



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Overview of Legislative items of interest to NINDS

September 2022

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

	FY 2022 Appropriations	FY 2023 President's Budget	FY 2023 House Appropriations Bill	FY 2023 Senate Appropriations Bill
NIH	\$45 billion, including \$496 million CURES funding (incl. \$152 million for the BRAIN Initiative) and \$615 million for the HEAL Initiative and \$1 billion to establish the Advanced Research Projects Agency for Health (ARPA-H)	\$49 billion, including \$1.1 billion CURES funding, \$2.6 billion for opioid, stimulant, and pain research, and \$5 billion to establish the Advanced Research Projects Agency for Health (ARPA-H)	\$47.5 billion, including \$1.1 billion CURES funding (incl. \$450 million for the BRAIN Initiative) and \$615 million for the HEAL Initiative (ARPA-H funded separately)	\$48 billion, including \$1.1 billion CURES funding (incl. \$450 million for the BRAIN Initiative), \$715 million for the HEAL Initiative, and \$1 billion for ARPA-H
NINDS	\$2.611 billion, including \$76 million CURES funding for the BRAIN Initiative and \$270 million for the HEAL initiative	\$2.768 billion, including \$225 million CURES funding for the BRAIN Initiative and \$405.4 million for the HEAL initiative	\$2.834 billion, including \$225 million CURES funding for the BRAIN Initiative and \$270 million for the HEAL Initiative	\$2.766 billion, including \$225 million CURES funding for BRAIN Initiative and \$320 million for the HEAL Initiative

FY 2022 Appropriations. From October 1, 2021 through March 15, 2022, NIH operated under three continuing resolutions (CRs) which continued government operations at the FY 2021 enacted level, with no reduction. In early March, the House and Senate Appropriations Committees passed the FY 2022 omnibus spending bill, [Consolidated Appropriations Act, 2022](#). The President signed the bill (now Public Law No.: 117-35) on March 15. The agreement provides \$45 billion for NIH, including \$496 million from the 21st Century Cures Act, and \$2.611 billion for NINDS. NIH receives an increase of 2.25 billion (5.3 percent) above the FY 2021 enacted level, which provides no less than 3.4 percent funding increase above the FY 2021 enacted level for every Institute and Center at NIH. The agreement also provides a \$289 million increase for AD/ADRD research supported by NIA.

The agreement includes \$25 million for NIH to implement [ACT for ALS](#).

FY 2023 President's Budget. On March 28, 2022, the [President's Budget](#) for FY 2023 was released (NIH budget information starts on page 53). Overall, the proposed budget for NIH is \$49 billion, an increase of \$4.3 billion (9.6 percent) above the FY 2022 enacted level. For

NINDS, the President's Budget requests \$2.768 billion, including \$225 million CURES funding for the BRAIN Initiative. The proposed increase for NINDS in FY 2023 also includes an increase of \$135.1 million for the HEAL Initiative accompanied by a \$43.0 million increase in other NINDS opioid and pain research.

Across NIH ICs, the budget proposes \$2.6 billion for opioids, stimulant, and pain research, which includes \$811 million to support the HEAL Initiative. The budget proposes \$12.1 billion for NIH research and infrastructure to support pandemic preparedness.

The President's Budget requests \$5 billion for the Advanced Research Projects Agency for Health (ARPA-H), a new entity that will benefit the health of all Americans by catalyzing health breakthroughs that cannot readily be accomplished through traditional research or commercial activity. ARPA-H will have an initial focus on diseases such as dementia, diabetes, and cancer.

