Director’s Report

125th Advisory Committee to the Director Meeting
December 8, 2022

Lawrence A. Tabak, DDS, PhD
Performing the Duties of the NIH Director
Department of Health and Human Services
Topics for Today

- Appointments and Departures
- Awards and Honorees
- Special Events
- ESI Update
- eRA Update
- DEIA Strategic Plan Update
- Initiatives Updates
- Budget and Legislative Updates
- Reflection: Leading Through Turbulent Times
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ACD Departures

Wendy Chapman, Ph.D
University of Melbourne

Rebekah Drezek, Ph.D.
Rice University

Kristina Johnson, Ph.D.
Ohio State University

Dina Katabi, Ph.D.
Massachusetts Institute of Technology

Judith Kimble, Ph.D.
University of Wisconsin, Madison
Departure:
Director, National Institute of Allergy and Infectious Diseases

Anthony S. Fauci, MD
Selected:
Acting Director of NIAID

Hugh Auchincloss, MD
Departure:
Director, Center for Information Technology,
and NIH Chief Information Officer

Andrea Norris, MBA
Selected:
Acting Director, Center for Information Technology

Ivor D’Souza
Departure:
Director, Fogarty International Center

Roger Glass, MD, PhD
Selected:
Acting Director, Fogarty International Center

Peter Kilmarx, MD
Departure:
NIH Deputy Director and Director, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

James M. Anderson, MD, PhD
Selected:
Acting Director, Division of Program Coordination, Planning, and Strategic Initiatives

Bob Eisinger, PhD
Departure:
Chief Scientific Officer, Scientific Director of the NIH Clinical Center, Associate Director for Clinical Research in the Office of Clinical Research, OD

John Gallin, MD
Departure:
Director, NIH Office of Strategic Coordination

Elizabeth (Betsy) Wilder, PhD
Appointment:
Director, National Center for Advancing Translational Sciences

Joni L. Rutter, PhD
Appointment:
Deputy Director, Intramural Research

Nina Schor, MD, PhD
Appointment:
Director, National Cancer Institute

Monica M. Bertagnolli, MD
Appointment:
Inaugural Director,
Advanced Research Projects Agency for Health (ARPA-H)

Renee Wegrzyn, PhD
Appointment:
Director, Office of Equity, Diversity, and Inclusion

Kevin Williams, JD
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Nobel Prize in Chemistry 2022

Carolyn R. Bertozzi, PhD
Prize share: 1/3

K. Barry Sharpless, PhD
Prize share: 1/3
Lasker Awards
2022 Basic Medical Research Award

Richard O. Hynes, PhD

Erkki Ruoslahti, MD, PhD

Timothy A. Springer, PhD
Service to America Awards 2022
Paul A. Volcker Career Achievement

H. Clifford Lane, MD
NIAID
2022 National Academy of Medicine
New Members

Carlos Blanco, MD, PhD
NIDA

Eugene V. Koonin, PhD
NCBI, NLM

Bruce J. Tromberg, PhD
NIBIB

Jennifer Webster-Cyriaque, DDS, PhD
NIDCR, NIAID
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NIH’s goal is to fund 1100 ESI per year.

In 2022, NIH funded a record 1589 ESI applicants.

Early Stage Investigators (ESI) Funded on First R01-Equivalents

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- In 2022, NIH funded a record 1589 ESI applicants.
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Improving Quality of Public Information about R&D Contracts

• R&D contract awards represent ~8% of the NIH budget
• Current public data on R&D contracts lacks the richness of grants data
• Later this year, NIH will begin requiring extramural R&D contract awardees to upload information about the science being done into eRA Commons
• The new process will:
  • Allow contract awardee to accurately characterizes contracts
  • Improve transparency into contract data, commensurate to grants
  • Replace manual process of uploading information by NIH staff
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Objective 1: Grow and Sustain DEIA through Structural and Cultural Change

Objective 2: Implement Organizational Practices to Center and Prioritize DEIA in the Workforce

Objective 3: Advance DEIA through Research
Process & Timeline

- **Summer 2021**
  - **Phase 1**: Planning & WG Launch
  - **Phase 2**: Strategic Plan Framework
  - **Phase 3**: Public & NIH Input
  - **Phase 4**: Framework Refinement, Content Selection, & Drafting Process
  - **Phase 5**: Review & Approval of Strategic Plan

