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 4, 2019
Legislative Update
116th Congress: House Leadership

- Democrats win House majority
  - Speaker of the House: Rep. Nancy Pelosi (D-CA)
  - Minority Leader: Rep. Kevin McCarthy (R-CA)
House Committee Leadership

House Appropriations Committee
- Chair: Rep. Nita Lowey (D-NY)
- Ranking Member: Rep. Kay Granger (R-TX)

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

Chairwoman of the House Health and Human Services Appropriations Subcommittee
Senate Committee Leadership

- Senate Appropriations Committee
  - Chair: Sen. Richard Shelby (R-AL)
  - Ranking Member: Sen. Patrick Leahy (D-VT)

- Labor-HHS Appropriations Subcommittee
  - Chair: Sen. Roy Blunt (R-MO)
  - Ranking Member: Sen. Patty Murray (D-WA)
Sen. Roy Blunt (R-MO)

Chairman of the Senate Health and Human Services Appropriations Subcommittee
Budget Update
## FY 2019 Budget for 8 Largest NIH Institutes

<table>
<thead>
<tr>
<th>Institute</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$6.1B</td>
</tr>
<tr>
<td><strong>NIAID</strong></td>
<td>$5.5B</td>
</tr>
<tr>
<td>NHLBI</td>
<td>$3.5B</td>
</tr>
<tr>
<td>NIA</td>
<td>$3.1B</td>
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<tr>
<td>NIGMS</td>
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</tr>
<tr>
<td>NINDS</td>
<td>$2.3B</td>
</tr>
<tr>
<td>NIDDK</td>
<td>$2.2B</td>
</tr>
<tr>
<td>NIMH</td>
<td>$1.9B</td>
</tr>
</tbody>
</table>

**Total NIH Budget (enacted): $39.3B**
# National Institutes of Health

## Budget Comparison by Institute/Center
(Dollars in Thousands)

<table>
<thead>
<tr>
<th>IC</th>
<th>FY 2019 Enacted</th>
<th>FY 2020 P.B.</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$6,143,892</td>
<td>$5,246,737</td>
<td>-14.6%</td>
</tr>
<tr>
<td>NIAID*</td>
<td>5,567,230</td>
<td>4,792,182</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NHLBI</td>
<td>3,488,335</td>
<td>3,002,696</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NHGRI</td>
<td>575,579</td>
<td>495,448</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NCATS</td>
<td>806,373</td>
<td>694,112</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NIGMS*</td>
<td>2,828,874</td>
<td>2,435,035</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NIA</td>
<td>3,083,410</td>
<td>2,654,144</td>
<td>-13.9%</td>
</tr>
<tr>
<td>NIDA</td>
<td>1,419,844</td>
<td>1,296,379</td>
<td>-8.7%</td>
</tr>
<tr>
<td>NIRSQ</td>
<td>-</td>
<td>255,960</td>
<td>-</td>
</tr>
<tr>
<td>Other ICs</td>
<td>13,081,788</td>
<td>11,368,792</td>
<td>-13.1%</td>
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<tr>
<td><strong>Subtotal</strong></td>
<td><strong>$36,995,325</strong></td>
<td><strong>$32,241,485</strong></td>
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<tr>
<td>OD</td>
<td>2,117,675</td>
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<td>B&amp;F</td>
<td>200,000</td>
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</tr>
<tr>
<td><strong>Total NIH Program Level</strong></td>
<td><strong>$39,313,000</strong></td>
<td><strong>$34,367,629</strong></td>
<td><strong>-12.6%</strong></td>
</tr>
</tbody>
</table>

*Figures include AIDS portfolio transfers from NIGMS to NIAID: $44M in FY 2019 and an estimated $38M in FY 2020
How to Absorb a 13 Percent Cut in the NIH Base Budget?
The President Proposes a Budget

