Director’s Report

124th Advisory Committee to the Director Meeting
June 9, 2022

Lawrence A. Tabak, DDS, PhD
Acting Director, NIH
Department of Health and Human Services
In Memoriam

Topics for Today

- Appointments and Departures
- Awards and Honorees
- Budget and Legislative Updates
- Initiative Updates
- Update on NIH Efforts to Redress (Sexual) Harassment
- Two Things that Keep Me Up at Night
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- Two Things that Keep Me Up at Night
Advisory Committee to the (NIH) Director
Acting Associate Deputy Director, NIH

Courtney Aklin, PhD

Acting Director of the Office of Science Policy

Lyric Jorgenson, PhD
Norman E. “Ned” Sharpless, MD
Director, National Cancer Institute
Acting Director, National Cancer Institute (NCI)

Doug R. Lowy, MD
Acting Director,
National Center for Advancing Translational Sciences

Joni L. Rutter, PhD
Acting Associate Director for Behavioral and Social Sciences Research; Acting Director of Office of Behavioral and Social Sciences Research

Christine Hunter, PhD, ABPP
Acting Associate Director for Communications and Public Liaison

Renate H. Myles
Acting Deputy Director of
Advanced Research Projects Agency for Health
(ARPA-H)

Adam Russell, DPhil
CEO,
Foundation for the NIH (FNIH)

Julie Louise Gerberding, MD, MPH
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Congratulations!
Service to America Medal Finalists

Diana W. Bianchi, M.D.
Director, NICHD
COVID-19 Response Finalist

H. Clifford Lane, M.D.
Deputy Director for Clinical Research and Special Projects, NIAID
Career Achievement Finalist
2022 RESEARCH AMERICA ADVOCACY AWARDS

JOHN EDWARD PORTER LEGACY AWARD, GENEROUSLY SUPPORTED BY ANN LURIE

Francis S. Collins, MD, PhD
Acting Science Advisor to the President; Senior Investigator, Center for Precision Health Research, National Human Genome Research Institute, NIH

OUTSTANDING ACHIEVEMENT IN PUBLIC HEALTH AWARD

Vivian W. Pinn, MD
Inaugural Director, Office of Research on Women’s Health, NIH (Retired)

RAPID TRANSLATION AWARD

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Elliot L. Richardson Prize for Excellence in Public Service

Francis Collins, MD, PhD

Anthony Fauci, MD
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House Appropriations Committee Hearing
Budget Update

NIH Director’s Report to the Advisory Committee to the Director
June 9, 2022

Neil K. Shapiro
Associate Director for Budget, NIH
FY 2022 Appropriations Action

• The consolidated appropriations bill, including Labor/HHS/Education, became law on March 15th after four continuing resolutions spanning nearly half the fiscal year.

• It provided NIH with the full-year discretionary appropriation, as well as creating the new Advanced Research Projects Agency for Health (ARPA-H).

• The Type 1 Diabetes mandatory funding was reauthorized last year, but it was reduced by $8.55 million (to $141.45 million) due to sequestration.
FY 2022 at a Glance

<table>
<thead>
<tr>
<th>($ in thousands)</th>
<th>FY 2021</th>
<th>FY 2022</th>
<th>Change from FY 2021 ($)</th>
<th>Change from FY 2021 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Program Level</td>
<td>$42,812,323</td>
<td>$46,177,990</td>
<td>+$3,365,667</td>
<td>+7.9%</td>
</tr>
<tr>
<td>ARPA-H (non-add)</td>
<td>$1,000,000</td>
<td>+$1,000,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- $3.4 billion increase over FY 2021 final budget.
- $1 billion for ARPA-H, which was transferred to NIH by the Department in April. The funds are available for obligation over three years.
- General increase for Institutes and Centers of 3.4 percent.
Highlights of Omnibus:
Largest Targeted Increases

- Alzheimer’s Disease $289 M
- NCI success rate 150
- HEAL Initiative 75
- BRAIN Initiative 60
- COVID-19 53
- NIMHD Health Disparities 50
- Buildings & Facilities 50
- All of Us Research Program 41
- Cybersecurity 40
### FY 2023 President’s Budget

