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
April 12, 2017

Price Replaces Burwell as HHS Secretary

Thomas E. Price, M.D.
Sylvia Mathews Burwell

The Hill
January 13, 2017

White House Holds Disaster-Response Exercise with Trump Officials

Price Makes First Visit to NIH as HHS Secretary, February 21, 2017

Califf Resigns as FDA Commissioner; Ostroff Acting

Robert M. Califf, M.D.
Stephen Ostroff, M.D.
**Gottlieb Nominated to be FDA Commissioner**

Scott Gottlieb, M.D.

**Frieden Resigns as CDC Director; Schuchat Acting**

Thomas R. Frieden, M.D., M.P.H.  
Anne Schuchat, M.D., M.P.H.

**Erbelding Named Director of NIAID Division of Microbiology and Infectious Diseases (DMID)**

Emily J. Erbelding, M.D., M.P.H.

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**Budget Update**

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**National Institutes of Health Budget Comparison by Institute/Center (Dollars in Thousands)**

<table>
<thead>
<tr>
<th>IC</th>
<th>FY 2016 Enacted</th>
<th>FY 2017 President’s Budget</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$6,210,600</td>
<td>$6,850,500</td>
<td>10.5%</td>
</tr>
<tr>
<td>NIAID</td>
<td>$4,715,697</td>
<td>$4,715,697</td>
<td>0.0%</td>
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<tr>
<td>NHLBI</td>
<td>$3,113,523</td>
<td>$3,113,523</td>
<td>0.0%</td>
</tr>
<tr>
<td>NHGRI</td>
<td>$113,237</td>
<td>$113,237</td>
<td>0.0%</td>
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<tr>
<td>NCATS</td>
<td>$685,417</td>
<td>$685,417</td>
<td>0.0%</td>
</tr>
<tr>
<td>NIGMS</td>
<td>$2,512,437</td>
<td>$2,512,437</td>
<td>0.0%</td>
</tr>
<tr>
<td>NIA</td>
<td>$1,598,248</td>
<td>$1,598,248</td>
<td>0.0%</td>
</tr>
<tr>
<td>Other ICs</td>
<td>$12,259,220</td>
<td>$12,259,220</td>
<td>0.0%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$30,611,286</td>
<td>$31,291,386</td>
<td>2.2%</td>
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<tr>
<td>OD</td>
<td>$1,571,200</td>
<td>$1,716,700</td>
<td>9.2%</td>
</tr>
<tr>
<td>B&amp;F</td>
<td>$120,863</td>
<td>$120,863</td>
<td>0.0%</td>
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<tr>
<td><strong>Total</strong></td>
<td>$32,711,349</td>
<td>$33,136,349</td>
<td>2.6%</td>
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</tbody>
</table>

*Increase of $483M for National Cancer Research Initiative  
FY 2016 enacted as略有 $483M for Zika funding from HHS Global Fund and Secretary’s transfer from other NIH ICs  
*Increase of $118M for Precision Medicine Initiative and $43M for Ebola Initiative  

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**NIAID Funding, FY 2000-2017**

*Beginning in FY 2012, budget no longer passes through funds to the Global Fund.
**Status of FY 2017 Budget**

- No HHS appropriation enacted for FY 2017
- Operating under a Continuing Resolution (CR) until April 28, 2017

**Three Possible Scenarios Upon Conclusion of Continuing Resolution on April 28, 2017**

- Continuing resolution (CR) extended
- CR replaced by Omnibus bill that cuts/increases/maintains current funding level
- Closure of federal government

**NIAID FY 2017 Interim Financial Management Plan**

- R01 Payline
  - Established PI: 10th percentile
  - New PI: 14th percentile
- Non-competing and competing grants: No adjustments
- Competing research initiatives: Cut up to 10%
- Estimated success rates: 20-22%

**FY 2018 President’s Budget Request**

- Feb. 5, 2017 statutory deadline missed for submission; release now expected mid-May 2017

**White House Releases Budget Blueprint (“Skinny Budget”) – March 16, 2017**

**Proposed Cuts/Increases to Selected Agencies in Budget Blueprint**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA</td>
<td>-31.4%</td>
</tr>
<tr>
<td>USDA</td>
<td>-26.7%</td>
</tr>
<tr>
<td>Agriculture</td>
<td>-20.7%</td>
</tr>
<tr>
<td>Labor</td>
<td>-17.5%</td>
</tr>
<tr>
<td>Health &amp; Human Services</td>
<td>-15.7%</td>
</tr>
<tr>
<td>Commerce</td>
<td>-13.5%</td>
</tr>
<tr>
<td>Education</td>
<td>+5.9%</td>
</tr>
<tr>
<td>Veterans</td>
<td>+6.8%</td>
</tr>
<tr>
<td>Homeland Security</td>
<td>+10%</td>
</tr>
<tr>
<td>Defense</td>
<td>+10%</td>
</tr>
</tbody>
</table>
NIH-Specific Language in Budget Blueprint

- FY 2018 funding would be $25.9 billion, a $5.8 billion (-18%) cut from the FY 2017 Continuing Resolution (CR) level
- Major reorganization of NIH’s Institutes and Centers
  - Eliminating the Fogarty International Center
  - Consolidating the Agency for Healthcare Research and Quality (AHRQ) within NIH
  - Other consolidations and structural changes across NIH organizations and activities

How does an NIH institute absorb an 18 percent cut in its base budget?

HIV-Related Language in Budget Blueprint

- PEPFAR: “Provides sufficient resources to maintain current commitments and all current patient levels on HIV/AIDS treatment…”
- Global Fund: “Meets U.S. commitments to the Global Fund... by providing 33 percent of projected contributions from all donors, consistent with the limit currently in law.”
- Ryan White HIV/AIDS Program: A “high priority.”

