COSSA Town Hall:
Understanding Current NIH Reform Proposals

Featuring: Wendy Naus, COSSA Executive Director

September 12, 2024

Stand by, we will begin momentarily.

*"To promote the value of social and behavioral science research to policymakers and the public with the goal of **enhancing federal support**."*

Our Priorities:

- Advocate for robust, sustained **funding** for federally supported social and behavioral science research, and STEM research and education more broadly.
- Support and strengthen the federal **statistical and data enterprise**.
- **Expand the use** of social and behavioral science and data in policymaking.
- Equip and provide **opportunities for members** of the SBS community to become advocates themselves.

Membership Organizations

Academy of Criminal Justice Sciences
African Studies Association
American Association of Geographers
American Council of Learned Societies
American Evaluation Association
American Historical Association
Association for Behavioral and Cognitive Therapies
Association for Public Policy Analysis and Management
Association of Academic Survey Research Organizations
Association of American Law Schools
Association of Research Libraries
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Midwest Sociological Society
National Association of Social Workers
National Communication Association
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Southern Political Science Association
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Southern Political Science Association
Southwestern Social Science Association

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The Context

- Republicans claim NIH is losing bipartisan support in Congress due to agency's response to COVID-19.

- House Select Subcommittee on the Coronavirus Pandemic continues to hold hearings critiquing and criticizing NIH (i.e., NIAID and Fauci).

- Some Members of Congress contend it will be hard for NIH to receive funding increases without reform.

"Dr. Fauci showed no remorse for the millions of lives affected by his divisive rhetoric and his unscientific policies."

- June 2024 Select Subcommittee Hearing

Congressional Response

- **September 2023:** Sen. Bill Cassidy, M.D. (R-LA), Ranking Member of HELP Committee, issues RFI

- **May 2024:** Sen. Cassidy releases white paper based on feedback received

- **June 2024:** Rep. Cathy McMorris Rodgers (R-WA), Chair of House Energy & Commerce Committee, releases framework

- **June 2024**: Rep. Robert Aderholt (R-AL), Chair of LHHS Appropriations Subcommittee, includes framework in FY 2025 appropriations bill

- **June 2024:** Rep. Diana DeGette (D-CO) and Rep. Larry Bucshon, M.D. (R-IN) issue RFI on Next Generation Cures Bill
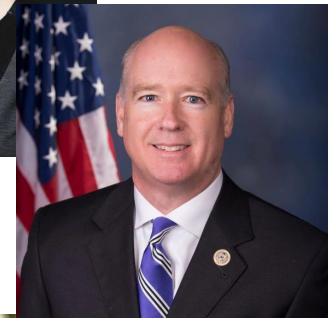
Past NIH Authorizations

- NIH Reform Act of 2006 (became law in 2007)
  - Scientific Management Review Board, Council of Councils
  - Created Common Fund
  - Established RePORT – electronic system for reporting and categorizing funded research
- 21st Century Cures Act (enacted in 2016) – Expired FY 2020
  - Rep. DeGette (D-CO) and Rep. Fred Upton (R-MI)
  - Built on NIH Reform Act
  - Included funding for specific cross-NIH, large-scale research initiatives (All of Us, BRAIN initiative, Cancer Moonshot, Regenerative Medicine)
- Authorized through appropriations since

Authorization vs. Appropriations

- Authorization bills:
    - Create and/or continue agencies, programs or activities.
    - "Authorizes" the enactment of appropriations – sets funding parameters/caps or "such sums."
    - The authorization-appropriation process is set by House and Senate rules.
    - NIH Reform Act of 2006 was an *authorization* bill.

- Appropriations bills:
    - Cut the check – allocate federal funding to agencies and programs for each fiscal year.
    - Power over appropriations is granted to Congress in the U.S. Constitution.
    - The FY 2025 Labor, HHS, Education Appropriations bill is an *appropriations* bill.

> "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time."
>
> *- Article I, Section 9, Clause 7 of the U.S. Constitution*

Cassidy Request for Information

- Cassidy issued RFI in September 2023, seeking feedback on current NIH activities and statutory framework; stakeholders submitted comments in October.

"NIH and its officials became a lightning rod for partisan debates during the COVID-19 pandemic response, eroding public trust in the institution and distracting from its core mission. Congress should work with NIH and stakeholders to modernize the agency so it is more transparent, nimble, and forward-thinking."

