Fiscal Year 2023 Omnibus Appropriations Bill Summary

Prepared for UsAgainstAlzheimer's

Executive Summary

On December 20, Congress released the text for the Consolidated Appropriations Act, 2023 ("omnibus") to fund the federal government through the end of Fiscal Year (FY) 2023. After months of stalemates followed by hurried negotiations on top-line numbers in the past few weeks, Congress included the $1.7 trillion funding package includes major increases for key discretionary and non-discretionary programs. The bill includes several of UsAgainstAlzheimer's (UsA2) priorities, both specific appropriations requests and policy provisions UsA2 has supported throughout the 117th Congress.

The omnibus includes notable funding increases for Alzheimer's disease research and prevention programs at the National Institute on Aging (NIA), Centers for Disease Control and Prevention (CDC), and Administration for Community Living (ACL). The bill also includes increases in funding for the Advanced Research Projects Agency for Health (ARPA-H) and Federally-Qualified Health Centers (FQHCs). A summary of the funding levels for agencies and programs of interest to UsA2 is included in the table below.

	FY 2023 Amount	Change from FY 2022	UsA2 Request
NIH	$47,459,000,000	Increase of $2,500,000,000	–
NIA	$4,407,623,000	Increase of $187,687,000	–
Alzheimer's Disease and Related Dementia Research	$3,700,000,000 (estimated)	Increase of $226,000,000	Increase of $226,000,000
CDC	$9,217,590,000	Decrease of $1,283,239,000	–
Center for Chronic Disease Prevention and Health Promotion	$1,430,414,000	Increase of $91,750,000	–
Alzheimer's Disease and Healthy Aging Program	$38,500,000	Increase of $8,000,000	$60,000,000
ACL Alzheimer's Disease Program	$31,500,000	Increase of $2,000,000	–
ARPA-H	$1,500,000,00	Increase of $500,000,00	–
Federally Qualified Health Centers	$5,857,772,000 *Mandatory Budget Authority – $4,000,000,000* *Discretionary Budget Authority – $1,857,772,000*	Increase of about $100,000,000	"Robust" funding

UsA2 made several report language requests for FY 2023. These requests included language about a national strategy for recruitment and participation in Alzheimer's and related dementia clinical research, CDC's

Alzheimer's Program, NAPA Goal Six on Prevention, and the CMS National Coverage Determination on anti-amyloid monoclonal antibodies.

The following is a summary of report language included in the omnibus that is substantively the same as or similar to what UsA2 requested or supported. The full report language is included in **Attachment 1.**

- **NAPA Goal 6** - The language commends HHS for adding a goal on promotion of healthy aging to the NAPA Plan and directs HHS to develop "specific strategies to achieve this goal and to align specific, measurable, time-bound milestones with budget requests". As it has previously been difficult to track how actions funding is allocated to NAPA activities, the latter part of this language, which UsA2 championed, is especially important. (Page 123).
- **NIA Study with NASEM** - The report directs NIA to enter into a contract with the National Academies of Science, Engineering, and Medicine (NASEM) to conduct a study on research priorities for Alzheimer's disease and related dementias (Page 70).
- **Diversity in Clinical Trials** - The report directs NIA to work with the Alzheimer's Disease Research Centers and other organizations "to promote participation in clinical trials within underrepresented populations and… reduce the burden of participating" (Page 72).

In addition to FY 2023 appropriations, the omnibus included multiple policy riders that were considered throughout the 117th Congress. Although the omnibus did not include the UsA2-championed CHANGE Act authorization or a reauthorization of the NAPA Act (which is set to expire at the end of 2025), it did include two other policy riders of interest to UsA2. These are summarized below and described in more detail in **Attachment 2.**

- **Accelerated Approval** - Language that gives the FDA more clear authority to specify requirements for post-approval studies prior to approving products, to expedite withdrawal of products, and to enforce sponsor completion of post-approval studies. It also establishes an intra-agency coordinating council to ensure consistent and appropriate use of accelerated approval across FDA. As more prospective therapies for Alzheimer's move through the development pipeline, it will be critical that the FDA has these clear authorities to use accelerated approval to bring innovative therapies to market.
- **Advanced Research Projects Agency for Health (ARPA-H)** - Language to formally authorize the creation of ARPA-H - a key priority that UsA2 advocated for through its leadership of the "Friday Group". The language establishes ARPA-H within NIH and specifies that the Director will report to the HHS Secretary (rather than the NIH Director). To create further separation from NIH, ARPA-H may not be located on the NIH campus and shall have offices in at least three different geographic areas. The bill gives ARPA-H important flexibility in hiring and compensation of employees, the use of a flexible funding mechanism called "other transactions authority", and protection of trade secrets of funded entities that will be essential in the agency operating in a nimble manner. Much of the language in the bill aligns with the model bill prepared by the "Friday Group", reflecting UsA2's critical influence on the development and passage of this portion of the bill.

