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Legislative Update:
Clinical Trials and Translational Research Advisory Committee (CTAC)

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I. Budget and Appropriations

After months of a virtual stalemate on the FY2022 appropriations spending bills and two continuing resolutions (CRs), Congressional leaders and House and Senate Appropriations Chairs and Ranking Members announced on February 9th that they had reached a deal on top-level funding for defense and non-defense spending. To allow for additional time to finalize the omnibus spending package, a third short-term stopgap to keep the government funded until March 11th was passed and signed by President Biden on February 18th.

On March 4th, the President requested $10 billion in emergency aid for Ukraine and $22.5 billion in additional funds for the ongoing response to COVID-19. As the conflict in Ukraine continued to intensify, momentum within Congress also continued to build for including aid to Ukraine in the final FY22 Omnibus package. Congress ultimately incorporated approximately $13.6 billion in aid to Ukraine in the final package, but funds for the ongoing COVID-19 response were removed from the bill in response to concerns about funding offsets that would subsume previously-appropriated COVID funds that had not yet been distributed to states. The COVID-19 response aid was introduced in separate legislation that will need to be considered at another time.

In the early hours of Wednesday, March 9th, congressional leaders released the $1.5 trillion FY2022 Omnibus appropriations bill. The legislation includes $45 billion in funding for NIH overall, an increase of $2.25 billion over FY21. The NIH total also includes $6.9 B for NCI, which represents a $353 million increase over FY21. The bill provides $1 billion for ARPA-H within the HHS Office of the Secretary, and gives the Secretary the authority to transfer funding and administration of ARPA-H to any part of the Department, including NIH, within 30 days of enactment of the Omnibus. A summary table is included below for reference, which notes the proposed FY2022 funding levels for NIH, ARPA-H, and NCI in the President's Budget Proposal, the House-passed Labor-HHS Appropriations bill, the draft Labor-HHS Appropriations bill released in the Senate, and the Omnibus text released on March 9th.

The Omnibus also includes several policy provisions of interest. Of note, the bill includes provisions that would clarify authority for the Food and Drug Administration to regulate synthetic nicotine (a component in some electronic nicotine delivery systems or ENDS), and also includes provisions extending several telehealth flexibilities for 151 days beyond the COVID-19 public health emergency period.

The House passed a four-day Continuing Resolution and the FY22 Omnibus on Wednesday, March 9th, and the Senate passed both pieces of legislation on Thursday, March 10th. The short-term CR provided additional time for preparation of the final FY22 bill for the President's signature. The President is expected to sign the Omnibus before the CR expires on Tuesday, March 15th.

Summary Table: Proposed FY2022 Appropriations

	President's Budget Request	House Passed 7/29/21 (219-208)	Senate DRAFT released 10/18/21	FY22 Omnibus Released 3/9/22
NIH	$52 B (+$9 B*)	$49.4 B (+$6.5 B*)	$47.9 B (+$5 B*)	**$45 B (+ $2.25 B*)**
ARPA-H	$6.5 B	$3.0 B	$2.4 B	**$1.0 B**
NCI	$6.73 B (+$174 M)	$6.99 B (+$434 M)	$6.77B (+$212 M)	**$6.9 B (+ $353 M)**

**Initial proposals from the President, and House and Senate Appropriators included funding for ARPA-H within the total proposed allocations for NIH. The Omnibus provides funds for ARPA-H through the HHS Office of the Secretary, and grants the Secretary authority to transfer funding and administration of ARPA-H within HHS within 30 days of enactment.*

II. Recent Congressional Events

Littlest Tumor Foundation Virtual Congressional Briefing (January 7, 2022): Dr. Jack Shern provided updates on NCI's research on neurofibromatosis (NF), particularly his recent work in collaboration with Washington University on blood-based early detection of Malignant Peripheral Nerve Sheath Tumors (MPNSTs). The overall goal of the briefing was to educate staffers about NF and the importance of NF federally funded research. Other speakers included Dr. Steven Rhodes, Indiana University School of Medicine; Dr. Annette Bakker, Children's Tumor Foundation; Dr. Theresa Miller, the Department of Defense Congressional Directed Medical Research Programs; Tammy O'Brien, parent advocate; and Garrett Dohlke, patient advocate.