- *Cassidy RFI, September 2023*
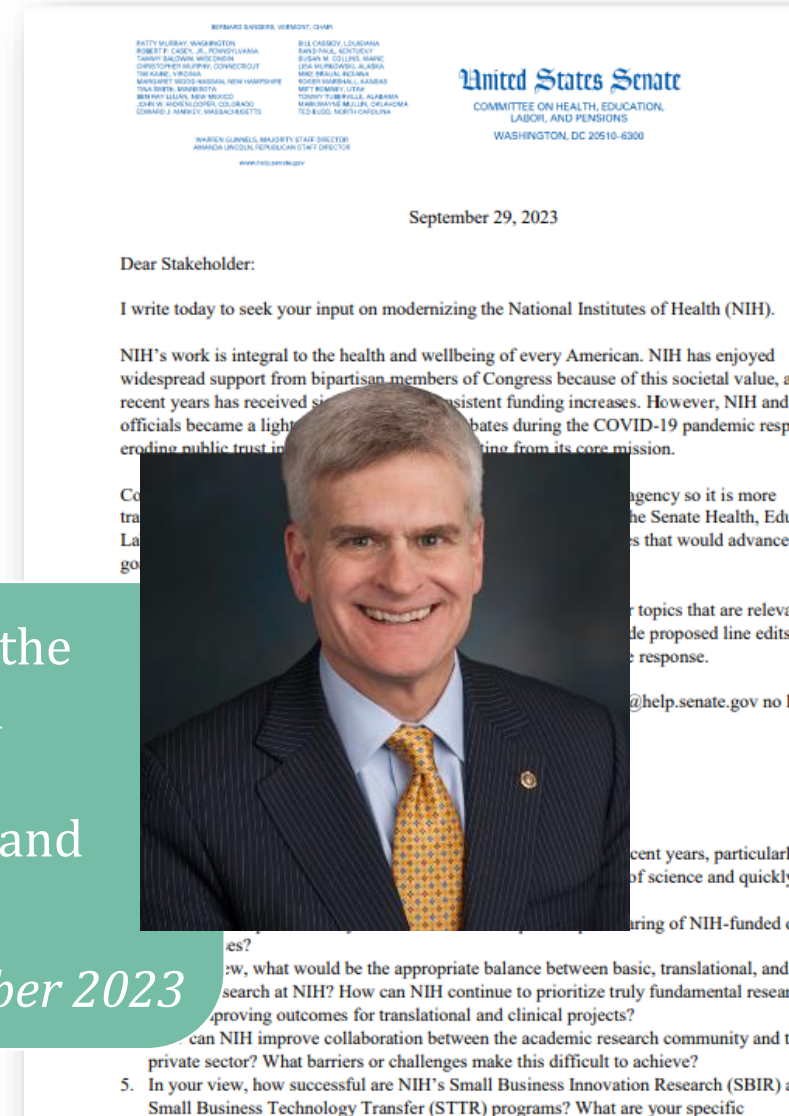
Community Response to RFI

1. NIH requires a robust and sustainable budget.

2. Basic science must be a central funding priority.

3. Strong support for the current peer review process, tweaks may be necessary.

4. Concerns around public access costs and publishing.

5. Enhance diversity, equity and inclusion in extramural research funding.

Community Response to RFI

6. Time from application to award is too long.

7. Support for the Common Fund
   - ARPA-H should complement, not replace, NIH's high-risk, high-reward activities.

8. Improve interagency collaboration and policy standardization.

9. Caution against Congress being too directive with funding.

10. Support for parent reseachers.

11. Increase field and institution-type diversity on advisory councils; greater transparency on the selection of IC council members; seek nominations from the public.

Cassidy White Paper

- White paper released in May 2024 using input received from stakeholders.