<table>
<thead>
<tr>
<th>($ in thousands)</th>
<th>FY 2022</th>
<th>FY 2023 PB</th>
<th>Change from FY 2022 ($)</th>
<th>Change from FY 2022 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Program Level</td>
<td>$46,177,990</td>
<td>$62,502,703</td>
<td>+$16,324,703</td>
<td>+35%</td>
</tr>
<tr>
<td>ARPA-H (non-add)</td>
<td>$1,000,000</td>
<td>$5,000,000</td>
<td>+$4,000,000</td>
<td>+400%</td>
</tr>
<tr>
<td>Pandemic Prep. (non-add)</td>
<td>$12,050,000</td>
<td>+$12,050,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Released March 28th using the continuing resolution level for FY 2022 as the current-year baseline, rather than the omnibus that had just been enacted. Typically, it takes two months or more to develop the Budget.

- Some PB levels are close to or below the FY 2022 enacted level due to the size of the unanticipated congressional increase, not the Administration’s intent.
FY 2023 President’s Budget (cont.)

• Intended general increase of 2 percent for Institutes and Centers (over continuing resolution).

• Largest targeted increases
  - Opioids/Pain Research (inc. HEAL) $552M
  - Health Disparities 350
  - Climate Change 100
  - Nutrition Science 96
  - Cybersecurity 60
  - Buildings & Facilities 50
Pandemic Preparedness Proposal

- Preclinical R&D of prototype vaccines/therapeutics against high profile viral families ($4.0 billion)
- Expansion of laboratory capacity and pilot cGMP manufacturing ($2.35 billion)
- Development and clinical evaluation of vaccines and therapeutics ($2.0 billion)
- Establish, expand, and/or improve large and flexible clinical trials networks and infrastructure ($1.7 billion)
- Biosafety and biosecurity ($1.0 billion)
- Develop affordable, accessible, and novel diagnostics and innovations in early warning ($1.0 billion)
FY 2023 Appropriations Hearings

Themes Discussed:
- ARPA-H
- Success Rates
- Undiagnosed Diseases Network
- COVID-19
- RECOVER (Long COVID)
- Mental Health
- Alzheimer’s Disease
- School Closures during the pandemic
Congressional Areas of Interest

Events held by OLPA

<table>
<thead>
<tr>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
</table>
| • Topics  
  • COVID  
  • Grants  
  • RADx | • Topics  
  • COVID  
  • ARPA-H  
  • Diversity  
  • CTSAs  
  • Maternal Health & COVID  
  • RADx  
  • Opioids & COVID | • Topics  
  • COVID  
  • Mental Health  
  • Alzheimer’s Disease  
  • ALS  
  • Long COVID  
  • Diversity  
  • Women’s Health  
  • ARPA-H |

Over 50 events  
Over 300 events  
100 events so far...
Sexual Harassment Policy

- NIH will require notification by the NIH-funded institution within 30 days of removal or disciplinary action.
- Effective July 8, 2022.

SEC. 239. The Director of the National Institutes of Health shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.
ACT for ALS

- Implementation for the Accelerating Access to Critical Therapies for ALS Act (ACT for ALS)

- FOA posted May 12, 2022 to support research utilizing data from expanded access to investigational drugs and biological products for those otherwise not eligible for ALS clinical trials

- Grants available to phase 3 clinical trials sponsored by small businesses
Bayh-Dole Act

- Background
  - Facilitate US technological innovation by establishing a uniform set of federal rules
  - Enable universities/nonprofit research institutions/small business to own/patent/commercialize inventions supported, in part, by federal funds

- Two Areas of Congressional Interest
  - Use of march-in for drug pricing
  - Concerns about royalties paid to scientists for federally funded inventions.
Future Forecast: Must Pass Provisions

- FDA User Fee Agreements for medical products
  - Expires September 30, 2022
- Small Business Innovation Research Program and Small Business Technology Transfer (SBIR/STTR)
  - Sunsets September 30, 2022
- Appropriations
- Annual Defense Authorization
- ACA premium increase?
Future Forecast

May Pass Provisions

- ARPA-H Authorization
- Health Omnibus
- Pandemic Preparedness
- Cures 2.0
- U.S. Competes Act
Amendments to Watch

SEC. 30227. PROHIBITION ON FEDERAL FUNDING FOR CERTAIN GAIN-OF-FUNCTION RESEARCH BY A FOREIGN ADVERSARY.

