

NIAID HIV Vaccine Summit

AIDS Vaccine Research: A Re-Evaluation

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March 25, 2008



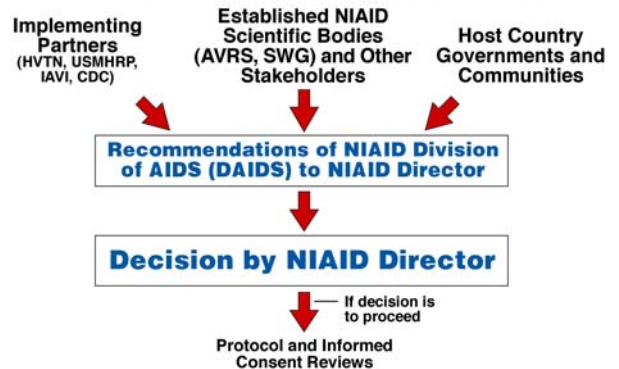
Purpose and Selected Goals of Today's Summit

- The summit is an important step in ongoing efforts to examine the current direction of HIV vaccine research; part of an iterative process
- NIAID is seeking input on the entire HIV vaccine research endeavor, including (but not limited to)
 - the optimal balance between vaccine discovery and development
 - NHP model development, optimization and utilization
 - Integration of clinical research with discovery
- **Based upon input and feedback, NIAID will make adjustments to existing efforts to attract and support novel, high-priority science**

What Today's Summit is NOT

- Not a forum on the future of PAVE 100
 - No vote will be taken (or decision made) regarding the future of PAVE 100 or any other specific clinical trial

PAVE 100 Decision-Making Process



Today's Summit Builds on Previous and Ongoing Efforts to Engage the Scientific Community in Optimizing HIV Vaccine Research and Development Efforts

Science 27 June 2005
Vol. 305 No. 5628
Pages 1169-1170

The Need for a Global HIV Vaccine Enterprise

R.D. Klausner, A.S. Fauci, L. Corey, G.J. Nabel, H. Gayle, S. Berkley, B.F. Haynes, D. Baltimore, C. Collins, R.G. Douglas, J. Esparza, D.P. Francis, N.K. Ganguly, J.L. Gerberding, M.I. Johnston, M.D. Kazatchkine, A.J. McMichael, M.W. Makgoba, G. Pantaleo, P. Piot, Y. Shao, E. Tramont, H. Varmus, J.N. Wasserheit

PLOS MEDICINE
Published online January 18, 2005

Policy Forum

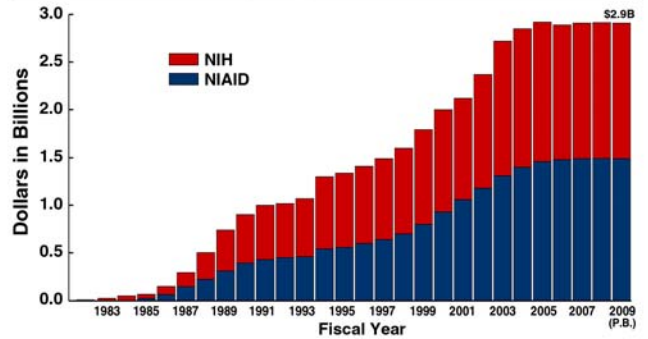
The Global HIV/AIDS Vaccine Enterprise: Scientific Strategic Plan

Coordinating Committee of the Global HIV/AIDS Vaccine Enterprise

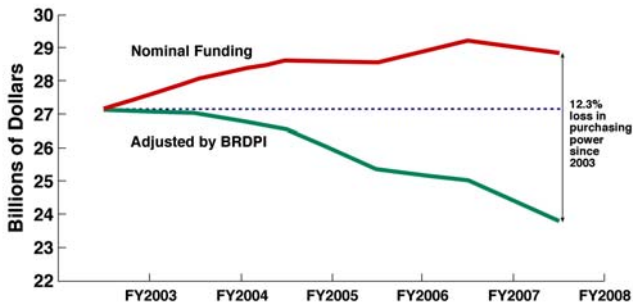
www.plosmedicine.org

NIH Financial Resources: What Do We Have to Work With?

