NIAID: State of the Institute and Priorities in HIV/AIDS Research

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
June 17, 2015
Hamburg Resigns, Ostroff Selected as Acting FDA Commissioner

Margaret A. Hamburg, M.D.
FDA Commissioner 2009-2015

Stephen M. Ostroff, M.D.
Varmus Resigns, Lowy Named Acting NCI Director

Harold E. Varmus, M.D.
NCI Director 2010-2015

Douglas R. Lowy, M.D.
Whitescarver to Resign as Director, NIH Office of AIDS Research (OAR)

Jack E. Whitescarver, Ph.D.
Director, NIH Office of AIDS Research
2000-2015
Eisinger Selected as Acting Director, NIH Office of AIDS Research (OAR)

Robert W. Eisinger, Ph.D.
Budget Update
NIH FY 2015 Budget Comparison by Institute/Center

Total = $30.3B
# National Institutes of Health
## Budget Comparison by Institute/Center (Dollars in Thousands)

<table>
<thead>
<tr>
<th>IC</th>
<th>FY 2015 Enacted</th>
<th>FY 2016 President’s Budget</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$ 4,953,028</td>
<td>$ 5,098,479</td>
<td>2.9%</td>
</tr>
<tr>
<td><strong>NIAID</strong></td>
<td>4,417,558</td>
<td>4,614,779</td>
<td>4.5%</td>
</tr>
<tr>
<td>NHLBI</td>
<td>2,995,865</td>
<td>3,071,906</td>
<td>2.5%</td>
</tr>
<tr>
<td>NHGRI</td>
<td>498,677</td>
<td>515,491</td>
<td>3.4%</td>
</tr>
<tr>
<td>NCATS²</td>
<td>632,710</td>
<td>660,131</td>
<td>4.3%</td>
</tr>
<tr>
<td>NIGMS</td>
<td>2,372,301</td>
<td>2,433,780</td>
<td>2.6%</td>
</tr>
<tr>
<td>Other ICs³</td>
<td>$12,898,613</td>
<td>$13,345,292</td>
<td>3.5%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$28,768,752</td>
<td>$29,739,858</td>
<td>3.4%</td>
</tr>
<tr>
<td>OD⁴</td>
<td>1,413,734</td>
<td>1,442,628</td>
<td>2.0%</td>
</tr>
<tr>
<td>B&amp;F</td>
<td>128,863</td>
<td>128,863</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$30,311,349</td>
<td>$31,311,349</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

¹Includes $62M for AIDS ($22M Cure), $100M AMR, $20M Flu Vaccine, and $15M Precision Medicine
²Includes $23.5M for Cures Acceleration Network (CAN)
³Includes $246M for new competing RPGs, $70M for BRAIN, $63M for Precision Medicine, $50M for Alzheimer’s, and $54M for NCBI/PA
⁴Includes $20M for Common Fund
NIH HIV/AIDS Research Funding, FY 2000 to FY 2016 (P.B.)

Excludes ARRA funds in FY 09/10
NIH FY 2016 President’s Budget for HIV/AIDS, by Institute and Center

- NIAID ($1.65B) 53%
- NCI ($281M)
- NICHD ($147M)
- NIMH ($163M)
- NIDA ($302M)
- NHLBI ($66M)
- NCATS ($65M)
- Other ICs ($426M)

Total = $3.1B
NIH FY 2016 President’s Budget for HIV/AIDS, By Area of Emphasis

- Training/Infrastructure/Capacity Building ($36M)
- Natural History and Epidemiology ($237M)
- Information Dissemination ($36M)
- Vaccines ($568M)
- HIV Microbicides ($113M)
- Behavioral and Social Science ($423M)
- Etiology and Pathogenesis ($698M)
- Therapeutics ($760M)

Total = $3.1B
NIH HIV/AIDS Funding: Two Key Issues

- Realignment of budget toward four focus areas

- Congressional activity
NIH HIV/AIDS Funding: Two Key Issues

- Realignment of budget toward four focus areas

- Congressional activity
Realignment of NIH HIV/AIDS Budget

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
NIH HIV/AIDS Funding: Two Key Issues

- Realignment of budget toward four focus areas

- Congressional activity
House Appropriations Committee, Subcommittee on Labor-HHS-Education

Chair: Rep. Tom Cole (R-OK)
Ranking: Rep. Rosa DeLauro (D-CT)

March 3, 2015

*Topic: FY 2016 NIH Budget Request*

Dr. Francis Collins, Director, NIH
- Accompanied by
  Dr. Anthony Fauci, Director, NIAID
  Dr. Thomas Insel, Director, NIMH
  Dr. Jon Lorsch, Director, NIGMS
  Dr. Nora Volkow, Director, NIDA
  Dr. Gary Gibbons, Director, NHLBI
NIH HIV/AIDS Funding Discussed at House Appropriations Hearing