- **Fall 2022/Winter 2023**: WE ARE HERE
Current Status

Community Input
- Internal NIH
- External community

Review and Approval Process
- Pending final sign-off by NIH Leadership

Plan Implementation
- Comprehensive, inclusive, and intentional approach to implementation
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Eating, Sleeping and Consoling for Neonatal Opioid Withdrawal
A Randomized Controlled Trial
Background and Objective

• Neonatal opioid withdrawal syndrome (NOWS) follows *in utero* opioid exposure
  o Opioid epidemic ➔ high incidence of NOWS
  o Newborns are irritable, do not eat or sleep well, spend many days in hospital
  o If symptomatic enough, clinicians traditionally treat with replacement opioids

• Substantial variation in management of NOWS
  o No evidence-based standard of care

• Objective: Effectiveness and safety of new approach vs. usual care
  o Simpler assessment—Eat, Sleep, Console
  o Prioritize non-pharmacologic care, e.g., holding, swaddling, rocking
  o Caretaker involvement
Study Design

• Collaboration across 2 NIH pediatric clinical trial networks
  o Office of the Director and NICHD

• Stepped wedge cluster randomized trial
  o Randomly allocated 26 hospitals to transition from usual care to Eat, Sleep, Console care at designated time

• Whole of practice change
  o Trained ~5000 nurses

• Led by 3 Early Stage Investigators
Results, Conclusions, Next Steps

• Eat, Sleep, Console care approach
  o Substantially decreased time until infants medically ready for discharge from hospital
  o Substantially decreased pharmacologic treatment
  o Did not affect safety outcomes through 3 months of age
  o Provides strong support for standard care for NOWS

• Presented at national meeting Dec 5, 2022
• Manuscript under review
• Next
  o 2-year follow-up for family wellbeing, child neurodevelopment
Goals:

• to enhance the participation and representation of researchers and communities currently underrepresented in the development of artificial intelligence and machine learning (AI/ML) models
• to address health disparities and inequities using AI/ML
• to improve the capabilities of this emerging technology, beginning with the use of electronic health record (EHR) and extending to other diverse data

https://aim-ahead.net/
https://datascience.nih.gov/artificial-intelligence/aim-ahead
AIM-AHEAD Accomplishments

- **22 Research Fellowships** awarded in 2022, engaging early-career researchers from under-represented populations in biomedical research that involves the use of AI/ML methodologies on Electronic Health Record Data.
- **25 Leadership Fellowships** awarded in 2022, preparing a diverse leaders to champion the use of AI/ML in addressing persistent health disparities.
- **27 PRIME training practicum** awards made in 2022, enhancing technical competencies in AI/ML for graduate students from MSIs.
- **46 Professional Development awards** made in 2022 to underrepresented health care workers to enhance awareness and understanding of AI and health equity.
- **22 Pilot research projects** awarded in 2022, to test new paradigms of research, data analysis, and the new ways for underrepresented groups to derive value from their own health data.
- **AIM-AHEAD connect** platform launched as virtual hub for research at the intersection of AI/ML and health equity.
- Numerous **webinars** and symposia, including AI for Health Equity (**AIEHS 2022**)
## Consortium Development Pilot Projects

The AIM-AHEAD Coordinating Center supports a range of pilot projects deemed to address high priority opportunities in AI/ML and health equity.