FY 2023 House L-HHS Appropriations Bill. On June 22, 2022, the House released a draft of their FY23 [appropriations bill](#). The proposed budget for NIH is \$47.5 billion, an increase of \$2.5 billion above FY22 appropriations. This amount includes \$1.1 billion in CURES Act funding (\$450 million for the BRAIN Initiative) and \$615 million for the HEAL Initiative. The bill specifies \$3.7 billion for Alzheimer's disease and related dementias research (an increase of \$200 million above FY22), \$75 million to support research and expanded access authorized in the ACT for ALS Act, and \$90 million for the INCLUDE Initiative for research on Down syndrome. The bill also provides a \$98 million increase for research on opioids, stimulants, and pain; a \$100 million increase for health disparities research; and an across-the-board increase of 3.2% for all NIH Institutes and Centers.

The House bill proposes \$2.834 billion for NINDS, an increase of \$222 million above FY22 appropriations. The proposed NINDS funding includes \$259 million for the BRAIN Initiative (\$225 million from the CURES Act), \$270 million for the HEAL Initiative and an additional \$11.5 million to support research on opioids, stimulants, and pain.

Separate from the NIH budget, the bill proposes \$2.75 billion to fund ARPA-H.

FY 2023 Senate Appropriations Bill. On July 28, 2022, the Senate released a draft of their FY23 [appropriations bill](#). The proposed budget for NIH is \$48 billion, an increase of \$3 billion above FY22 appropriations. This amount includes \$1.1 billion in CURES Act funding (\$450 million for the BRAIN Initiative), \$715 million for the HEAL Initiative, \$40 million for other opioid and pain research, and \$1 billion for ARPA-H. The bill also provides a \$90 million increase for health disparities research and an across-the-board increase of 3.1% for all NIH Institutes and Centers.

The Senate bill proposes \$2.766 billion for NINDS, an increase of \$155 million above FY22 appropriations. NINDS funding includes \$299 million for the BRAIN Initiative (\$225 million from the CURES Act) and \$320 for the HEAL Initiative.

Public Laws in the 117th Congress

Amyotrophic Lateral Sclerosis (ALS)

[Public Law No: 117-79](#): *Accelerating Access to Critical Therapies (ACT) for ALS Act*

Background: On July 29, 2021, the House Energy and Commerce Health Subcommittee held a [hearing](#) to discuss research and drug development for neurodegenerative diseases, and Dr. Koroshetz provided witness testimony and responses to follow-up questions. ALS researchers and persons living with ALS or other neurodegenerative diseases and their family members, were witnesses at the hearing, and they showed their support for the *ACT for ALS Act* and other bills related to neurodegenerative diseases. (See more detail on the hearing [below](#).)

Provisions of the Legislation/Impact on NIH: ACT for ALS ([Public Law No: 117-79](#)) requires that the Secretary of Health and Human Services establish an Expanded Access Grant Program for research utilizing data from expanded access to investigational drugs for individuals who are not otherwise eligible for clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of ALS. Only phase 3 clinical trial sites sponsored by a small business concern are eligible to apply for grants through this program. The Government Accountability Office (GAO) is required to evaluate the grant program within 4 years of enactment, and the program sunsets in 2026. The legislation also establishes a Public Private Partnership (PPP) for Neurodegenerative Diseases between the NIH, the FDA, and one or more additional entities and requires FDA to publish an action plan and to establish a grant program for research on ALS and other rare neurodegenerative diseases. The law authorizes \$100 million per year for 5 years to be appropriated for purposes of carrying out this act.

Status: On May 5, 2021, S. 1813 was introduced by Sen. Christopher Coons (D-DE) and was referred to the Senate Health, Education, Labor, and Pensions Committee. On May 25, 2021, H.R. 3537 was introduced by Rep. Mike Quigley (D-IL) and was referred to the House Committee on Energy and Commerce. An Amendment in the Nature of a Substitute was submitted on December 8, 2021, which substantially modified H.R. 3537. On December 23, 2021, H.R. 3537 became Public Law No: 117-79.