“...84 million Americans have heart disease. And yet the amount we spend per death is 100 times less on heart disease than it is on HIV/AIDS, 100 times less per death. That kind of discrepancy just needs to be justified.”
Chair: Sen. Roy Blunt (R-MO)
Ranking: Sen. Patty Murray (D-WA)

April 30, 2015

**Topic:** FY 2016 NIH Budget Request

Dr. Francis Collins, Director, NIH
- Accompanied by
  Dr. Anthony Fauci, Director, NIAID
  Dr. Thomas Insel, Director, NIMH
  Dr. Jon Lorsch, Director, NIGMS
  Dr. Gary Gibbons, Director, NHLBI
  Dr. Doug Lowy, Acting Director, NCI
NIH HIV/AIDS Funding Discussed at Senate Appropriations Hearing

“….we are spending almost $190,000 per HIV death, and we are spending $6,700 per Alzheimer’s death. Ten percent of our budget on HIV/AIDS, 1.9 percent on Alzheimer’s.”
Senator Cassidy vs Anthony Fauci
Debating AIDS Research Funding

Created by Peter Staley
May 2, 2015
NIH Research: Think Globally

AS Fauci and FS Collins

“Engagement in global health protects the nation's citizens, enhances the economy, and advances U.S. interests abroad.”
Meeting with HIV Activists to Occur Summer, 2015
June 15, 2015

Open Letter to Congress from the HIV/AIDS Community: Sustain HIV Research Funding

June 15, 2015

Open Letter to House and Senate Appropriators from HIV/AIDS Researchers: Sustain Funding For HIV/AIDS Research at The National Institutes of Health
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
Focusing to Achieve a World Without AIDS

AS Fauci and HD Marston

“...as the final goal [of a world without AIDS] becomes closer, efforts must become more specific and focused.”
HIV risk is not uniformly distributed: countries often have microepidemics with very different levels of transmission and risk groups/behaviors

HIV prevention efforts should focus on high-transmission geographies and populations -- "hot zones" -- and provide tailored packages of interventions
Broadly Neutralizing Antibodies
Envelope Trimer with Selected bNAbs

Source: Sharma et al., Cell Reports, 2015 & Myerson et al. PNAS, 2013.
Strategies to Deliver bNAbs

- Passive transfer of bNAbs

- Gene therapy – vector-based expression of genes encoding bNAbs
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
“90-90-90” Targets for 2020

90% Diagnosed

90% On Treatment

90% Virally Suppressed

Source: UNAIDS, 2014
Treating HIV-Infected Individuals: A “Trifecta” of Pivotal ART Studies

- **SMART**  Episodic ART inferior to continuous ART

- **HPTN 052**  Early ART reduces HIV transmission to uninfected sexual partner by 96%

- **START**  Early ART reduces serious illness/death by 53%
The Promise of Long-Acting Agents for the Treatment of HIV Infection

- Antiretroviral Drugs, e.g.
  - Rilpivirine (TMC278) -- RT inhibitor
  - Cabotegravir (GSK1265744) -- integrase strand transfer inhibitor

- Monoclonal Antibodies
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
Towards an HIV Cure: Addressing the HIV Reservoir

Eradicate the reservoir

Control viral rebound – Sustained virologic remission
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including Vaccines)
- Improvement/Optimization of Therapies
- Cure
- Co-Morbidities (Infectious and Non-Infectious)
NIH Launches Largest Clinical Trial Focused on HIV-Related Cardiovascular Disease

- Randomized Trial to Prevent Vascular Events in HIV (REPRIEV), co-sponsored by NHLBI and NIAID
- Will test whether statin administration can reduce risk for major adverse cardiovascular events for HIV+ adults ages 40-75 years who do not meet current national guidelines for statin therapy
- ~100 sites in Canada, Puerto Rico, Thailand and United States; n = 6,500
HIV-Associated Tuberculosis (TB)

- 1/3 of HIV$^+$ people worldwide are infected with *Mtb*

- TB is the leading cause of death among HIV$^+$ people, causing 360,000 deaths in 2013

- ~1.1 million new cases of TB among HIV$^+$ people in 2013

- HIV$^+$ people are 26 to 31 times more likely to develop active TB disease than HIV$^-$ people

Source: WHO, 2015
Accelerating TB Regimen Development

- New TB agents
  - Define safety, PK, PD and drug-drug interactions
  - Evaluate novel combination regimens, including promising host directed therapies
  - Shorten duration of therapy for drug-sensitive and MDR TB

- Biomarkers of response to therapy
HIV-AIDS: Much Accomplished, Much to Do

AS Fauci, GK Folkers and CW Dieffenbach

“...the end of the HIV-AIDS pandemic [is] a feasible goal. However, there is still much to do... Now is not the time for a 'victory lap' but the time for racing ahead.”

- Anthony S. Fauci, Gregory K. Folkers, Carl W. Dieffenbach