<table>
<thead>
<tr>
<th>#</th>
<th>Institutions/Organization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>University of Puerto Rico</td>
<td>Identify reference intervals of cardiometabolic related laboratory tests for Hispanic populations using Machine Learning Methods (MLM)</td>
</tr>
<tr>
<td>2</td>
<td>Kula no na ‘O Pe Hawai‘i a Papakolea, Kukui‘u, Kalawahi University of Hawai‘i at Manoa Hawai‘i Pacific University Ulu Hi Tech</td>
<td>Ka Muu o Moanaui: Bridging the cardiometabolic diseases gap in the US Affiliated Pacific Islands (USA-PI) by providing AI/ML tools to Community Health Workers</td>
</tr>
<tr>
<td>3</td>
<td>University of Hawai‘i at Manoa</td>
<td>Leveraging AI and Machine Learning to address intersex under-diagnosis/under-recognition</td>
</tr>
<tr>
<td>4</td>
<td>Medical Decision Logic, Inc. Nah Tah Wahsh Hennepin High School Michigan Department of Education Prince George’s County Public Schools</td>
<td>Establishing student project capabilities to improve suicide prevention (PROTECT): Rich data access, ML algorithm optimization, translation to practice</td>
</tr>
<tr>
<td>5</td>
<td>Houston Methodid Research Institute University of Houston</td>
<td>Using Artificial Intelligence to improve cardiometabolic health: Validating a kidney transplant denials index to predict transplant drop-out risk for African American and Hispanic patients</td>
</tr>
<tr>
<td>6</td>
<td>University of Florida College of Medicine - Jacksonville</td>
<td>Conducting research leveraging AIM-AHEAD centralized patient-level data resource - Outpatient Opioid use and consequences</td>
</tr>
<tr>
<td>7</td>
<td>Accelirate</td>
<td>Culturally tailored participatory action research (CURATOR) to identify AI/ML applicable health disparities approach</td>
</tr>
<tr>
<td>8</td>
<td>Alexandria City Public Schools George Washington University</td>
<td>AI for You: Data mining to improve mental health through shared decision-making in minority adolescents and their parents</td>
</tr>
<tr>
<td>9</td>
<td>Emory University</td>
<td>Radiology AI/ML to address disparities in cardiometabolic diseases and cancer research through the AIM-AHEAD Consortium</td>
</tr>
<tr>
<td>10</td>
<td>University of Miami Florida Atlantic University Carolod Center</td>
<td>Developing a precise, localized, community focused, population health framework in an FQHC to tackle chronic disease disparities through EHR data</td>
</tr>
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<tr>
<td>11</td>
<td>Vibrant Health Association of Community Cancer Centers Loyal Jones Appalachian Center at Berea College</td>
<td>Stratifying health care biases and determinants of high cancer death rates in rural Appalachia by AI/ML facilitated EHR data Analytics</td>
</tr>
<tr>
<td>12</td>
<td>Providence</td>
<td>Leveraging the Center for Kidney Disease Research, Education, and Hope (CURE-CKD) Registry as a toll to reduce cardiometabolic disparities</td>
</tr>
<tr>
<td>13</td>
<td>Baylor College of Medicine</td>
<td>Building AI/ML algorithm to predict and prevent cancer treatment complications in underserved and minority patients in a metropolitan catchment area</td>
</tr>
<tr>
<td>14</td>
<td>University of North Texas</td>
<td>Evaluating bias in predictive and explainable ML algorithms among older adults with cancer</td>
</tr>
<tr>
<td>15</td>
<td>University of Colorado Denver University of California, Irvine</td>
<td>Cardiometabolic risk prediction among American Indian and Alaska Native (AI/AN) adult using machine learning (ML) approaches and electronic health record (EHR) data</td>
</tr>
<tr>
<td>16</td>
<td>Norwich University</td>
<td>Modeling exposure to gun violence and trajectory of behavioral health outcomes</td>
</tr>
<tr>
<td>17</td>
<td>University of Miami Florida Memorial University Miami Dade College</td>
<td>Creating an educational AI/ML-based infrastructure and job readiness (CAIR) program to increase workforce diversity and professional development amongst URM faculty and students</td>
</tr>
<tr>
<td>18</td>
<td>MedCottage, Inc.</td>
<td>Racially unbiased Artificial Intelligence (AI) algorithms for breast cancer detection</td>
</tr>
<tr>
<td>19</td>
<td>American Samoa Community Cancer Coalition University of Hawai‘i Cancer Center</td>
<td>A pilot study assessing AI/ML models to increase colorectal cancer detection for indigenous American Samoa adults</td>
</tr>
<tr>
<td>20</td>
<td>University of Hawai‘i at Manoa</td>
<td>Machine learning (ML) - based approaches to understand lung cancer health disparities by integrating genomics and health record data</td>
</tr>
<tr>
<td>21</td>
<td>University of Georgia</td>
<td>Improving prediction of beneficiary-level medical costs by incorporating social determinants of health indicators in risk adjustment models to address health disparities: A machine learning approach</td>
</tr>
</tbody>
</table>
All of Us Enrollment Update as of December 5, 2022

- **559,000+** Participants
- **339,000+** Electronic Health Records
- **393,000+** Participants who have completed initial steps of the program
- **411,000+** Biosamples

### Diversity
- Includes racial and ethnic minorities as well as sexual and gender minorities, people with low income or limited education, and other groups.