Pending Legislation Directly Relevant to NINDS

Parkinson's Disease

H.R. 8585: *National Plan to End Parkinson's Act*

Provisions of the Legislation/Impact on NIH. This bill requires HHS to carry out a project to prevent and cure Parkinson's disease and related conditions. HHS must (1) implement and periodically update a national plan to coordinate and guide efforts to prevent and cure the disease; (2) improve diagnosis, treatment, and care of those with the disease; and (3) address health and other disparities related to the disease. HHS must also conduct annual assessments on the preparation for and response to the increased burden of Parkinson's disease. The bill also establishes a council, comprised of federal and nonfederal stakeholders, to advise HHS on and make recommendations concerning the prevention and cure of Parkinson's disease. The bill's provisions terminate at the end of calendar year 2035.

Status. On July 28, 2022, H.R. 8585 was introduced in the House by Paul Tonko (D-NY) and referred to the Committee on Energy and Commerce. No further action has occurred.

Alzheimer's Disease

H.R. 7773: *Alzheimer's Accountability and Investment Act*

S. 4202: *Alzheimer's Accountability and Investment Act*

Provisions of the Legislation/Impact on NIH: The bill requires NIH to submit an annual budget estimate for the initiatives related to this Act, including an estimate of the number and type of personnel needs for the NIH (professional judgment budget).

Status: The Senate bill was introduced by Sen. Susan Collins (R-ME) on May 12, 2022, and referred to the Committee on Health, Education, Labor, and Pensions. The House bill was introduced by Rep. Chris Smith (R-NJ) and referred to the Committee on Energy and Commerce on May 13, 2022. No further action has occurred.

H.R. 7775: *NAPA Reauthorization Act*

S. 4203: *NAPA Reauthorization Act*

Provisions of the Legislation/Impact on NIH. The bill extends through 2035 and makes other changes to the National Alzheimer's Project. This project supports coordination of federal planning, programs, and other efforts to address Alzheimer's disease and related dementias. The bill also requires the NIH to submit an annual Alzheimer's research budget proposal directly to Congress (a "bypass budget").

The bill incorporates a focus on addressing health disparities and on promoting healthy aging and reducing risk factors associated with cognitive decline. The bill also expands the membership of the Advisory Council on Alzheimer's Research, Care, and Services to include (1) a researcher with experience recruiting and retaining diverse clinical trial participants, (2) an individual

diagnosed with Alzheimer's disease, and (3) representatives from additional federal agencies (e.g., the Department of Justice and the Office of Management and Budget).

Status. The Senate bill was introduced by Sen. Susan Collins (R-ME) on May 12, 2022, and referred to the Committee on Health, Education, Labor, and Pensions. The House bill was introduced by Rep. Paul Tonko (D-NY) and referred to the Committee on Energy and Commerce on May 13, 2022. No further action has occurred.

Cerebral Palsy

H.R. 7265: *Cerebral Palsy Research Program Authorization Act of 2022*

Provisions of the Legislation/Impact on NIH. The bill would require NINDS and NICHD to hold a workshop on promising cerebral palsy research and to update and publish their strategic plan for cerebral palsy research.

Status. On March 29, 2022, H.R. 7265 was introduced in the House by Rep. Steve Cohen (D-TN) and referred to the Committee on Energy and Commerce. No further action has occurred.

Neurological Impacts of COVID-19

H.R. 6813: *A Bill to Direct the National Institutes of Health to Conduct a Study on the Neurological Impacts of COVID-19 on Individuals with a Neurological Disease*

Provisions of the Legislation/Impact on NIH. The bill would require NIH to conduct a study on the neurological effects of COVID-19 on individuals with a neurological disease and to report the results to Congress within 120 days after enactment.

Status. On February 22, 2022, H.R. 6813 was introduced by Rep. Bill Keating (D-MA) and referred to the Committee on Energy and Commerce. No further action has occurred.

Cerebral Cavernous Malformations

S. 3390: *Cerebral Cavernous Malformations Clinical Awareness, Research, and Education (CCM-CARE) Act of 2021*

Background: The CCM-CARE Act has previously been introduced in both the House and Senate in the 114th, 115th, and 116th Congresses. No further action was taken.

