

NIH AIDS Research Priorities

Jack Whitescarver, Ph.D.
NIH Associate Director for AIDS
Research and Director, OAR

May 8, 2007

NIH AIDS Research Program

- Largest public investment in AIDS research in the world
- Encompasses nearly all NIH ICs
- Transcends every area of clinical medicine and basic scientific investigation
- Multi-IC, multi-disciplinary, global
- Comprehensive program of basic, clinical, and behavioral research on HIV infection, its associated co-infections, OIs, malignancies, and other complications
- Requires unprecedented scientific coordination and management of research funds



NIH Office of AIDS Research

- Annual trans-NIH strategic plan
- Annual trans-NIH budget tied to the strategic plan
- Trans-NIH coordination, management, and evaluation
- A unified NIH research front against the AIDS pandemic



**OFFICE OF AIDS
RESEARCH**

Annual Trans-NIH Strategic Plan

Setting Scientific Priorities

OFFICE OF AIDS RESEARCH



NIH AIDS Scientific Research Areas

- Foundational Science
 - Natural History and Epidemiology
 - Etiology and Pathogenesis
- Therapeutics
- Prevention
 - Microbicides
 - Vaccines
 - Behavioral and Social Science
- Cross-cutting Resources
 - Training, Infrastructure, and Capacity Building
 - Information Dissemination
 - Specific Populations: Women and Girls, Racial and Ethnic Minorities, International



**OFFICE OF AIDS
RESEARCH**

Prevention Research Priorities of the FY 2008 Plan

Microbicide Research Priorities

- Conduct basic science that targets viral and/or cellular elements of HIV transmission
- Develop methodologies to assess preclinical/clinical safety and efficacy of microbicides
- Develop combinations of multiple active compounds of different chemical classes, specificities, and mechanisms of action
- Develop acceptable formulations and modes of delivery
- Expand research capacity, infrastructure and coordination to conduct clinical trials
- Conduct behavioral and social science research on use and acceptability



Vaccine Research Priorities

- Support basic and preclinical research on innovative vaccine concepts
- Conduct studies on mucosal immunity, antibody responses, and correlates of immunity
- Conduct expanded clinical trials
- Expand research infrastructure, training, and cohort development



Behavioral and Social Science Priorities

- Develop and evaluate interventions to reduce HIV acquisition and transmission associated with sexual behavior as well as with drug and alcohol use
- Integrate basic behavioral and social science research into the design and evaluation of HIV prevention and care interventions
- Develop and test innovative models and interventions that reflect the cultural and social context of the lives of racial and ethnic minorities



**OFFICE OF AIDS
RESEARCH**

New Challenges in Therapeutics Research



DHHS/NIH/OAR

Therapeutics Research Priorities

- Support basic science and preclinical development of novel compounds
- Conduct clinical trials, including multi-drug regimens
- Develop and evaluate new agents to treat and prevent HIV co-infections (TB, HCV) and co-morbidities (malignancies, cardiovascular diseases, metabolic disorders and other complications)
- Conduct studies to reduce drug resistance and drug toxicities
- Conduct studies to further reduce mother-to-child transmission