- Themes:
  - Maximizing the Effectiveness of Current NIH Funding
  - Sustaining the U.S.' Competitive Advantage in Biomedical Research
  - Restoring Public Trust in Science

> "Public sentiment toward scientific institutions has degraded in recent years, exacerbated by a perceived lack of transparency and concerns about political biases during the COVID-19 pandemic responses."
>
> - *Cassidy White Paper, May 2024*

NIH IN THE 21st CENTURY: ENSURING TRANSPARENCY AND AMERICAN BIOMEDICAL LEADERSHIP

Senate Committee on
Health, Education, Labor & Pensions
Senator Bill Cassidy, M.D., Ranking Member
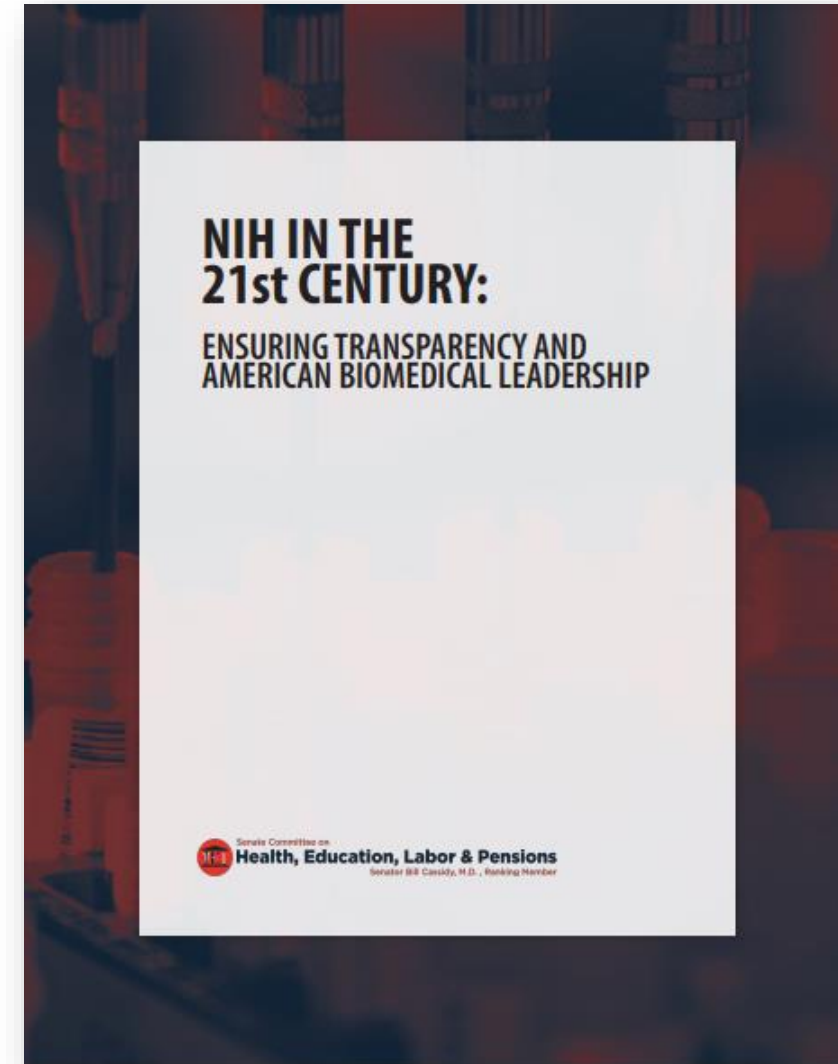
Recommendations

- Balancing NIH's portfolio:
  - Concern about growth in applied research (45% in FY 2022 compared to 38% in FY 2009)
  - Concern that increase in translation/clinical research will come at the expense of basic/fundamental research and investigator-initiated projects.
  - Balanced needed with respect to targeted research vs. investigator-initiated.

"The U.S. Government plays a unique role in supporting basic discovery, which enables long-term biomedical innovation… Unlike certain areas of clinical research, the private sector would not be equipped to fill gaps in support for basic research."

- Cassidy White Paper, May 2024

Recommendations (2)

- Reducing redundancy and finding efficiencies:
  - Duplication among IC research portfolios
  - Redundant research infrastructure across ICs (e.g., clinical trial networks)
- Learning from scientific successes and failures:
  - More granular data is needed about how specific proposals fare through the peer review process and are ultimately selected or rejected
  - Consider strategies to encourage the voluntary sharing of negative results (e.g., a negative results repository within NLM)

Recommendations (3)

- Incentivizing innovation:
  - Pilot approaches to change the application and peer review process:
    - Putting more "generalists" on study sections.
    - Regularly reviewing the focus and membership of study sections to align with current science.
    - Improve training for peer reviewers.
    - Streamline application process (e.g., methodology and preliminary results).
  - Consider using NSF's "rotator" model to allow for temporary program officers.