Provisions of the Legislation/Impact on NIH: The bill would require NIH to expand and coordinate activities for the purpose of conducting research and related activities concerning Cerebral Cavernous Malformations (CCM) and prioritize the provision of grant funding for small biotech entities that are working to develop treatments for CCM. The bill would also create a CCM Consortium which would include representatives of NIH and would require the consortium to establish or expand a training program for clinicians and scientists.

Status: On December 14, 2021, S. 3390 was introduced by Sen. Ben Ray Lujan (D-NM) and referred to the Committee on Health, Education, Labor, and Pensions. No further action has occurred.

Neuroscience Center of Excellence at the FDA

[S. 3427](#): *Neuroscience Center of Excellence Act of 2021*

[H.R. 5435](#): *Bringing Regulatory Advances Into Neuroscience (BRAIN) Act*

Provisions of the Legislation/Impact on NIH: S. 3427 proposes a Neuroscience Center of Excellence within FDA to facilitate collaborative relationships regarding diseases affecting the brain or CNS. S. 3427 also includes a provision mandating that the Government Accountability Office (GAO) complete a study and submit a report to Congress that reviews the participation of traditionally underrepresented populations in clinical trials for medical products for the treatment or diagnosis of neuroscience diseases and disorders.

H.R. 5435 is similar to S. 3427 in that it also proposes a Neuroscience Center of Excellence within FDA to facilitate collaborative relationships regarding diseases affecting the brain or CNS. H.R. 5435, if enacted, would also establish a Neuroscience Translation Working Group, consisting of the Director of NINDS, the Director of NCATS, patient advocates, clinical trial experts, and a regulatory expert to advise the Director of the Neuroscience Center of Excellence on issues with respect to translating discoveries to approved treatments, developing guidance, and incorporating patient preferences, patient-reported outcomes, and real-world data in the development of regulations

Status: On December 16, 2021, S. 3427 was introduced by Sen. Susan Collins (R-ME) and referred to the Committee on Health, Education, Labor, and Pensions. On September 30, 2021, H.R. 5435 was introduced by Rep. Earl Blumenauer (D-OR) and referred to the Committee on Energy and Commerce. On October 1, 2021, it was referred to the Subcommittee on Health. No further action has occurred on either bill.

NIH Innovation Projects and Pain Research

[H.R. 3](#): *Elijah E. Cummings Lower Drug Costs Now Act*

Background: This authorization bill was previously introduced in the House in the 116th Congress. No further action was taken.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would extend funding for NIH Innovation Projects (the Cancer Moonshot, the Precision Medicine Initiative, the BRAIN Initiative, and the Regenerative Medicine Innovation Project) through FY 2031, as well as create and provide funding for new NIH Innovation Projects on Antimicrobial Resistance and Rare Diseases. It would require the HHS Secretary, acting through the NIH Director, to establish and implement a pilot program to award multi-year contracts to eligible entities to support phase II clinical trials and phase III clinical trials. The bill also would create an NIH Clinical Trial Accelerator Account and require the NIH Director to award grants or contracts to eligible entities

to develop, expand, and enhance the commercialization of biomedical products. Lastly, the bill would create an Overdose Epidemic Response fund, which includes authorization of various amounts of funding for agencies to tackle the overdose epidemic, including \$280 million for NIH to carry out pain/opioid research for each of fiscal years 2022-2026.

Status: On April 22, 2021, H.R. 3 was introduced by Rep. Frank Pallone (D-NJ) and referred to the Committee on Energy and Commerce. On April 23, 2021, it was referred to the Subcommittee on Health. No further action has occurred within this committee.

SBIR/STTR

S. 3109: *Research Advancing to Market Production for Innovators Act*

Provisions of the Legislation/Impact on NIH: This authorization bill, if enacted, would provide commercialization services for federally funded small business research and development under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. This bill, would shorten the timeline under which NIH must make SBIR/STTR award decisions to 180 days, would require the application peer review process to include commercialization potential in addition to scientific and technical merit, and would require each Agency to designate a new Technology Commercialization Official to help SBIR awardees commercialize. The bill would also extend the authorization for the Phase Flexibility Pilot Program through Fiscal Year 2027 while limiting the NIH to using 15 percent of SBIR/STTR funds for this purpose.