Congress is currently operating under a continuing resolution (CR) set to expire on December 23. In order to pass the omnibus before the CR expires, both chambers of Congress must move swiftly through their review and voting process. The Senate is expected to vote on December 22 and the House is expected to vote on December 23, with the bill anticipated to pass in both chambers.

Attachment 1: Report Language

The following is the report language requested by or otherwise of interest to UsA2 that was included in the omnibus. Links to the overall bill; Labor, Health & Human Services, Education, and Related Agencies (Labor-H) report; and a summary of the report are included below. The hyperlinks at the start of each entry are to the section of the report where the language appears.

- Full Omnibus Bill Text
- Labor-H Report
- Summary of Labor-H Report

National Institutes on Aging

Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/DRD).-The agreement includes an increase of $226,000,000 across NIH for AD/ADRD research, including an increase $151,000,000 in NIA and an increase of $75,000,000 in NINDS, ensuring it remains the largest single effort of its kind within the agency. The agreement directs NIA, working with NINDS, to enter into an agreement with NASEM within 60 days of enactment of this Act to identify research priorities for preventing and treating AD/ ADRD. An ad hoc committee of NASEM will conduct a study and recommend research priorities to advance the prevention and treatment of AD/ADRD. In conducting its study, the committee will:

1. examine and assess the current state of biomedical research aimed at preventing and effectively treating AD/ADRD, along the R&D pipeline from basic to translational to clinical research
2. assess the evidence on nonpharmacological interventions aimed at preventing and treating AD/ADRD;
3. identify key barriers to advancing AD/ ADRD prevention and treatment (e.g., infrastructure challenges that impede large scale precision medicine approaches, inadequate biomarkers for assessing response to treatment, lack of diversity in biobanks and clinical trials), and opportunities to address these key barriers and catalyze advances across the field; and
4. explore the most promising areas of research into preventing and treating AD/ADRD.

The committee's study will include dementia caused by Alzheimer's disease as well as related conditions such as frontotemporal disorders, Lewy body dementia, vascular dementias, and multiple etiology dementias. Dementias with a clear etiology (e.g., incident stroke, AIDS, traumatic brain injury) will be excluded from the analysis. Based on its review of the literature, consultations, and other expert input, the committee will develop a report with its findings, conclusions, and specific recommendations on research priorities for preventing and treating AD/ADRD, including identifying specific near and medium-term scientific questions (i.e., in a 3 to 10 year period) that may be addressed through NIH funding. The report will also include strategies for addressing major barriers to progress on these scientific questions. The agreement includes $1,500,000 within the total funding for NIA for AD/ADRD research to cover the costs of this study.

Alzheimer's Disease Research Center (ADRC).-The agreement directs NIA to provide a report to the Committees within 180 days of enactment of this Act detailing the number of individual Alzheimer's disease patients who have gained access to a clinical trial through the outreach of an ADRC, the number of Alzheimer's disease diagnoses given to patients at an ADRC, and a detailed report on patients' and caregivers' needs that were met through the work of ADRCs that cannot be attained at a provider office.

Brain Health and Exposome Studies.- The agreement encourages NIA to address the research gaps and opportunities identified in the 2021 Alzheimer's Disease Research Summit as NIA works to establish Centers on Exposome Studies in ADRD as directed in the Consolidated Appropriations Act, 2022 (P.L. 117-103), especially

those gaps and opportunities focused on understanding healthy brain aging and applying this understanding to disease prevention.