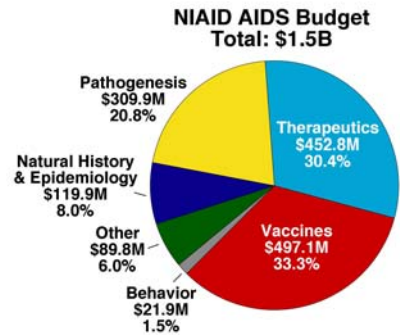
NIH and NIAID AIDS Research Funding FY 1982-2009 (PB)



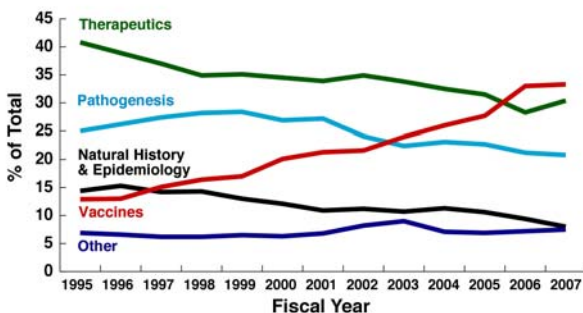
Inflation Eroded Gains in NIH Funding Real and Nominal NIH Funding Levels Since 2003



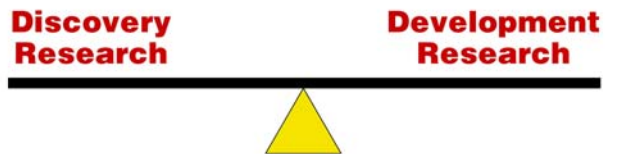
NIAID AIDS Research Budget FY 2007



Proportion of NIAID AIDS Budget by Major Category, FY 1995 - FY 2007



Finding the Ideal Balance in HIV Vaccine Research

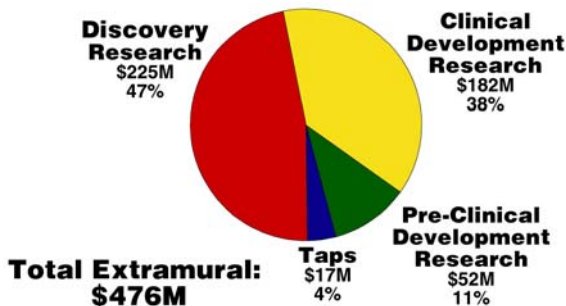


HIV Vaccine Discovery and Development: Definitions

- **Discovery Research:** Studies (basic, structural, animal, human, other) that inform and guide the design of candidate vaccines (grants)
- **Pre-Clinical Development Research:** Animal and laboratory studies required to advance a candidate vaccine into a human clinical trial, as well as resources (access to animals, reagents, sequence and epitope data, etc.) that support discovery research (contracts)
- **Clinical Development Research:** Preparing for and conducting clinical research to support product licensure and/or to guide the design of improved vaccines (grants and contracts)

A Considerable Amount of HIV Vaccine Discovery Research is Already Underway

NIAID Extramural Spending on HIV Vaccine and HIV Vaccine-Related Research (FY 2007)



- NIAID is committed to bolstering the *quality* and *quantity* of HIV vaccine discovery research.
- We need new/novel ideas, both from current investigators and from a new generation of scientists who will help energize the field.
- We will make every effort to fund meritorious applications.

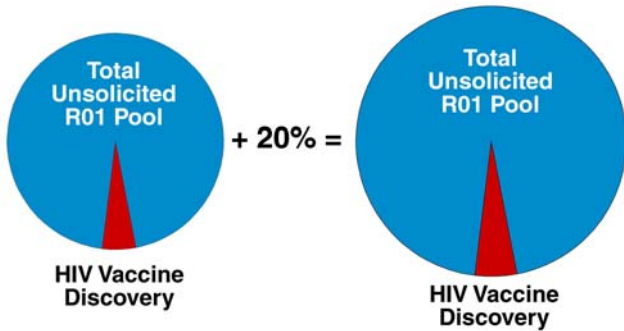
Options for Increasing NIAID Funding of HIV Vaccine Discovery Research

- Raising the payline -- increasing the size of the unsolicited R01 pool
- “Select payment” of unsolicited grants of programmatic interest
- New and expanded initiatives – RFAs for solicited R01s and other programs

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Increasing the Payline, i.e. the Size of the Unsolicited R01 Pool, Has Little Effect



Raising the Payline is an Inefficient Way of Bolstering Vaccine Discovery

Percentile	HIV vaccine basic and discovery research grants funded*	
12 (current level)	N = 8	
14	+1	9
16	+2	11
18	+0	11
20	+2	13

*NIAID FY 2007 Data

- Each 2 percentile point increase costs **\$35-38M**
- >\$140M yields only 5 new vaccine discovery grants

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At the End of the Day

- We hope to receive from the group **specific recommendations** on:
 - The *types* of research to foster
 - *How* to attract these proposals