murders combined
- Adult smoking rates have stalled since 2004 at 20%

Decline in Youth Tobacco Use Has Slowed

- 20-25% of high school students report current use
- Each day, 3,500 young people start smoking and 850 become daily cigarette smokers
- 90% of adult U.S. smokers start tobacco use as a teen
- Almost half of new smokeless tobacco users are under 18

Family Smoking Prevention and Tobacco Control Act

June 22, 2009

FDA Designated Primary Federal Regulatory Authority

- FDA granted authority to regulate
  - tobacco products intended for human consumption
  - cigarettes, roll-your own, and smokeless tobacco products
- FDA intends to assert jurisdiction over other tobacco products
  - cigars, pipe tobacco, e-cigarettes, etc.

FDA
Center for
Tobacco Products

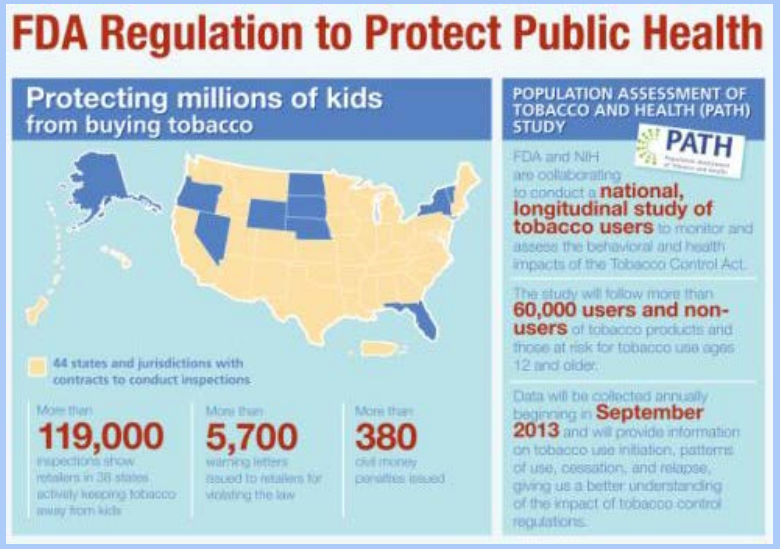
- CTP is funded by user fees from the tobacco industry ~$500M for FY13
  - Approximately 1/3 to be used for research to support regulatory science

A Population Health Regulatory Standard

- Tobacco products cannot be regulated using FDA's traditional 'safe and effective' standard
- The Tobacco Control Act mandates a population health standard
  - Considers the risks and benefits to the population as a whole, including both users and non-users

Authority to Conduct Research to Support Product Regulation

- A strong science base is precondition to successfully regulating tobacco products including:
  - Setting tobacco product standards
  - Identify biomarkers associated with tobacco exposure and disease risk
  - Developing, implementing, and evaluating communications



New Research Will Provide Scientific Evidence in 7 Areas

- Diversity of tobacco products
- Reducing addiction
- Reducing toxicity and carcinogenicity
- Adverse health consequences
- Communications
- Marketing of tobacco products
- Economics and policies

CTP has identified 56 research priorities under these 7 research interest areas.

Example Research Priorities

- How do components and design features affect the bioavailability of nicotine, other addictive substances, and harmful tobacco constituents?
- What is the potential impact of modifying nicotine levels and other addictive substances in tobacco on prevalence, initiation, progression, and cessation?

Example Research Priorities

- What is the potential impact on public health of decreasing nicotine and other addictive substances and reducing harmful and potentially harmful constituents in tobacco products?
- What is the impact of tobacco advertising around schools, parks and playgrounds on youth attitudes, beliefs, perceptions, and tobacco use?

NIH-FDA Tobacco Regulatory Science Program (TRSP)

- Initial activities
  - NCI and OER - key NIH participants
  - Tobacco Regulatory Science Working Group
    - Co-chairs: Bob Croyle, NCI and Cathy Backinger, CTP
  - Coordination Committee
    - Weekly meetings to coordinate NIH and FDA activities

TRSP Initial Activities

- OER established mechanisms to use FDA funds
  - Intradepartmental delegation of authority (IDDA) allows NIH to spend funds from FDA accounts to make awards for grants, supplements, and competitive revisions
  - Intra-agency agreements (IAAs) allow NIH to charge FDA for services rendered in the form of administrative effort, contracts, and intramural activities
  - IDDA and IAAs are renewable and include provisions for monitoring by both NIH and FDA

NIH-FDA
Tobacco Regulatory Science Program

- Initial funding opportunities in FY10, FY11, and FY12
  - Contracts
  - Investigator initiated awards
  - Administrative supplements
  - Competitive revisions

TRSP Initial Projects - Examples

- Evaluating new nicotine standards for cigarettes
- Mainstream smoke composition and toxin exposure from prototypical cigar products
- Communicating smoking risks through graphic warning labels
- Population assessment of tobacco and health study (PATH)
  - Cohort study of 60,000 users and non-users to study patterns of initiation, use, and cessation and effects of regulatory changes

Current And Planned Funding Opportunities For FY13

- Intramural research projects
- R01s, R03s, R21s
- P50 Tobacco Centers of Regulatory Science
- P30 competitive revisions
- K01 announcement

Review And Management Process

- IC program staff are primary points of contact for applicants
- CTP and NIH program staff screen applications for responsiveness to FDA's regulatory authority
- CSR reviews responsive applications for scientific merit
- IC Councils provide second-level of review
- CTP signs off on applications to be funded
- Awards are made and managed by ICs

TRSP Expenditures

	Expenditures by FY ($Millions)		
	FY10	FY11	FY12
Grants, supplements, competitive revisions	1.0	3.4	35.4
Research contracts	0.0	8.5	31.0
TOTAL	1.0	11.9	66.4

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Office of Disease Prevention

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E-mail Updates from the FDA Center for Tobacco Products

Going Forward

- ODP will have the lead for NIH
  - Central point of contact for NIH and FDA staff
  - Convener for meetings of grantees, committees, and working groups
  - Preparation and management of new FOAs
  - Management of the TRSP website and logistics support contract
- CTP will continue to have the lead for FDA
- OER, CSR and other NIH components will continue to play critical roles

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