- **50%+** Racial and Ethnic Minorities
- **80%+** Underrepresented in Biomedical Research

COVID-19 in-person enrollment pause
In-person enrollment restart
Genomic Health-Related Return of Results in Pilot Testing

- **Hereditary disease risk** (starting with ACMG59) and **medicine and your DNA** (pharmacogenomics)
- Participants can choose results they want
- Interpretation begins at Clinical Validation Laboratories
- All results supported by Genetic Counselors
- Participants can obtain clinical results available for ACMG59 at no cost
All of Us Researcher Workbench Usage and Diversity

Research on the Researcher Workbench

3,600+ Registered Researchers
3,099+ Active Projects
100+ Publications using All of Us data

435+ Organizations:
- 28 Historically Black Colleges & Universities
- 36 Hispanic Serving Institutions

Race/Ethnicity
- Black or African American
- AI/AN
- Asian
- White
- Two or More Races
- None of These
- Describe Me (Race)
- Hispanic or Latino
- NHPI

Career Level
- Undergraduate Trainee
- Graduate Trainee
- Research Fellow
- Early Career Tenure Track Researcher
- Mid-Career Tenure Track Researcher
- Late Career Tenure Track Researcher
- Senior Researcher
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Budget Update

NIH Director’s Report to the Advisory Committee to the Director
December 8, 2022

Neil K. Shapiro
Associate Director for Budget, NIH
FY 2023 So Far

- Currently under a Continuing Resolution
  - First through December 16, 2022.
  - Second expected, into at least early January.
  - Funding level is FY 2022 enacted, prorated for the time period.
- Congress is working on an omnibus, which may include both annual and supplemental appropriations.
- Type 1 Diabetes mandatory funding is already appropriated for FY 2023 but reduced by 5.7 percent (from $150 to $141.45 million) due to sequestration.
Appropriations Action: House

- FY 2023 bill was approved by Subcommittee on June 23 and full Committee on June 30. It was not included in a consolidated bill that passed the House in July.
- Includes a $2.5 billion increase over FY 2022 for NIH Institutes and Centers.
- Across-the-board increase of at least 3.2 percent, as well as targeted increases for several research areas.
- ARPA-H is funded at $2.75 billion, a $1.75 billion increase over FY 2022, but in HHS without authority to transfer to NIH.
Appropriations Action: Senate

• FY 2023 bill recommended by the Subcommittee Chair was released on July 28.
• Funding level for NIH is $2 billion above FY 2022.
• Across-the-board increase of at least 3.1 percent, as well as targeted increases for several research areas.
• ARPA-H is funded at $1 billion, the same level as FY 2022, within NIH.
• Includes $16 billion of emergency supplemental funding to HHS for COVID-19, including development of next-generation vaccines.
## FY 2023 Comparison

<table>
<thead>
<tr>
<th>$ in billions</th>
<th>FY 2022 Enacted</th>
<th>FY 2023 PB</th>
<th>FY 2023 House</th>
<th>FY 2023 Senate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Level*</td>
<td>45.18</td>
<td>45.45</td>
<td>47.68</td>
<td>47.18</td>
</tr>
<tr>
<td>+/- FY 2022</td>
<td>+0.27</td>
<td>+2.50</td>
<td></td>
<td>+2.00</td>
</tr>
<tr>
<td>ARPA-H</td>
<td>1.00</td>
<td>5.00</td>
<td>2.75</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*less ARPA-H and the Pandemic Preparedness mandatory proposal

- The Pandemic Preparedness proposal ($12.05 billion) has not advanced in Congress, but more emergency supplemental funding has been requested for HHS to respond to COVID-19, including Long COVID.
# FY 2023 Targeted Increases

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<th>FY 2023 PB</th>
<th>FY 2023 House</th>
<th>FY 2023 Senate</th>
</tr>
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<tr>
<td>Opioids/pain (inc. HEAL)</td>
<td>552</td>
<td>98</td>
<td>140</td>
</tr>
<tr>
<td>Health disparities</td>
<td>350</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
<td>--</td>
<td>200</td>
<td>--</td>
</tr>
<tr>
<td>Buildings &amp; Facilities</td>
<td>50</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Nutrition Science</td>
<td>96</td>
<td>39</td>
<td>24</td>
</tr>
</tbody>
</table>