The Congress Determines the Budget
Draft bill by the House Appropriations Committee provides a total of $41.1 billion for NIH for fiscal year 2020, an increase of $2 billion above the 2019 enacted level and $6.9 billion above the President’s budget request.
“.... Furthermore, the Committee rejects the Administration’s proposal to cut NIH’s HIV research budget by more than $400,000,000. Instead the Committee continues to invest in research that led to breakthroughs in current treatments such as PrEP and ART. The bill includes an increase of $149,000,000 for NIH to continue funding research that could lead to an HIV vaccine or a cure.”
# National Institutes of Health
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<tr>
<td>NCI</td>
<td>$6,143,892</td>
<td>$6,444,165</td>
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</tr>
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<td>NIAID</td>
<td>5,523,324</td>
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<td>NHLBI</td>
<td>3,488,335</td>
<td>3,658,822</td>
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<td>575,579</td>
<td>603,710</td>
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<td>NCATS</td>
<td>806,373</td>
<td>845,783</td>
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<tr>
<td>NIGMS</td>
<td>2,872,780</td>
<td>3,033,183</td>
<td>5.6%</td>
</tr>
<tr>
<td>NIA</td>
<td>3,083,410</td>
<td>3,286,107</td>
<td>6.6%</td>
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<td>1,419,844</td>
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<td>$41,313,000</td>
<td>5.1%</td>
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*Estimates made for Type I Diabetes (mandatory) and Superfund (non-HHS/Labor Appropriations) funding*
HIV/AIDS Update
Ending the HIV Epidemic

Controlling and Ultimately Ending the HIV/AIDS Pandemic
GK Folkers and AS Fauci

Ending the HIV/AIDS Pandemic
RW Eisinger and AS Fauci

Ending the HIV–AIDS Pandemic — Follow the Science
AS Fauci and HD Marston

Ending the HIV Epidemic in the United States: Closing the Implementation Gaps
HD Marston, CW Dieffenbach and AS Fauci
Ending the HIV Epidemic

The Beginning of the End of AIDS?
D Havlir and C Beyrer

Goal of Ending AIDS Gains Traction
J Cohen

UNAIDS Board Calls for Ending the AIDS Epidemic as a Public Health Threat by 2030

A Prescription for Ending the HIV Epidemic
J Mermin and A Laxton
Scientific Basis for the Plan:
We have the Tools
The Pivotal HPTN 052 Study

Prevention of HIV-1 Infection with Early Antiretroviral Therapy

HPTN 052 Study Team

- 1,763 HIV-serodiscordant couples in 9 countries
- 96% reduction in HIV transmission when ART started in HIV-infected partner at CD4 count of 350-550 compared to <250

Antiretroviral Therapy for the Prevention of HIV-1 Transmission

HPTN 052 Study Team

- After 5+ years of follow-up, protective effect of early ART was sustained (93% lower risk)
- No linked infections when HIV was stably suppressed by ART (i.e. undetectable viral load) in HIV+ partner
Major Studies Demonstrating Treatment as Prevention

- **PARTNER Study (2016); 58,000 acts of condomless sex**
- **Opposites Attract (2018); 16,800 acts of condomless sex**
- **PARTNER 2 Study (2019); 76,088 acts of condomless sex**

These studies showed no linked HIV transmissions involving a total of 150,888 acts of condomless sex when the partner with HIV was stably suppressed by ART.
HIV Viral Load and Transmissibility of HIV Infection
Undetectable Equals Untransmittable

RW Eisinger, CW Dieffenbach, and AS Fauci
HIV Pre-Exposure Prophylaxis (PrEP)

One pill per day

>95% effective in preventing HIV acquisition
The Fundamental Scientific and Clinical Basis for the Plan to End the HIV Epidemic in the United States

Treatment as Prevention (TasP) + Pre-Exposure Prophylaxis (PrEP)
Evolving Concept in Addressing HIV

Saving lives, alleviating suffering, preventing new infections

Saving lives, alleviating suffering, preventing new infections

+ Ending the epidemic
Theoretically, if we accessed and put on antiretroviral therapy everyone who has HIV and provide PrEP for all at high risk of HIV, we could rapidly end the epidemic.
Ending the HIV Epidemic in the United States

Theoretical Concept of Ending HIV

Realistic Concept of Ending HIV

Bridging the Gap
The Implementation Gap in Addressing the HIV Epidemic in the United States
Rates of Viral Suppression in People Diagnosed with HIV Infection, United States

- **U.S. National Average**: 59.8%
- **Ryan White HIV/AIDS Program**: 85.9%

Source: HRSA, 12/2018
HIV Pre-Exposure Prophylaxis (PrEP) is Underutilized

- 1.1 million individuals in United States are at substantial risk for HIV and should be offered PrEP (CDC)

- Estimated number of U.S. PrEP users, end-2018: 269,000 (AVAC PrEPWatch, 2/2019)
Diagnoses of HIV Infection, United States, 2012-2017