**OFFICE OF AIDS
RESEARCH**

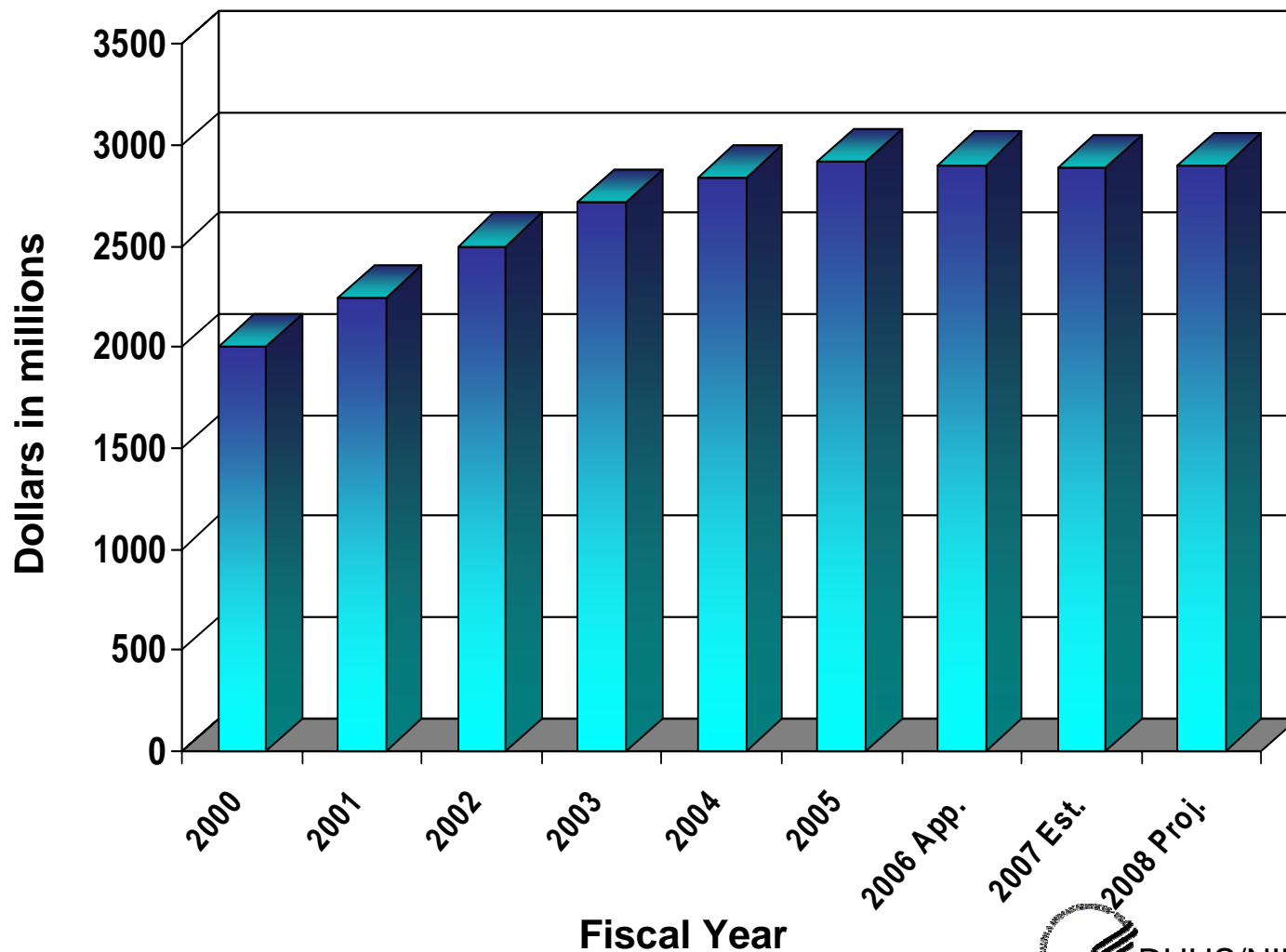
Trans-NIH Budget

**Linked to Plan
Funding Highest Priorities**

**OFFICE OF AIDS
RESEARCH**

NIH AIDS Research Funding

FY 2000 – FY 2008



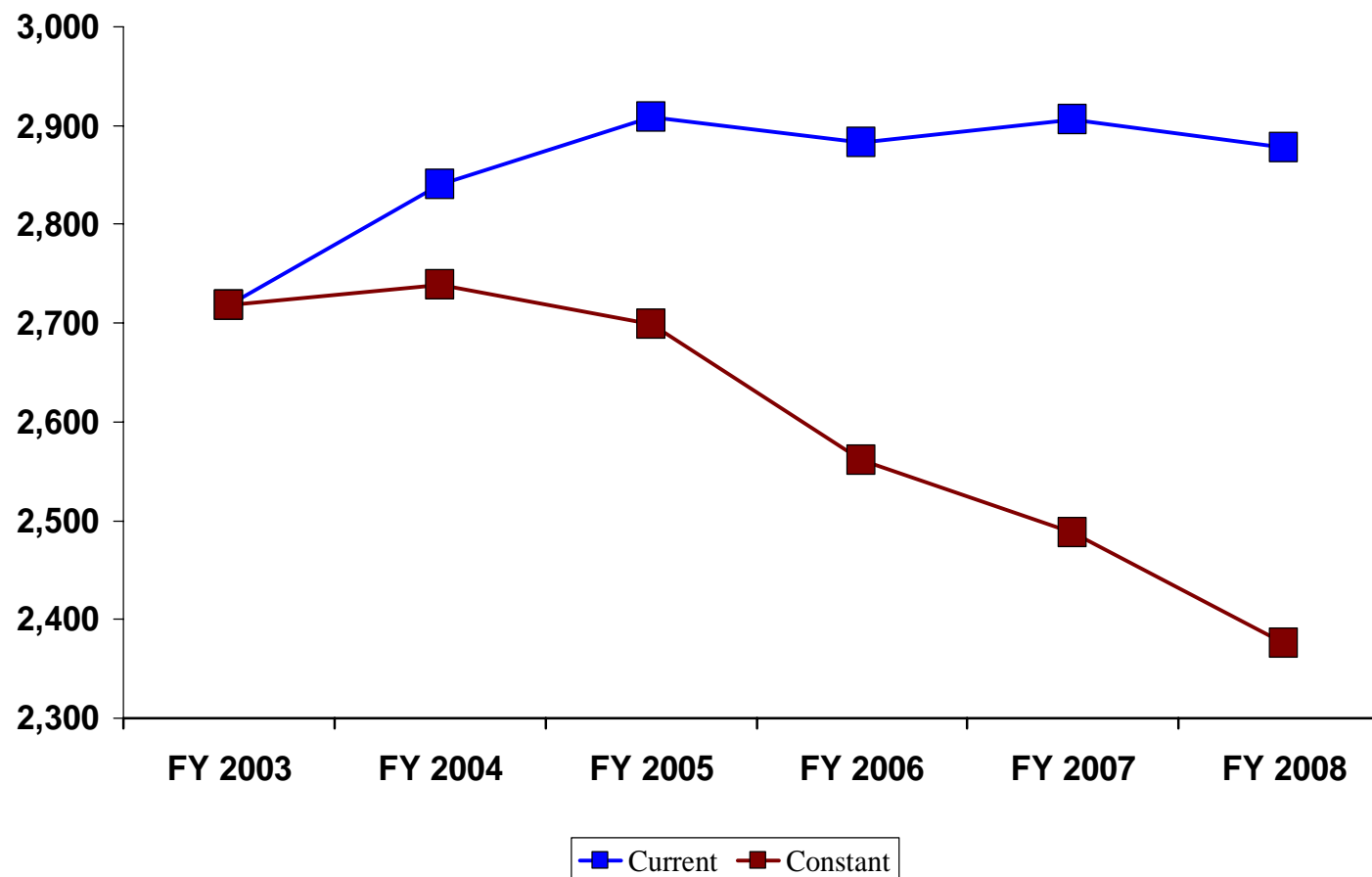
DHHS/NIH/OAR

Current and Constant Projections

AIDS Research Dollars

FY 2003–FY 2008 President's Budget

(dollars in millions)



**OFFICE OF AIDS
RESEARCH**

Trans-NIH Coordination

Trans-NIH Coordination

- Manage multi-institute research
 - CFAR Steering Committee
 - HPTN Steering Committee
 - Restructured Clinical Trials Networks
- Targeted Initiatives/Designated Funding
 - Prevention science initiative
 - Microbicide research initiative
- Facilitate international research and agreements
 - India Initiative
 - MENA workshop



Restructured Clinical Trials Networks

- Pivotal role in coordinating multi-institute participation and collaboration
- Convened OAR Advisory Council and series of meetings with potential IC co-sponsors of the networks
- Negotiated MOUs between ICs and NIAID for scientific expertise and support, particularly in areas of HIV-related complications, malignancies, and co-infections
- Ensuring efficient and effective use of AIDS dollars in support of these domestic and international clinical trial networks



**OFFICE OF AIDS
RESEARCH**

Targeted Initiatives/Designated Funding

OAR Prevention Priority

- Convened outside experts to advise on how to most effectively redirect funds to catalyze future initiatives and multi-disciplinary endeavors
- Recommended focus on “next generation” prevention strategies
- Reestablished Prevention Science Working Group to suggest specific research strategies
- Set aside OAR funds for Prevention Science Initiative



New Microbicide Priority

- New OAR staff dedicated to enhancing microbicide research and developing strategic plan
- New coding to track microbicide research
- NIH Coordinating Committee
- New branch in NIAID
- Establish Microbicide Research Working Group to advise NIH and other funders
- India agreement with priority to microbicides
- Joint efforts with Gates Foundation and other funders

**OFFICE OF AIDS
RESEARCH**

International Research and Agreements



DHHS/NIH/OAR

India Initiative