Status: On October 28, 2021, S. 2109 was introduced by Sen. Christopher Coons (D-DE) and referred to the Committee on Small Business and Entrepreneurship. No further action has occurred.

Pending Legislation of Broad Interest to NIH

Participation in Clinical Trials

[H.R. 6584](#): *Diverse and Equitable Participation in Clinical Trials Act*

Provisions of the Legislation/Impact on NIH. The bill would require NIH to conduct, coordinate, or support activities to increase engagement with and outreach to underserved communities to facilitate inclusion in clinical research and clinical trials.

Status. On February 3, 2022, H.R. 6584 was introduced by Rep. Anna Eshoo (D-CA) and referred to the Committee on Energy and Commerce. No further action has occurred.

[H.R. 7845](#): *NIH Clinical Trial Diversity Act of 2022*

Provisions of the Legislation/Impact on NIH. The bill would require the HHS Secretary, acting through the NIH Director, to take steps to increase clinical trial diversity, including carrying out a national campaign to increase the awareness and knowledge of the need for diverse clinical trials. The bill would also require applicants that would like to conduct a clinical trial to submit an application that includes a plan for recruitment, strategies to retain participants and follow-up with participants, the role of community partners, and the plan for education and training requirements for researchers for how they can enroll and retain patients in clinical trials.

Status. The bill was introduced to the House by Rep. Robin Kelly (D-IL) and referred to the Committee on Energy and Commerce on May 19, 2022. No further action has occurred.

CURES 2.0

[H.R. 6000](#): *Cures 2.0 Act*

Background: This authorization bill is a follow-up legislation to the [21st Century Cures Act](#) (enacted in 2016) which, among its many provisions, provided funding to the BRAIN Initiative. Cures 2.0 aims to revolutionize how the U.S. provides care to patients and speeding up the delivery of groundbreaking, new cures, treatments, and innovations to those who need them. While the majority of the bill includes provisions directed at the FDA and CMS, there are several provisions of interest to NIH which are included below.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would enable several NIH-relevant provisions. It would establish ARPA-H within NIH and authorize \$6.5 billion in FY 2022 for the ARPA-H budget. The bill also would provide \$10 billion to NIH for activities to address pandemic-related research disruptions, including supplementation of research grants, research infrastructure improvement, equipment refurbishment and replacement, extensions of research training, support for virtual/online undergrad, graduate, and post-doc research training, etc. Another provision directs NIH to make grants for research on the long-term effects and treatment of COVID-19 in children, including Long COVID. Another provision directs the President, acting through HHS, to establish a National Strategy for Future Pandemics. The bill

would also direct the HHS Secretary to convene a permanent Task Force made up of NIH, FDA, patient groups and academic researchers to make clinicaltrials.gov more user-friendly.

A separate, self-contained ARPA-H authorization bill, [H.R. 5585](#), was introduced by Rep. Anna Eshoo on October 15, 2021 and referred to the Committee on Energy and Commerce. That bill, if enacted, would establish ARPA-H within HHS and does not mention NIH at all. H.R. 5585 authorizes \$3 billion for FY 2022 to remain available until expended. Another ARPA-H authorization bill was introduced in the Senate by Sen. Patty Murray (D - WA) and referred to the Committee on Health, Education, Labor, and Pensions on March 10, 2022. That bill, [S. 3819](#), which would establish ARPA-H within NIH but place the agency outside of the National Capital region, was amended to [S. 3799](#) on March 15, 2022.