Budget Cut for FY 2017?

STAT
March 29, 2017

That $1.2B Cut to the NIH this Year? Going Nowhere, Key GOP Congressman Says

U.S. Representative Tom Cole (R-OK)

WASHINGTON — The White House is proposing a $1.2 billion cut this year (FY 2017) to the National Institutes of Health's budget, targeting research grants....
The President Proposes a Budget

The Congress Determines the Budget

The “Mexico City” Policy

- On Jan. 23, 2017 President Donald Trump reinstated the Mexico City Policy via presidential memorandum.

- The policy requires foreign NGOs to certify that they will not “perform or actively promote abortion as a method of family planning” with non-U.S. funds as a condition for receiving U.S. global family planning assistance, and, as of Jan. 23, any other U.S. global health assistance.

- First announced in 1984 by the Reagan administration, the policy has been rescinded and reinstated by subsequent administrations along party lines. It has been in effect for approximately 17 of the past 32 years.

Senate Leadership in 115th Congress

- Majority Leader: Mitch McConnell (R-KY)

- Minority Leader: Chuck Schumer (D-NY)

House Leadership in 115th Congress

- House Speaker: Paul Ryan (R-WI)

- Majority Leader: Kevin McCarthy (R-CA)

- Minority Leader: Nancy Pelosi (D-CA)

Senate Committee Leadership

- Senate Appropriations Committee
  - Chair: Thad Cochran (R-MS)
  - Ranking Member: Patrick Leahy (D-VT)

- Labor-HHS Appropriations Subcommittee
  - Chair: Roy Blunt (R-MO)
  - Ranking Member: Patty Murray (D-WA)
House Committee Leadership

- House Appropriations Committee
  - Chair: Rodney Frelinghuysen (R-NJ)
  - Ranking Member: Nita Lowey (D-NY)

- Labor-HHS Appropriations Subcommittee
  - Chair: Tom Cole (R-OK)
  - Ranking Member: Rosa DeLauro (D-CT)

- House Energy and Commerce Committee
  - Chair: Greg Walden (R-OR)
  - Ranking Member: Frank Pallone (D-NJ)

Visit of House Labor-HHS Appropriations Subcommittee to NIH, Feb. 6, 2017

HIV Prevention in The NIH HIV Research Agenda

The Global HIV/AIDS Pandemic: Current Estimates

- 36.7 million people living with HIV (end-2015)
- 1.1 million AIDS deaths in 2015
- 2.1 million new HIV infections in 2015

Number of HIV-Infected People Globally Receiving Antiretroviral Therapy (ART), 2000-6/2016

Source: UNAIDS, 11/2016
The Global HIV/AIDS Pandemic: Current Estimates

- 36.7 million people living with HIV (end-2015)
- 1.1 million AIDS deaths in 2015
  - Decline of 43% since 2003
- 2.1 million new HIV infections in 2015

Source: UNAIDS, 11/2016

New HIV Infections Globally Among People Aged ≥15 Years, 1990-2015

New HIV infections static at ~1.9 million, 2010-2015

Source: UNAIDS, 2016

Members of key populations (and their sexual partners) accounted for 45% of new HIV infections globally in 2015

- Sex workers
- People who inject drugs
- Transgender people
- Prisoners
- MSM

HIV/AIDS in Women

- 17.8 million women living with HIV globally
  - 285,000 women living with HIV in U.S.
- Of 5,300 new adult HIV infections/day globally
  - 47% are among women
  - 20% are among women aged 15-24 yrs.

Source: UNAIDS, CDC

Diagnoses of HIV Infection among Adults and Adolescents, by Sex, 2010–2015 — United States

New HIV Diagnoses in the United States for the Most-Affected Subpopulations, 2015

- Black MSM: 10,315
- White MSM: 7,370
- Hispanic/Latino MSM: 7,013
- Black Heterosexual Women: 4,142
- Black Heterosexual Men: 1,926
- Hispanic/Latino Heterosexual Women: 1,010
- White Heterosexual Women: 966

Source: CDC, 11/2016
NIH HIV/AIDS Research: Four Focus Areas

- Prevention (including vaccines)
- Novel/innovative therapies
- Cure
- Co-morbidities (infectious and non-infectious)

NIAID HIV Prevention Research Funding, FY 2000-2016

- 2000: $258.9
- 2005: $579.0
- 2010: $768.5
- 2016: $736.8

NIAID HIV Prevention Research Funding, FY 2016

<table>
<thead>
<tr>
<th>Category</th>
<th>$(Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidemiology of Transmission</td>
<td>19.1</td>
</tr>
<tr>
<td>Biology of Transmission</td>
<td>17.5</td>
</tr>
<tr>
<td>Microbicides</td>
<td>84.2</td>
</tr>
<tr>
<td>Vaccines</td>
<td>533.7</td>
</tr>
<tr>
<td>Behavioral Prevention</td>
<td>23.9</td>
</tr>
<tr>
<td>Antiretrovirals as Prevention</td>
<td>58.3</td>
</tr>
<tr>
<td><strong>Total NIAID HIV Prevention</strong></td>
<td><strong>$736.8</strong></td>
</tr>
<tr>
<td><strong>Total NIAID HIV/AIDS</strong></td>
<td><strong>$1.67 Billion</strong></td>
</tr>
</tbody>
</table>

Major NIAID-Supported HIV Prevention Trials, 2016-2017

- Dapivirine vaginal ring
- Antibody-mediated Prevention (AMP)
- HIV vaccines
- Long-acting, injectable ARVs for PrEP
Ending the HIV-AIDS Pandemic — Follow the Science

AS Fauci & HD Marston