- Several of the NIH priorities with initiative funding in the President’s Budget received support from both House and Senate.
Legislative Update

Adrienne Hallett
Associate Director for Legislative Policy & Analysis
December 8, 2022
Lame Duck Legislation

- FY 2023 Appropriations - government funding expires Dec. 16, 2022
- National Defense Authorization Act (NDAA)
- Other Health Provisions - FDA technical fixes; Pandemic Preparedness; ARPA-H authorization
- Debt limit?
2022 Midterm Election Outcomes

Voters Sought Stability and Incumbents Won

**Senators**

100 % of incumbents won

51D – 49R

**House**

97 % of incumbents won

219R – 212D

*Races still pending
Majority = 218

**Governors**

98 % of incumbents won

26R – 24D
118th Congress

• Convenes on January 3, 2023

• Each Congress rebuilds itself – new rules and orders are made
  • Leadership elections
  • Committee assignments and leaders determined

• New Majority in the House – rules to watch:
  • Remote and proxy voting debate
  • Term limits debate for committee chairs and ranking members
  • Debate on whether and how to allow earmarks
  • Debate on rule change for removing the Speaker
Majority Size Matters

• Narrow margins of control in both Chambers.

• House – 1-vote majority empowers caucuses
  • Freedom Caucus ~50 members
  • Republican Governance (Tuesday Group) ~45 members
  • Problem Solvers ~50 bipartisan members
  • Blue Dog Democrats ~20 members
  • Progressive Caucus ~100 members

• Senate Majority – Democrats gained 1 seat
  • Determines Committee power structure and subpoena power.

Narrow margins empower factions
Congressional Leadership - Democrats

Generational shift for House Democrats.

Rep. Pete Aguilar
Democratic Caucus Chair

Rep. Hakeem Jeffries
Minority Leader

Rep. Katherine Clark
Minority Whip
Congressional Leadership - Democrats

Pressure on the Senate to follow suit...

Sen. Chuck Schumer
Majority Leader

Sen. Dick Durbin
Majority Whip

Sen. Patty Murray
President Pro Tempore
Congressional Leadership - Republicans

Election for the new Speaker of the House in January.

Rep. Kevin McCarthy
Speaker?

Rep. Steve Scalise
Majority Leader

Rep. Tom Emmer
Majority Whip
Congressional Leadership - Republicans

Senate.

- Sen. Mitch McConnell
  Minority Leader
- Sen. John Thune
  Minority Whip
- Sen. John Barrasso
  Republican Conference Chair
New Leadership of Health Policy Panel
New Priorities

“...will focus on universal health care, lowering the cost of prescription drugs, increasing access to higher education, and protecting workers’ right on the job”
~Senator Bernie Sanders (expected Chairman of HELP)

“HELP passed the Surprise Medical Billing bill. The administration has not implemented it well. I’d like to have oversight over surprise medical billing.”
~Senator Bill Cassidy (expected Ranking Member of HELP)
House Leaders Proclaiming a Renewed Focus on Oversight

“The American people deserve the facts. Part of our constitutional duty, when I take the oath of office on Jan. 3 in a new Congress...is to do those investigations, do the oversight so the people, we the people, get the facts, get the truth.

~ Rep. Jim Jordan (expected Chairman of House Judiciary)

“We believe that there have been hundreds of billions, if not trillions of dollars wasted over the past three years, so that spans two administrations, in the name of COVID. We want to have hearings on that.”

~Rep. James Comer (expected Chairman of House Oversight)
House Leaders Proclaiming a Renewed Focus on Oversight

“How the pandemic started, that’s probably the most important public health question that needs to be answered.”


Stated Priorities

1. Afghanistan
2. Hunter Biden
3. COVID-19 Response and Origins
NIH Priorities for the 118th Congress

1. Introducing NIH broadly
   - Record number of retirements the last 3 election cycles.
   - Newer Members only know NIH from COVID and controversy

2. Develop champions for programs and policies
   - General support for scientific and public health priorities
   - Additional knowledge for sensitive topics, such as:
     - animal research, genomic data sharing, international collaboration.

3. NIH Director nominee?
Questions?
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NIH...
Turning Discovery Into Health

Lawrence.Tabak@nih.gov
@NIHDirector/Twitter