A separate, self-contained authorization bill, [H.R. 869](#), *Research Investment to Spark the Economy (RISE) Act*, contains the exact language that appears in Cures 2.0 which provides support for research regarding and/or disrupted by COVID-19. The bill was referred to the Health subcommittee of the Energy and Commerce committee

Status: On November 17, 2021, [H.R. 6000](#) was introduced by Reps. DeGette and Upton and was referred to the Health Subcommittee of the Committee on Energy and Commerce. No further action has occurred.

Foreign Influence in American Scientific Research

Background: Members of the House Energy & Commerce Committee have introduced 7 bills to combat foreign influence in American scientific research. Six of the bills were introduced throughout mid to late 2021, and [H.R. 6363](#), *Genetic Sequencing Accountability Act*, was introduced by Rep. Larry Bucshon (R-IN) on January 10, 2022. While these bills may not have a direct impact on NIH programs, they do have a broad applicability to NIH and biomedical research.

[H.R. 5442](#): *Fix Nondisclosure of Influence in Health (NIH) Research Act* (Rep. John Curtis (R-UT))

Would require the HHS Secretary to submit an annual report to Congress on actions taken to document, prevent, and address cases of research misconduct related to foreign influence.

[H.R. 5478](#): *Protecting the Integrity of our Biomedical Research Act of 2021* (Rep. Gus Bilirakis (R-FL))

Would direct the HHS Secretary to require disclosure of participation in foreign talent programs, including providing related documents to HHS, as a condition of receiving NIH funding.

[H.R. 5515](#): *Protecting Americans' Genomic Information Act of 2021* (Rep. Neal Dunn (R-FL))

Would direct the HHS Secretary to consult with national security experts to ensure that biomedical research involving human genomic information appropriately considers national security risks.

H.R. 5626: *Securing and Fortifying Everyday (SAFE) Biomedical Research Act* (Rep. John Joyce (R-PA))

Would establish new duties for the Director of the NIH related to national security, including consultation with relevant agencies regarding research that may be relevant to national security matters and ensuring recipients of NIH funding adhere to appropriate technology practices to secure identifiable, sensitive information.

H.R. 6305: *Protect America's Biomedical Research Enterprise Act of 2021* (Rep. Richard Hudson (R-NC))

Would task HHS with developing a framework for assessing and managing national security risks and implementing controls to ensure appropriate data access. Would require the HHS Secretary to identify and regularly update ways to improve the protection of intellectual property, proprietary information, and identifiable data in biomedical research, develop a framework for evaluating emerging threats related to foreign influence on biomedical research, and make recommendations to protect proprietary information.

H.R. 6363: *Genetic Sequencing Accountability Act* (Rep. Larry Bucshon (R-IN))

Would require GAO to conduct a study to assess the extent to which HHS funds human genome sequencing services conducted by or shared with countries of concern. The report would include recommendations on how to address national security vulnerabilities.

American Competitiveness

Background: On April 30, 2021, S. 1260, *United States Innovation and Competition Act (USICA) of 2021*, was introduced by Sen. Chuck Schumer (D-NY) and passed in the Senate on June 8, 2021. The bill, which started off as the *Endless Frontier Act* and had previously been introduced to the House in the 116th Congress and again in the House on April 21, 2021, is aimed at combating the rise in technological and innovative expertise in China. On July 19, 2021, Rep. Eddie Bernice Johnson (D-TX) introduced an alternative to S. 1260: H.R. 4521, *the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (America COMPETES) Act of 2022*. This bill addresses U.S. technology and communications, foreign relations and national security, domestic manufacturing, education, trade, and other matters. The bill, which includes language from several other bills, passed the House on February 4, 2022, and passed with amendment by the Senate on March 28, 2022. On April 28, 2022, the Senate agreed to a conference with the House to negotiate a proposal that can be agreed to by both chambers.