(a) In General.—No Federal funds may be made available, whether directly or indirectly, or used by an entity, to conduct or support any gain-of-function research involving a potential pandemic pathogen by a foreign adversary, including—

(1) China, Russia, Iran, and North Korea; and

(2) any other country the Secretary of State, in consultation with the Secretary of Defense, the Director of National Intelligence, or any other appropriate Federal official, determines to be a foreign adversary for the purposes of this section.

(b) Funding Freeze for Violations.—Any entity the Secretary of State finds to have used Federal funds in violation of this section may not receive any Federal funding for a period of 5 years, beginning on the date of such finding.

(c) Prohibition.—

(1) In general.—No Federal funds authorized or made available pursuant to this Act may be used or expended to laboratories in China or other countries identified by the United States government as foreign adversaries to conduct gain of function research.
Congressional Confirmations

- President Announces Nomination
- Meetings with Members
- Senate HELP Committee Hearing
- Senate HELP Committee Vote
- Full Senate Confirmation Floor Vote

- NIH Director
- OSTP Director
Retirement Watch

- Who will retire in 2022?
- Leadership changes
- So far...
  - 33 Democrats
  - 23 Republicans

Senator Patrick Leahy
First elected in 1974

Senator Richard Burr
First elected in 1994

Senator Roy Blunt
First elected in 1997
The President’s party historically loses seats in the midterms.

Voter turnout higher than average in 2018, what will happen in 2022?

In 2021, there was record high campaign spending for an off-cycle year.

The Democratic majority in both Chambers is unusually narrow:
  - House (+10 Seats)
  - Senate (Even split)
Redistricting has changed the map.
NRCC targeting 72 Democrats in the House.
DCCC announced 40 “Districts in play”.

The disappearance of competitive districts will continue in 2022
Number of House seats for each party since 1996, according to FiveThirtyEight's partisan lean

<table>
<thead>
<tr>
<th>Year</th>
<th>SOLID D</th>
<th>COMPETITIVE D</th>
<th>HIGHLY COMPETITIVE</th>
<th>COMPETITIVE R</th>
<th>SOLID R</th>
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</thead>
<tbody>
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<td>88</td>
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<td>2014</td>
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<td>2016</td>
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<td>2018</td>
<td>137</td>
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<td>50</td>
<td>168</td>
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<tr>
<td>2020</td>
<td>140</td>
<td>39</td>
<td>40</td>
<td>68</td>
<td>168</td>
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<tr>
<td>2022</td>
<td>143</td>
<td>48</td>
<td>41</td>
<td>33</td>
<td>170</td>
</tr>
</tbody>
</table>
Most Senate races go the same way as state presidential votes.
Thank you
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President Biden Reignites the Cancer Moonshot

CANCER MOONSHOT

INITIATIVES 2017–2022

OVER

70

CONSORTIUMS
OR PROGRAMS

OVER

240

RESEARCH PROJECTS

NCI Investments
President Biden Reignites the Cancer Moonshot

Ambitious Goals Include:
• Reduce the death rate from cancer by at least 50 percent over the next 25 years
• Improve the experience of people and their families living with and surviving cancer— and, by doing this and more
• End cancer as we know it today
Rx and Illicit Drug Summit
HEAL Advances

• Discovery and validation of novel targets for safe & effective pain management
  o 2 patents for small-molecule modulators of pain receptors to treat chronic pain, migraine
  o Investigational New Drug, a first-in-class, non-additive drug candidate for treating chronic pain

• Novel therapies for opioid use disorder and overdose
  o 50+ compounds being developed, 23 INDs filed with FDA, study of opioid vaccine

• Devices targeting nerve signaling to treat pain and opioid use disorder
VPOTUS Maternal Health Action Plan Cabinet Meeting
Maternal Health Action by NIH