House Cancer Caucus Virtual Roundtable (December 9, 2021): The House Cancer Caucus held a bipartisan virtual roundtable on the importance of NCI funding, with the goal of celebrating and acknowledging the 50th anniversary of the National Cancer Act and the achievements of cancer research while looking at the future of cancer research and confronting the challenges of the COVID-19 pandemic. NCI Director Dr. Ned Sharpless provided opening remarks highlighting National Cancer Act commemoration efforts across the cancer community, as well as celebrating notable recent cancer research advances. Caucus co-chairs leading the briefing included: Reps. Derek Kilmer (D-WA), Brian Fitzpatrick (R-PA), Brian Higgins (D-NY), and Mike Kelly (R-PA). Additional speakers included Drs. Pam Sharma of MD Anderson Cancer Center, Charles Roberts of St. Jude Children's Research Hospital and Candace Johnson of Roswell Park Cancer Center.

Congressional Staff Visit to Ft. Detrick (November 3, 2021): At the invitation of the Army, representing the National Interagency Confederation of Biological Research (NICBR), four staff members of the House and Senate L-HHS and Defense Appropriations Subcommittees, including the minority clerk of the Senate L-HHS Appropriations Subcommittee, toured the Ft. Detrick campus, including Frederick National Laboratory (FNL), Army, and NIAID facilities. NCI Principal Deputy Director Dr. Doug Lowy shared an overview of NCI-Frederick, and Dr. Melinda Hollingshead led a tour of her laboratory, providing an overview of the Patient-Derived Models Repository, a unique resource that NCI makes available to the broader research community.

III. Special Legislation

ARPA-H and Competitiveness

Senate and House leaders have indicated that they remain supportive of ARPA-H and are exploring legislative avenues by which they can authorize the agency. Senate HELP Committee Chair Patty Murray (D-WA), who is also the Chair of the Senate L-HHS Appropriations Subcommittee, voiced her support for the new agency, and one of her committee aides was quoted in *Politico* on October 8th: *"Senator Murray is looking at all possible ways to get ARPA-H across the finish line – and is committed to getting this done."* Similarly, Senate L-HHS Appropriations Subcommittee Ranking Member Roy Blunt (R-MO) stated, *"I'm a supporter of the concept…I think it's a little too early to tell how we get it done, but I do think we can, and should, get it done."*

Possible vehicles for the authorization of ARPA-H include: a stand-alone bill (H.R. 5585) introduced by Rep. Anna Eshoo (D-CA) in the House on October 15th; the Cures 2.0 legislative proposal (H.R. 6000), introduced on November 16th by Reps. Diana DeGette (D-CO) and Fred Upton (D-MI); and a Senate-backed bill (S. 3819) introduced by Sens. Patty Murray (D-WA) and Richard Burr (R-NC) on March 10th. Rep. Eshoo's proposal would authorize $3 billion in funding for the new agency and would situate ARPA-H within HHS. The Cures 2.0 bill would authorize $6.5 billion for the establishment of ARPA-H and originally proposed housing the new agency within NIH. The Senate bill would establish ARPA-H within NIH, with several provisions aimed at maintaining ARPA-H's independence within the agency, and authorize "such sums as may be necessary for each of fiscal years 2023 through 2027." Under all of the proposals, the ARPA-H Director would be presidentially appointed to either a four or five-year term, with the possibility of being appointed for one additional term.

Additionally, on Tuesday, February 8th, the Health Subcommittee of the House Energy and Commerce Committee held a hearing, "*ARPA-H: The Next Frontier of Biomedical Research*," featuring researchers and policy analysts from UC San Francisco, the Milken Institute, and Johns Hopkins serving as witnesses. In general, lawmakers continued to express support for ARPA-H, with many members articulating a preference for housing the agency within HHS but outside of NIH. Several members and witnesses expressed strong support for NIH, and most noted that while NIH's culture is appropriate for its research mandate, a new culture is necessary for ARPA-H to be successful. [1]

On Tuesday, January 25th, House leadership released the America COMPETES Act, (H.R. 4521), which is aimed at boosting U.S. competitiveness in the semiconductor industry. The bill also contains climate provisions that attempt to improve interagency coordination on climate change, increase the State Department's emphasis on the issue, and foster partnerships between financial institutions investing in clean energy. An amendment that would reauthorize SBIR/STTR for an additional five years was adopted into the bill the week of January 31st. The House passed the America COMPETES Act on Friday, February 4th, along a mostly party-line vote. The bill will now head to a conference committee to iron out the differences between the House and Senate versions of the legislation. The Senate originally passed the United States Competition and Innovation (USICA) Act (S. 1260) in June 2021, and there are several differences to resolve between the two legislative packages.