Clinical Trials. -Although Alzheimer's disease and other dementias disproportionately affect Black Americans, Hispanic Americans, Asian American and Pacific Islanders, and Native Americans, they continue to be underrepresented in AD/ADRD clinical trials. The agreement directs NIA to work with ADRCs and other organizations to promote participation in clinical trials within underrepresented populations and, to the maximum scientifically-feasible extent, reduce the burden of participating. These efforts should include expanding community engagement and outreach to these populations, incentivizing trial locations in areas of unmet need, encouraging the diversity of clinical trial staff, allowing appropriate flexibility in trial design and inclusion and exclusion criteria, and utilizing technology like remote patient monitoring, where appropriate, to facilitate clinical trial participation and retention. Further, the agreement urges NIA to provide an assessment of the data and metrics it collects related to the planning, recruitment, and retention of clinical trial participants from underrepresented communities and, when possible, how those data have been or plan to be used in grant-making decisions. The assessment should also address how NIA plans to provide more timely data to the Committees and greater transparency to the public about the planning, engagement, and recruitment efforts of its extramural grantees, including a focus on addressing barriers to inclusive and representative enrollment such as eligibility criteria, language accessibility, and adequate planning for diverse enrollment among grantees. The agreement requests that NIA provide this assessment within 180 days of enactment of this Act. In addition, with various treatments for Alzheimer's disease in the pipeline, the agreement encourages NIA to support a wide range of trials, including those with a patient-based national registry of regulatory grade, longitudinal evidence for patients receiving any FDA-approved disease-modifying therapies for Alzheimer's disease in real-world clinical practice

CMS

Alzheimer's Disease (AD) Diagnostics.- CMS' bundled payment policy for advanced radiopharmaceuticals in the hospital outpatient setting can make these diagnostic imaging services cost prohibitive for many hospitals and doctors, especially those providing care to racial and ethnic minorities, and patients in rural areas. The agreement directs CMS to review the utilization of AD diagnostics and consider potential modifications that could make access to advanced imaging for AD more equitable.

HHS Office of the Secretary

Alzheimer's Disease National Plan.- The agreement notes the update of the National Plan to include promotion of healthy aging and directs the Secretary to include specific strategies to achieve this goal and to align specific, measurable, time-bound milestones with budget requests. Milestones should be developed in collaboration with a broad group of non-governmental stakeholders focused on each of the risk factors for Alzheimer's disease and related dementias (Page 123).

ARPA-H

ARPA-H.**—**The agreement includes $1,500,000,000 for ARPA-H. The agreement strongly encourages HHS to collaborate with the Defense Advanced Research Projects Agency (DARPA) to develop the foundational policies, procedures, and staff training for ARPA-H employees. The agreement believes ARPA-H will require a very different culture and mission than NIH's other 27 Institutes and Centers. To foster the development of an entrepreneurial culture, the agreement expects ARPA-H to be physically located away from the main NIH campus. The agreement directs NIH to brief the Committees no later than 30 days prior to conducting the location search on its criteria and the Committees should be notified of the decision no less than 5 days prior to a location

being announced publicly. While the NIH workforce is composed of dedicated, talented, and frequently brilliant scientists, recruitment from the existing NIH workforce should be avoided. Instead, the agreement recommends that ARP A-H consider recruiting from industry, academia, and think tanks, as well as from proven advanced research project organizations. The agreement directs ARP A-H to provide quarterly briefings to the Committees on its establishment process, hiring, and scientific priorities and progress. These briefings should specifically address how its activities may advance biomedical research and development and the mission to create breakthrough health technologies, as well as how to balance long-term scientific challenges with short-term research goals (pages 144-145).

Attachment 2: Summary of Notable Policy Provisions

Modernizing Accelerated Approval (link to text)

- If post-approval studies are not required, FDA must publish a rationale on their website.
- By the time of approval, FDA must specify the conditions for post-approval studies which may include milestones, enrollment targets, protocol, and target completion date.
- FDA may require sponsors to begin confirmatory studies prior to approval.
- Expedited withdrawal procedures, FDA must:
    - Provide sponsor with:
        - Due notice of withdrawal and explanation for withdrawal
        - Opportunity to meet with FDA
        - Opportunity to appeal to FDA
    - Provide public comment opportunity on withdrawal proposal, then publish those comments and FDA's responses on the FDA website
    - Convene an Ad Comm on the withdrawal if requested by the sponsor
- Sponsors must submit progress reports on confirmatory studies within 180 days of approval and every 180 days thereafter until the study is completed or terminated.
- Adds stronger language prohibiting the sponsor from not conducting post-approval studies with due diligence or failing to submit progress reports
- Within 18 months, FDA shall issue draft guidance on the topics below and shall issue final guidance within one year of the close of the public comment period on those drafts.
    - How sponsor questions about novel surrogate or intermediate endpoints can be addressed in early-stage meetings with FDA
    - How novel trial designs may be used for post-approval studies
    - The expedited withdrawal process for accelerated approval products
    - "Considerations related to the use of surrogate or intermediate clinical endpoints that may support" accelerated approval
- Intra-agency coordinating council: FDA shall establish this council within one year to ensure "consistent and appropriate use of accelerated approval across the FDA".
    - Members will include directors of:
        - Center for Drug Evaluation and Research (CDER)
        - Center for Biologics Evaluation and Research (CBER)
        - Oncology Center of Excellence (OCE)
        - Office of New Drugs (OND)
        - Office of Orphan Products Development (OOPD)
        - Office of Tissues and Advanced Therapies (OTAT)
        - Office of Medical Policy (OMP)
        - At least three review divisions or offices, including one from the Office of Neuroscience
    - Council must meet at least three times/year
    - Council must engage with review teams to support consistent and appropriate use of accelerated approval, which may include;
        - Developing guidance for staff on best practices for use of accelerated approval
        - Training review teams
        - Advising review divisions on best practices "with respect to product specific development, review, and withdrawal of products under accelerated approval"
    - Report on council activities must be posted on FDA website within one year and every year thereafter