- NIH is committed to understanding and reducing maternal morbidity and mortality and disparities in maternal health
- In FY2021, NIH budget directed >$422 million to maternal health research with >$240 million specifically addressing maternal morbidity and mortality
- Increasing research by early-career and underrepresented researchers
- NIH-wide IMPROVE initiative—Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone
- NICHD supported studies leading to the first medicine, Orlissa, approved by the FDA to treat pain associated with endometriosis
Available data in the *All of Us* Research Program (as of May 16, 2022)

- **493,000+** Participants
- **338,000+** Participants who have completed initial steps of the program

*Plus: ~100k whole genomes + ~165K arrays*
All of Us’ Inclusion of Underrepresented Groups will Enhance Diversity of Genomic Studies

First genomic data set

- ~50% diverse by race/ethnicity,
- 80% underrepresented in biomedical research

All Global GWAS values from [www.gwasdiversitymonitor.com](http://www.gwasdiversitymonitor.com), Values current as of February 17, 2022
New Clinical Center Pharmacy Ribbon Cutting
New Clinical Center Pharmacy

Phase 1
May 2022
• Outpatient Pharmacy Opens

Phase 2
May 2022
• Unit-dose Pharmacy Opens

Phase 3
Fall 2022
• Intravenous Admixture Unit Opens
John Lewis National Institute of Minority Health Disparities (NIMHD) Research Endowment Revitalization Act of 2021
John Lewis National Institute of Minority Health Disparities (NIMHD) Research Endowment Revitalization Act of 2021

• The NIMHD Research Endowment Program (REP) aims to help institutions:
  o Build research infrastructure
  o Recruit, train, maintain a diverse student body and faculty

• Provides funding to the endowments of academic institutions (up to 5 years)—does not directly fund research projects

• Endowment funds must be invested and maintained for at least 20 years after the award period ends

• New law expands eligibility to include former NIMHD and HRSA Centers of Excellence
Research Focus of the NIH-BMGF Collaboration

- Sustained remission strategies
- Vaccinal effect
- Home assays detecting viral load
- HIV Reservoir

Shared Gene-based Strategies
- Vector tropism and efficiency
- Gene targeting
- *In vivo* delivery

- Epidemiology
- Point of care diagnostics
- Pilot infant screening
- Guideline-based care for infants with SCD

NIH-BMGF Collaboration
Project outcomes

**Phenotype data** (associated with genotype data)
- Demographic information
- Anthropometric data
- Disease and health related phenotype data

**Genomic data, human and pathogen**
- Sequence data (whole genome, exome, targeted)
- Genotyping chip array data
  - >60,000 samples run on H3Africa chip
- Epigenetic data
- Transcriptomic data

**Microbiome sequence data**
- Patient/sample phenotypes
- Non-human 16S rRNA sequence data for microbiome
- Non-human full genome sequence data for microbiome

**Qualitative data**
- Focus groups and surveys
- Deliberative workshops

**New discoveries:** novel genetic associations, risk factors, analysis methods, and research and training modalities (>650 publications and counting)
**Resources**

**Policies and guidelines:**
- H3Africa Guidelines for Community Engagement
- H3Africa Guidelines for Informed Consent
- Framework for African Genomics and Biobanking
- H3Africa Data Sharing, Access & Release Policy
- H3Africa Data and Biospecimen Access Committee Guidelines
- Recommendations for Feedback of Findings

**Regional Biorepositories:**
- Located in Nigeria, Uganda, and South Africa
- ISBR compliant
- Support for collection, processing, storage, retrieval, and shipping
- LIMS and catalog of samples
- Regional distribution, training & support
- Effective, affordable, & reliable regional courier shipping routes

**Research tools and products:**
- Phenotype harmonization
- Cardiovascular disease harmonized data
- Training modules and trained personnel
- Population genetics studies
- ADME study
- H3Africa genotyping array

**Bioinformatics Network:**
- 135TB genomic data stored
- 1.2 PB available for storage
- 80TB genomic data transferred
- 3432 cores for processing
- 18 computing facilities
- 4 containerized workflows