Cures 2.0

The Cures 2.0 Act was introduced in the House on November 16th, 2021, with bipartisan sponsorship led by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI). The legislative package incorporates several other legislative proposals, including the ***Precision Medicine Answers for Kids Today Act*****;** the ***Ensuring Patient Access to Critical Breakthrough Products Act*****;** the ***Telehealth Improvement for Kids' Essential Services (TIKES) Act*****;** the ***Telehealth Modernization Act*****; the *Research Investment to Spark the Economy (RISE) Act of 2021*,** and portions of the ***Meaningful Access to Federal Health Plan Claims Data Act*****.** Sponsors are reportedly in communication with Rep. Eshoo (D-CA), who introduced legislation in October to authorize ARPA-H, but there are significant differences between Eshoo's draft standalone ARPA-H legislation and ARPA-H as proposed in Cures 2.0. For example, while Cures 2.0 initially proposed to establish ARPA-H within NIH, recent reports indicate that Reps. DeGette and Upton are open to revisions that align their proposal more closely with Rep. Eshoo's bill, which would establish ARPA-H outside of NIH.

Cures 2.0 is broad in scope and has multiple items relevant to NCI and the larger cancer community, including authorizing $6.5B to establish ARPA-H, measures aimed at increasing diversity in clinical trials, providing funding to remedy research and training interruptions related to COVID-19, and introducing multiple provisions for Medicare and Medicaid recipients, including permanent improvements in telehealth access, increased access to breakthrough medical devices under Medicare, expanding genetic testing coverage under Medicaid, and provisions providing for linkages between clinician-led clinical data registries and Medicare claims data for research and other purposes.

Notable telehealth expansions include eliminating provisions that previously limited Medicare coverage for telehealth to rural areas and required patients receive telehealth services in an in-person clinic. If enacted, the bill would also give the HHS Secretary authority to expand the types of providers and care available via telehealth for Medicare recipients. Additional provisions outline guidance to states to integrate telehealth into Medicaid and Children's Health Insurance Programs.

[1] The full hearing, as well as written witness testimony, is available at https://energycommerce.house.gov/committee-activity/hearings/hearing-on-arpa-h-the-next-frontier-of-biomedical-research.

Recent Legislation of Interest

The following bills were selected for inclusion in this update due to anticipated interest among CTAC members. Legislation listed below reflects proposals introduced since CTAC's last meeting in November 2021.

Selected Bills – 117th Congress

A bill to establish an Advanced Research Projects Authority for Health within the National Institutes of Health (S.3819)

- Sens. Patty Murray (D-WA) and Richard Burr (R-NC) introduced this legislation on 3/10/22.
- The bill would establish ARPA-H within NIH and the ARPA-H Director would be presidentially appointed for a 4-year term (up to one reappointment). The bill includes provisions indicating that ARPA-H may not be located on any part of the NIH campuses, nor in the Washington, DC area. The bill would also authorize "such sums as may be necessary for each of fiscal years 2023 through 2027."

Give Kids a Chance Act (H.R.6972)

- Reps. G.K. Butterfield (D-NC-1) and Michael McCaul (R-TX-10) reintroduced this legislation (previous bill H.R.5416) on 3/8/22.
- This legislation would authorize the FDA to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances.

Diverse and Equitable Participation in Clinical Trials (DEPICT) Act (H.R.6584)

- Reps. Anna Eshoo (D-CA-18), Brian Fitzpatrick (R-PA-1) and Robin Kelly (D-IL-2) introduced this legislation on 2/3/22.
- The bill would require improved reporting standards for clinical trials and boost resources, such as workshops and community health center grants, to improve access to clinical trials in underrepresented communities.

KO (Knock Out) Cancer Act (H.R. 6342)

- The KO Cancer Act was introduced on 12/23/2021 (the 50th Anniversary of the National Cancer Act) by Reps. Brian Fitzpatrick (R-PA-1) and Debbie Dingell (D-MI-12).
- The bill aims to increase cancer research funding allocated to the NIH for FY 2023 through FY 2027.
- The bill proposes to allocate funds from U.S. Treasury that would not otherwise be appropriated. This proposed appropriation would be made to NIH in each year FY 2023-2027 in addition to its base appropriation.
- The bill calls for additional funds for each year of these five years in an amount "equal to 25 percent of the total amount allocated to the National Institutes of Health for cancer research for fiscal year 2021" to support cancer research.