"Treat All" Policy Proves Effective in San Francisco

‘RAPID’ HIV Treatment Initiation a Success in San Francisco

Source: SF Dept. of Public Health
Cuomo Announces Plan to Cut New AIDS Cases in New York
New HIV Diagnoses in New York City, 2007-2017

Source: NYC DoH
December 1, 2016

Mayor Bowser Announces 90/90/90/50 Plan to End the District’s HIV Epidemic
New HIV Diagnoses in Washington, DC, 2007-2017

Source: DC Dept. of Health
Ending the HIV Epidemic: A Plan for the United States

FOCUS

Incidence "Hot Spots"
Demographic Hot Spots
Demographic Hot Spots of HIV Infection: United States

- U.S. Population: 13% Blacks/African Americans
- All New HIV Diagnoses: 43% Blacks/African Americans
- 60% are MSM
- 75% are under age 35

Geographic Hot Spots
Major Geographic and Demographic Disparities for HIV Incidence in the U.S.

- 3007 counties in the United States
- During 2016-2017, > 50% of new HIV infections occurred in 48 counties, Washington, DC and Puerto Rico
- Majority of new HIV infections among Black/African American and Hispanic/Latino MSM; high incidence among transgender individuals and IDUs
- 7 mostly southern states have a disproportionate occurrence of HIV in rural areas
U.S. Areas with the Highest Burden of HIV Diagnosis

- States with disproportionate rural burden of HIV in 2016/2017
- Counties contributing to 50% of new HIV diagnoses in 2016/2017

Source: CDC, June 2018
Longtime AIDS Researcher Robert Redfield Picked to Lead CDC
Trump Announces Goal of Ending HIV/AIDS Epidemic by End of Next Decade
Editorial

Ending the HIV Epidemic
A Plan for the United States

AS Fauci, RR Redfield, G Sigounas, MD Weahkee, and BP Giroir
Ending the HIV Epidemic: A Plan for America

**Goal:**
- 75% reduction in new HIV infections in 5 years and at least 90% reduction in 10 years.

- **Diagnose** all people with HIV as early as possible after infection.
- **Treat** the infection rapidly and effectively to achieve sustained viral suppression.
- **Protect** people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.
- **Respond** rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

**Logos:**
- CDC
- NIH
- Health Resources & Services Administration
- Indian Health Service
- SAMHSA
Roles of the HHS Agencies in the Plan

Overall coordination of the plan

Intensification of existing programs with communities, state and local health authorities for HIV testing, diagnosis, epidemiologic investigation of clusters and rapid linkage to HRSA Ryan White HIV/AIDS Program (RWHAP)

Accelerate RWHAP treatment and care for those with HIV and provide PrEP for those at risk through the HRSA Health Centers Program

Focus on urban and rural tribal communities to expand access to diagnosis, prevention and treatment of HIV

Focus on Minority AIDS Program and Substance Abuse Prevention and Treatment Block grants for HIV/AIDS prevention for those with substance abuse or mental illness

Implementation science: collect and disseminate data on the effectiveness of approaches used in the initiative and inform HHS partners on best practices
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U.S. Areas with the Highest Burden of HIV Diagnosis

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Source: CDC, June 2018
CFAR and ARC Sites and HIV Hotspots in the United States

- University of Washington/Fred Hutch
- Medical College of Wisconsin
- Third Coast (Northwestern/University of Chicago)
- Case Western Reserve University/University Hospitals of Cleveland
- Einstein-Rockefeller-CUNY
- University of Rochester
- Harvard University
- Providence/Boston (Lifespan/Tufts/BU)
- Yale University
- Columbia University
- Penn
- University of PA Children’s Hospital
- Wistar Institute
- Johns Hopkins University
- District of Columbia
- Duke University
- University of North Carolina, Chapel Hill
- Tennessee Vanderbilt/Meharry
- Emory University
- University of Miami
- University of Alabama at Birmingham

Legend:
- States with disproportionate rural burden of HIV in 2016/2017
- Counties contributing to 50% of new HIV diagnoses in 2016/2017
- Center for AIDS Research (CFAR) site
- AIDS Research Center (ARC) site

Source: CDC, June 2018
What is new and different about this initiative and why are we optimistic that it will succeed?

It is the first time that an accelerated effort to implement HIV treatment and prevention in the U.S. has been simultaneously undertaken by multiple HHS agencies focused on highly specific and concentrated target populations.
OPINIONS

No More Excuses. We Have the Tools to End the HIV/AIDS Pandemic.

Anthony S. Fauci