Recommendations (4)

- Supporting the biomedical research workforce:
  - "Severe structural problems in how government and academia together finance biomedical researchers" (e.g., salaries, training/fellowship costs, etc.)
  - Congress and NIH should identify options to ensure each provide "appropriate degrees of support for federally funded academic researchers."

- Reimagining the Intramural Program:
  - Intramural program may perform research similar/same as projects funded through the extramural program.
  - Consider developing a decadal survey for the intramural program.

Recommendations (5)

- Ensuring transparency into NIH operations:
  - Lack of engagement with Congressional oversight requests related to COVID-19 response.
  - Lack of engagement of SMRB & ignoring recommendation to consolidate NIDA/NIAAA.
  - Reconstitute SMRB

- Promoting research integrity:
  - Concerns about HHS's Office of Research Integrity's capacity to identify or prevent research misconduct – needs strengthening.

- Adhering to grants management processes:
  - Cites HHS OIG reports on deficiencies in NIH oversight of award recipient compliance.
  - Balance needed to ensure oversight without additional administrative burden.

Community Comments NOT Addressed

- The need to increase annual appropriations for NIH/loss of purchasing power/keeping up with inflation

- Workforce diversity/DEI – including women and parents

- Public access/publishing

- Indirect costs (F&A)

- Interagency collaboration

- Research with animals

Next Steps

- Sen. Cassidy is in the minority.

- No legislation drafted yet.

- NIH reform is not a near term priority for Chairman Sanders.

- If Republicans take the Senate next year, Cassidy likely to serve as HELP Committee Chair – drive the agenda.

NIH IN THE 21st CENTURY:

ENSURING TRANSPARENCY AND AMERICAN BIOMEDICAL LEADERSHIP

Senate Committee on **Health, Education, Labor & Pensions**
Senator Bill Cassidy, M.D., Ranking Member
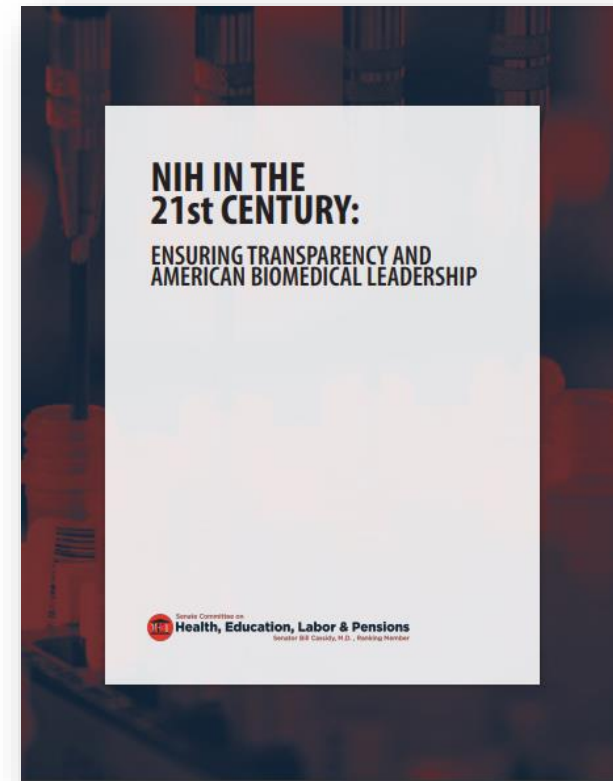
"I look forward to working with all interested stakeholders and my colleagues on the HELP Committee to harness this opportunity to strengthen NIH for the next generation of Americans."

- Cassidy White Paper, May 2024

CoSSA
40 YEARS OF ADVOCACY & ACTION

McMorris Rodgers Framework

- Framework released in June 2024

- Public comments were due August 16

- Themes:
  - Mission and leadership reform
  - Funding reform
  - Grant reform

U.S. HOUSE OF REPRESENTATIVES

Reforming the National Institutes of Healt
Framework for Discussion

The Time is NOW to Build a Stronger NIH for the Future

ENERGY & COMMERCE

Chair Cathy McMorris Rodgers
June 2024

"By encouraging each IC to utilize a holistic life stage approach, our goal is to eliminate the demographic- or disease-specific siloed nature of the current structure and ensure each IC is considering the whole individual and all populations across the entire lifespan."

- McMorris Rodgers Framework, June 2024

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House Context

"[NIH's] sprawling and siloed organizational structure has been an issue for longstanding interest to Congress and stakeholders"

"Decades of nonstrategic and uncoordinated growth created a system ripe for stagnant leadership, research duplication, gaps, misconduct, and undue influence."