S. 1260: *United States Innovation and Competition Act (USICA) of 2021* (Sen. Chuck Schumer (D-NY))

Would expand the authorization of the National Science Foundation to create a new Science and Technology Directorate and support additional commercialization efforts. Several proposed amendments to this bill are related to government-wide science policies and NIH's work on foreign influence and peer review. Section 6102 requires that the Secretary of HHS ensure that biomedical research supported or conducted by NIH that involves the sequencing of human genomic information, and collection, analysis, or storage of identifiable, sensitive information is conducted in a manner that appropriately considers national security risks, including national security implications related to potential misuse of such data. Section 6016 requires a report to Congress on NIH's progress to address undue foreign influence, and Section 6017 prohibits NIH funding for gain-of-function research conducted in China.

[H.R. 4521](#): *The America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (America COMPETES) Act of 2022 (Rep. Eddie Bernice Johnson (D-TX))*

Would expand the authorization of the National Science Foundation to create a new Science and Technology Directorate and support additional commercialization efforts. Several proposed amendments to this bill are related to government-wide science policies and NIH's work on foreign influence and peer review. The bill includes a provision to require that the Secretary of HHS ensure that biomedical research supported or conducted by NIH that involves the sequencing of human genomic information, and collection, analysis, or storage of identifiable, sensitive information is conducted in a manner that appropriately considers national security risks, including national security implications related to potential misuse of such data. Another provision requires a report to Congress on NIH's progress to address undue foreign influence, and another provision prohibits NIH funding for gain-of-function research conducted in China. Another provision would reauthorize SBIR/STTR programs until 2027.

PREVENT Pandemics Act

[S. 3799](#): *Prepare for and Respond to Existing Viruses, Emerging New Threats, and (PREVENT) Pandemics Act*

Background. The PREVENT Pandemics Act reflects sweeping legislation that incorporates ideas from 41 bills. Several other biomedical innovation and pandemic preparedness bills have been released, including the Tracking Pathogens Act ([S. 3534](#)) introduced by Sens. Bill Cassidy (R-LA) and Tammy Baldwin (D-WI). On March 15, 2022, the Senate Committee on Health, Education, Labor and Pensions held a full committee markup and added several amendments to the original bill text.

Provisions of the Legislation/Impact on NIH. There are numerous legislative provisions relevant to HHS (i.e., FDA, CDC, HRSA, ASPR), including the establishment of an Office of Pandemic Preparedness. Provisions most relevant for NIH include 1) continued support for research on long-term health effects of COVID-19 and dissemination of relevant guidance and educational materials for healthcare providers; 2) risk mitigation activities related to biosafety, genomic data security, and intellectual property protection; 3) requirements for disclosure of

foreign collaborations and reporting misconduct related to foreign influence; and 4) establishment of ARPA-H within NIH, specifying that the Director will report to the NIH Director and that the new agency will be located outside of the National Capital region.

Status. On March 10, 2022, S. 3799 was introduced in the Senate by Sen. Patty Murray (D-WA) and referred to the Committee on Health, Education, Labor, and Pensions. Full committee consideration and markup was held on March 15, 2022.

Recent Hearings of Interest

The Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee

Hearing on the FY 2023 Budget Request for NIH

May 17, 2022

The Senate appropriations [hearing](#) for the NIH budget was held on May 17, 2022. NIH participants included Lawrence Tabak, performing the duties of the NIH Director; Nora Volkow, Director of NIDA; Anthony Fauci, Director of NIAID; Gary Gibbons, Director of NHLBI; Josh Gordon, Director of NIMH; and Richard Hodes, Director of NIA. As with the House hearing, several committee members expressed concerns about funding ARPA-H “at the expense of” the NIH budget. Members were interested to hear about meaningful progress toward Alzheimer’s Disease and were concerned about cuts to the Undiagnosed Disease Network (a topic on which Dr. Tabak agreed to “continue to work to develop a better solution” after emphasizing NIH’s interest in the research aspect of the UDN rather than standard of care). Other topics that were briefly discussed include long COVID, a recent NASEM report on autoimmune research at NIH, and retaining young investigators in biomedical research.