[www.h3abionet.org](http://www.h3abionet.org)
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H.R.2471 – Consolidated Appropriations Act, 2022
Section 239: “The Director of the [NIH] shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.”
### Characteristics of harassment cases reported to NIH Office of Extramural Research

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N (%)</td>
<td>33 (6.9)</td>
<td>110 (23.0)</td>
<td>108 (22.6)</td>
<td>160 (33.5)</td>
<td>67 (14.0)</td>
</tr>
<tr>
<td>Allegation: Sexual Harassment Only</td>
<td>16 (48.5)</td>
<td>57 (51.8)</td>
<td>36 (33.3)</td>
<td>56 (35.0)</td>
<td>10 (14.9)</td>
</tr>
<tr>
<td>Allegation: Sexual Harassment Plus Other</td>
<td>12 (36.4)</td>
<td>30 (27.3)</td>
<td>19 (17.6)</td>
<td>28 (17.5)</td>
<td>2 (3.0)</td>
</tr>
</tbody>
</table>
## Findings and Outcomes of Harassment Cases Reported to NIH Office of Extramural Research (2018- May 2022)

<table>
<thead>
<tr>
<th>Finding/Outcome</th>
<th>Sexual Harassment Only</th>
<th>Sexual Harassment Plus Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N (%)</td>
<td>175 (36.6)</td>
<td>91 (19.0)</td>
</tr>
<tr>
<td>Contact with Institution</td>
<td>131 (74.9)</td>
<td>67 (73.6)</td>
</tr>
<tr>
<td>Formal Investigation</td>
<td>114 (65.1)</td>
<td>58 (63.7)</td>
</tr>
<tr>
<td>Allegation Substantiated</td>
<td>61 (34.9)</td>
<td>23 (25.3)</td>
</tr>
<tr>
<td>Principal Investigator Removed</td>
<td>52 (29.7)</td>
<td>14 (15.4)</td>
</tr>
<tr>
<td>Other Grant Actions</td>
<td>16 (9.1)</td>
<td>13 (14.3)</td>
</tr>
<tr>
<td>Left Institution</td>
<td>54 (30.9)</td>
<td>22 (24.2)</td>
</tr>
<tr>
<td>Removed from Peer Review</td>
<td>90 (51.4)</td>
<td>36 (39.6)</td>
</tr>
</tbody>
</table>
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## Funding by Ranks
### FY2021, Domestic Non-Profits

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Funding ($Billion)</th>
<th>Percent Total Funding</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 20</td>
<td>11.83</td>
<td>36.36</td>
<td>36.36</td>
</tr>
<tr>
<td>21 to 50</td>
<td>7.53</td>
<td>23.14</td>
<td>59.5</td>
</tr>
<tr>
<td>51 to 100</td>
<td>5.73</td>
<td>17.61</td>
<td>77.11</td>
</tr>
<tr>
<td>101 to 200</td>
<td>4.69</td>
<td>14.41</td>
<td>91.52</td>
</tr>
<tr>
<td>200 and up</td>
<td>2.76</td>
<td>8.48</td>
<td>100</td>
</tr>
</tbody>
</table>

Data from RePORT, [Awards by Location](#)
Non-profits only (N=1026)
Total FY2021 funding = $32.54 Billion
(Lack of) Trust in Science

Misinformation in and about science

Jevin D. West\textsuperscript{a,1} and Carl T. Bergstrom\textsuperscript{b}

\textsuperscript{a}Information School, University of Washington, Seattle, WA 98195; and \textsuperscript{b}Department of Biology, University of Washington, Seattle, WA 98195

Humans learn about the world by collectively acquiring information, filtering it, and sharing what we know. Misinformation undermines this process. The repercussions are extensive. Without reliable and accurate sources of information, we cannot hope to halt climate change, make reasoned democratic decisions, or control a global pandemic. Most analyses of misinformation focus on popular and social media, but the scientific enterprise faces a parallel set of problems—from hype and hyperbole to publication bias and citation misdirection, predatory publishing, and filter bubbles. In this perspective, we highlight these parallels and discuss future research directions and interventions.
NIH...

Turning Discovery Into Health

Lawrence.Tabak@nih.gov
@NIHDirector/Twitter