"The NIH needs to regain the public's trust by showing it can be transparent, accountable, and responsive, proving it is worthy of public and Congressional support… we must have a reset."

Institute & Center (IC) Consolidation

- Consolidate 27 institutes and centers into 15

- No structural change:
  - National Cancer Institute
  - National Institute of Mental Health
  - NIH Clinical Center
  - Center for Scientific Review
  - Center for Information Technology

IC Consolidation

- National Heart Lung and Blood Institute (NHLBI)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

→ **National Institute on Body Systems Research**

- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Eye Institute (NEI)

→ **National Institute on Neuroscience and Brain Research**

IC Consolidation

- National Institute of Allergy and Infectious Diseases (NIAID)

→

- National Institute on Infectious Diseases
- National Institute on the Immune System and Arthritis

- National Institute of General Medical Sciences (NIGMS)
- National Human Genome Research Institute (NHGRI)
- National Library of Medicine (NLM)

→

National Institute of General Medical Sciences

IC Consolidation

- National Institute of Child Health and Human Development (NICHD)
- National Institute on Deafness and Other Communication Disorders (NIDCD)

→ National Institute for Disability Related Research

- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute on Drug Abuse (NIDA)

→ National Institute on Substance Abuse

IC Consolidation

- National Institute on Environmental Health Sciences (NIEHS)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Center for Complementary and Integrative Health (NCCIH)
- National Institute of Nursing Research (NINR)
- John E. Fogarty International Center (FIC)

→ National Institute on Health Sciences Research

- National Center for Advancing Translational Sciences (NCATS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Advanced Research Projects Agency for Health (ARPA-H)
- Common Fund

→ National Institute on Innovation and Advanced Research

Other Recommendations

- Mission and Leadership Reform:
    - Congressionally mandated commission – Comprehensive review of NIH's performance, mission, objectives, and programs.
    - Support innovation – Encourage public-private partnership and collaboration.
    - Term limits for IC directors – 5-year terms with option for second consecutive term.
    - Eliminate silos between ICs – Require ICs to issue biennial reports on how they are using "life stage approach," grant funding decisions, and research priorities and portfolio.
    - Enforce financial disclosure and transparency requirements, address misconduct and expect accountability, and improve transparency from partners.

Other Recommendations (2)

- Funding Reform:
  - Repeal PHS Evaluation Tap
  - Reexamine/limit indirect costs (F&A) and make F&A costs public.
  - Prevent waste and fraud

Other Recommendations (3)

- Grant Reform:
  - Limit number of grants to PIs – Focus on awarding grants to investigators with less than 3 "ongoing concurrent NIH engagements."
  - Prohibit gain-of-function research
  - Create public, independent oversight body to review, modify, approve or reject gain-of-function research at NIAID.
  - Establish community oversight boards to review and approve protocols for research using "potentially dangerous agents."
  - Other recommendations pertaining to: grants in foreign countries, conflicts of interest, national security reviews, and animal research.

Community Responses

1. Structural changes/reform must include an open, thoughtful, and deliberative process that includes engagement with all stakeholders.

   - Concerns that NIH's current abilities will be inadvertently reduced or there will be disruptions to the scientific process.

   - Will the benefits outweigh the risks?

   - Current NIH structure allows for specialized focus on areas of study; reorg could inadvertently prioritize more general/larger research initiatives over smaller or emerging areas of research.

   - Lots of concerns raised about specific IC consolidations.

   - Some support for NIA/NIAAA merger since it was a past recommendation of SMRB.

Community Responses

2. IC Director term limits:
   - 5 years, renewable, is too short – could make the positions less attractive to top talent. Some recommend 10 years, renewable.
   - Could impeded the ability of senior scientists to mentor and train early career scientists.
   - Congressional terms are not limited…