The House Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee

Hearing on the FY 2023 Budget Request for NIH

May 11, 2022

The House appropriations [hearing](#) for the NIH budget was held on May 11, 2022. NIH participants included Lawrence Tabak, performing the duties of the NIH Director; Nora Volkow, Director of NIDA; Anthony Fauci, Director of NIAID; Gary Gibbons, Director of NHLBI; Diana Bianchi, Director of NICHD; and Douglas Lowy, Acting Director of NCI. Several committee members expressed concerns about housing ARPA-H within NIH, and there was bipartisan concern about the balance of ARPA-H and NIH funding. Members had questions about plans for the Undiagnosed Disease Network (UDN) after support from the Common Fund expires and requested an update on research progress for Alzheimer’s Disease research. Other general comments about NIH funding practices included questions about priority setting, interest in reductions in success rate despite increased NIH funding, concerns about age at first R01, which has increased over the years, and questions about NIH diversity efforts.

The House Energy and Commerce Health Subcommittee

Hearing on ARPA-H: The Next Frontier of Biomedical Research

February 8, 2022

The House Energy and Commerce Health Subcommittee held a [hybrid hearing](#) on February 8, 2022 to discuss Advanced Research Projects Agency for Health (ARPA-H). In addition to

Admiral Brett Giroir (Former Assistant Secretary for Health, HHS), the witness panel included representatives from research and healthcare policy, nonprofit, and pharmaceutical sectors. In discussions around the position of ARPA-H within HHS, committee members and witnesses were largely supportive of ARPA-H as a separate entity outside of NIH in order to challenge conventional wisdom, be nimble, and achieve radical innovation to close the “valley of death” gap. Witnesses emphasized that ARPA-H should focus on developing capability, unlike NIH’s goal of developing knowledge. Members expressed concern about duplication of efforts and the culture and lack of transparency at NIH amid concerns of undue foreign influence. Members and witnesses agreed a culture of accountability, collaboration, streamlined processes, and clear, measurable goals and deliverables are essential to the success of ARPA-H. Further, they agreed that ARPA-H priorities should be set through a transparent process and informed in consultation with external stakeholders; many agreed ARPA-H should prioritize health equity from the outset. Members also emphasized that ARPA-H activities must have the flexibility to promote innovation and adopt the DARPA motto “fail early, fail fast”.

Hearing on The Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases

July 29, 2021

The House Energy and Commerce Health Subcommittee held a [hearing](#) on July 29, 2021 to discuss research and drug development for neurodegenerative diseases. The Federal agency witness panel consisted of Dr. Walter Koroshetz (Director, NINDS), Drs. Richard Hodes (Director, National Institute on Aging), and Dr. Patrizia Cavazzoni (Director, Center for Drug Evaluation and Research, FDA). Their panel was followed by a second panel of witnesses that included researchers (ALS), patients (ALS and Huntington’s disease), caregivers (Alzheimer’s and Huntington’s disease), and industry. The hearing was focused on ALS, particularly FDA’s role in drug development and approval of ALS drugs. Other topics discussed during the first panel included the BRAIN Initiative’s contribution to neurodegenerative disease research, inflammation, Down syndrome, neuropsychiatric symptoms of Alzheimer’s disease, headache, COVID-19, and pediatric neurology. The hearing also included discussion of clinical trial design, enrollment, and participation, including telemedicine, geographic access, financial barriers, and diversity. The second panel also had a focus on ALS, expanded access, and the FDA process for approving new drugs. Witnesses showed their support for two bills on ALS: [ACT for ALS Act](#), which is focused on expanded access for ALS therapies, and [Promising Pathway Act](#), which would create a conditional approval pathway for drug therapies for diseases like ALS. The second panel also more broadly included caregiving and caregiver support and Social Security disability and Medicare benefits for people with Huntington’s disease ([Huntington’s Disease Parity Act](#)). Other topics that were discussed included diversity in clinical trials, access to clinical research, and importance of patient experience in clinical research and FDA approvals.