ARPA-H Authorization (link to text)

The following is a summary of the notable provisions in the ARPA-H authorizing language and how they compare to the Friday Group's "module" (model bill) and Rep. Eshoo's ARPA-H Act (H.R. 5585), which the House passed in June 2022.

	Provision Summary	**Friday Group Module**	**HR 5585 (Eshoo's bill)**
Location	Within NIH	Not specified	HHS
Director			
Appointment	Presidential appointment	Same	Same
Reporting structure	To HHS Secretary	Same	Same
Term	Four years with option for one consecutive term	Five years, option of one consecutive term	Five years, option of one consecutive term
Deputy Director	Director appoints	Same	Same
Organization			
Program Offices	Not more than eight, two-thirds of which must support R&D activities	Not specified	Not specified
Policy exemptions	Secretary may exempt ARPA-H from following NIH policies unless otherwise specified	Not specified	Not specified
Protection of trade secrets	Trade secrets/privileged or confidential information protected from FOIA requests	Same	Not specified
Hiring/Personnel			
Hiring authorities	Without regard for civil service hiring laws; compensation up to President's salary	Same	Same
Hiring from NIH	Unless staff are uniquely qualified, cannot hire someone who worked at NIH within the past three years	Not specified	Not specified
Number of personnel	210, must seek congressional approval for an increase	Not specified	Not specified
Program manager terms	Three years, option for one consecutive term	Sane	Same
Awards			
Award types	Contracts (including multi-year contracts), grants, cooperative agreements, cash prizes, other transactions	Same	Same
Other Transactions Authority?	Yes, but must get Director approval	No director approval required	No director approval required
Facilities and Physical Location			
Physical Location	Not on NIH campus, must have offices in three geographic areas	Not specified	Not specified
Facilities authorities	Purchase, lease, construct, improve property as necessary.	Same	Same
Inter-Agency Coordination			

	Provision Summary	Friday Group Module	HR 5585 (Eshoo's bill)
FDA	FDA may meet with ARPA-H to facilitate development of products. ARPA-H must reimburse FDA for activities related to ARPA-H.	Coordinate to facilitate expedited review of ARPA-H products	Coordinate to facilitate expedited review of ARPA-H products
Inter-Agency Advisory Council	Requires an interagency advisory council with NIH, CDC, FDA, ASPR, ASPE, DARPA, DOE, NSF, and other agencies as needed. Council will help develop a performance framework for ARPA-H.	No Council, just authority to seek advice	Same, with addition of BARDA, NCATS, OSTP, AHRQ, HHS OMH, and HRSA on Council
Reports to Congress			
Annual reports	Report with description of projects funded, terminated, and those planned for the next year; activities done with other federal agencies and any successes or barriers in that area; demographic information on recipients of ARPA-H funding.	Also required reporting on projects similar to other HHS activities	Also required reporting on projects similar to other HHS activities; did not require report on inter-agency activities
NASEM report	Contract with NASEM on a report five years after enactment of this act	Eight years after enactment	Eight years after enactment
Personnel reports	Annual reports and a GAO report on total number of employees, titles, how positions were filled, demographics, etc.	Not specified	Not specified
Independent Review	After one year and every four years thereafter, the Comptroller General shall conduct an independent review of the biomedical R&D portfolio of ARPA-H, NIH, FDA, and BARDA to assess any duplication and make recommendations on reorganization of projects	Not specified	Not specified
Authorization of Appropriations			
Authorization	$500 million per year, 2024-2028, available until expended	$3 billion for FY 22, available until expended	$3 billion per year, available until expended
Bypass budget authority	Not included	Included	Included