3. Strong objection to capping PIs at 3 active grants.

4. Objections to cutting or capping F&A (indirect costs).

5. Careful balance is needed among basic, translational, clinical, and population research.

6. NIH requires robust funding – a bigger challenge for NIH may be its funding level.
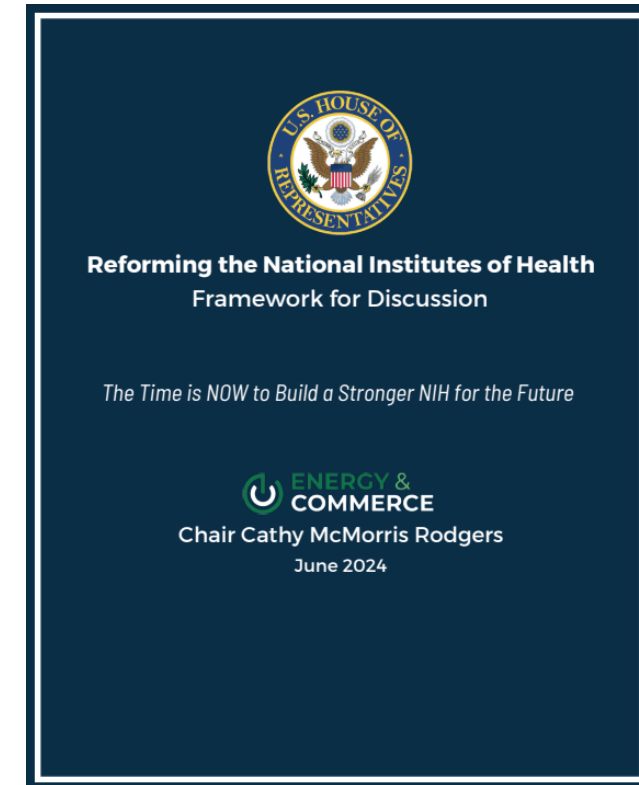
Other Community Comments

- Stipend levels and salary restrictions have failed to keep pace with labor market wage levels.

- The review life cycle needs to be shortened.

- Don't inadvertently increase administrative burden.

- NIH is not perfect, but its record is unparalleled.

- Is legislation required or can NIH make some changes on its own?

Next Steps

- McMorris Rodgers is retiring – hopes someone will pick up the mantle using her framework.

- No new action since the public comment period closed.

- No authorization legislation drafted yet.

- Eyes are on the appropriations process.

- If Republicans keep the House and take over the Senate next year, leadership is likely to try moving comprehensive NIH reform legislation.

Reforming the National Institutes of Health
Framework for Discussion

The Time is NOW to Build a Stronger NIH for the Future

ENERGY & COMMERCE
Chair Cathy McMorris Rodgers
June 2024

"The ideas and challenges presented in this framework are intended as a starting point and foundation to foster further discussion to keep America at the forefront of biomedical innovation."

- McMorris Rodgers Framework, June 2024

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40 YEARS OF ADVOCACY & ACTION

FY 2025 House Appropriations Bill

- FY 2025 spending bill introduced in the House incorporates the McMorris Rodgers reorganization.

- Bill was introduced BEFORE the public comment deadline on the McMorris Rodgers framework.

"The foundational biomedical science pioneered by **NIH does not need to be spread across 27 various institutes and centers**; doing so creates duplication, the potential for unrecognized gaps, and added administrative costs…" "Several of the proposed changes to the institutes have been requested by prior Administrations in budget requests or recommended by scientific bodies. The new structure seeks to **encourage a holistic life stage approach to all research**, with the goal of **eliminating the demographic- or disease-specific siloed nature** of the current structure and ensure each institute or center is considering the whole individual and all populations across the entire lifespan."

House Appropriations Democrats:

"[I have] my doubts about the majority's short-sighted decision to overhaul the National Institutes of Health in a partisan appropriations bill. The House needs to hold public hearings and engage in a thoughtful process to incorporate the best ideas to advance NIH as the crown jewel of biomedical research. Any discussion to reauthorize the NIH needs to be bipartisan and bicameral…"

- Rep. Rosa DeLauro, Ranking Member,
House Appropriations Committee

Next Steps

- House FY 2025 LHHS bill is partisan and will not become law in its current form.

- Republican leadership has not been able to pass the bill through the full House.

- Senate bill does not include the reorganization.

- Final FY 2025 funding bill not expected to include reorganization.

- But... timing of final FY 2025 appropriations is unclear.

Looking ahead

- It is possible that NIH reform *authorization* legislation could be introduced this year. Even so, it will not become law.

- Outcome of November elections will dictate the path forward on NIH reauthorization/reform.

- Expect discussions to continue next year, regardless of party leadership.

- Most importantly, get organized but **stay calm**.

In the meantime...

How should the social and behavioral science community prepare?

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