- 2006: U.S.-Indo Joint Statement on Collaboration on Prevention of STDs and HIV/AIDS signed. Lead agencies are NIH/OAR and Indian Council of Medical Research (ICMR)
- OAR established Joint Working Group (JWG) to develop strategic plans and facilitate expedited review and clearances of funded bilateral projects; prepared implementation plan; named U.S. members of Expert Panel to JWG
- 2007: Launched new research initiative: Program announcement issued sponsored by 8 ICs (including NIDA), to foster/expand collaborative prevention research and training opportunities between current NIH grantees and Indian researchers. Over 40 applications received for funding by September 1. OAR will provide up to \$2 million this year. Complementary funds from Indian Government
- FY 2008 plans include RFA for R21 grants to new U.S.-India collaborators
- Additional workshops, training, and grantsmanship efforts anticipated
- Possible model for future collaborations with China



Middle East and Northern Africa (MENA) Initiative

- February 2006: meeting convened in Cairo to set a coordinated prevention strategy for HIV for MENA nations
- Recommended further discussions focused on behavioral and social science research
- August 2006: OAR organized a planning meeting in Toronto, Canada at IAS Conference
- May 2007: OAR sponsored meeting last week in Tunis, Tunisia with IC staff, NIH-funded U.S. investigators, and representatives from 7 MENA nations
- Goals: to outline a behavioral and social science research agenda to address specific needs within the region; and to establish and foster U.S.-MENA research collaborations to pursue that critical agenda



Summary

- OAR identifies highest scientific priorities and opportunities to address changing epidemic
- OAR shifts AIDS research resources across ICs and across scientific areas to meet highest priorities
- OAR manages multi-IC collaboration and cooperation
- OAR facilitates implementation of international agreements for collaborative research
- OAR works with NIDA to: develop the strategic Plan; develop the AIDS budget; ensure support for highest scientific priorities; and support special initiatives, workshops, programs and study protocols.
- New challenges and opportunities ahead