Cures 2.0 Act (H.R. 6000)

- Reps. Diana DeGette (D-CO-1) and Fred Upton (R-MI-6) introduced this legislation on 11/16/21.
- The legislation would establish ARPA-H within NIH, make certain telehealth expansions permanent, give recommendations for decentralizing clinical trials, provide support for research interrupted by COVID-19, aim to increase diversity in clinical trials and expand access to breakthrough therapies, and expand access to genetics-based testing and case among other provisions.

Men's Health Awareness and Improvement Act (H.R.5986)

- Rep. Donald Payne, Jr. (D-NJ-10) introduced this legislation on 11/16/21 with 11 cosponsors.
- This bill would establish an Office of Men's Health at HHS, with a director appointed by the HHS Secretary.
- It would also mandate a study to be completed within 1 year of enactment by the HHS Assistant Secretary for Health in collaboration with NCI's Director and NIMH's Director on whether underscreening or

underdiagnosis of men's health issues exist, with an emphasis on colorectal cancer, prostate cancer, mental health and other high risk male health concerns; causes of any such underscreening or underdiagnosis; whether men underutilize health services; and any causes of such underutilization.

Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (S.1873 & H.R. 1946)

- This legislation was originally introduced by Sen. Mike Crapo (R-ID) on 5/27/2021 with 3 cosponsors and by Rep. Terri Sewell (D-AL-7) on 3/16/2021 with 10 cosponsors.
- The Senate version of the bill currently has 33 bipartisan cosponsors, and the House version has 147 bipartisan cosponsors.
- This bill proposes providing for Medicare coverage and payment for multi-cancer early detection screening tests that are approved by the Food and Drug Administration and that are used to screen for cancer across many cancer types. The Senate version would require the Government Accountability Office to report on the resulting utilization and effectiveness of such tests.

Additional Pending Legislation

Many legislative proposals have been introduced to date in the 117th Congress with an emphasis on biomedical and/or cancer research and cancer care. This includes legislation authorizing the establishment of an Advanced Research Projects Agency for Health (ARPA-H). There is also significant congressional interest in expanding telehealth flexibilities issued under the COVID-19 Public Health Emergency. More than 50 bills have been introduced in the 117th Congress to address telehealth expansion and flexibilities. Pending legislation listed below were selected for inclusion due to anticipated interest among CTAC members.

Cancer and Biomedical Research

- Companion Animal Release from Experiments (CARE) Act (H.R.5726, Introduced 10/26/21): This bill would require research facilities that use dogs, cats and rabbits for research purposes and receive funding from the National Institutes of Health (NIH) to develop and implement adoption policies for such animals when no longer used for research. The bill also requires facilities to maintain records of the animals and make them available to the public.
- Advanced Research Project Agency–Health Act (H.R.5585, Introduced 10/15/21): This legislation would establish ARPA-H, to coordinate with the NIH on "high-need cures", defined as a "drug, biological product, or device (A) that should be prioritized to detect, diagnose, mitigate, prevent, or treat any disease or medical condition; and (B) for which incentives in commercial market are unlikely to result in the adequate or timely development of such drug, biological project, or device".
- DIVERSE Trials Act (H.R.5030, Introduced 8/13/21): The legislation aims to improve diversity in clinical trials and data collection for COVID-19 and future public health threats to address social determinants of health.
- Jonny Wade Pediatric Cancer Research Act (H.R.3032, Introduced 5/7/21): The bill would increase funding for the 10-year Pediatric Research Initiative Fund by eliminating taxpayer financing of presidential election campaigns.
- Fairness to Kids with Cancer Act (H.R. 2210; Introduced 3/26/21): This bill requires the share of federal funds for cancer research that supports pediatric cancer research is to equal the percentage of the U.S. population that is under the age of 18.
- American Cures Act (S.962, Introduced 3/24/21): The bill would provide annual budget increases of five percent plus inflation at America's top four biomedical research agencies: the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Defense Health Program, and the Veterans Medical and Prosthetics Research Program.
- Women and Lung Cancer Research and Preventive Services Act of 2021 (S.699 & H.R.1800, Introduced 3/11/21): The proposed legislation would require the Department of Health and Human Services to conduct an interagency review of the status of women and lung cancer.

- Gabriella Miller Kids First Research Act 2.0 (H.R. 623 & S.1521, Introduced 1/28/21 & 4/29/21): The bill would require certain civil penalties collected from pharmaceutical, cosmetic, supplement, and medical device companies to be transferred to a fund at NIH for the Gabriella Miller Kids First Pediatric Research Program.
- Research Investment to Spark the Economy (RISE) Act (S.289 & H.R.869, Introduced 2/5/21): This legislation would authorize nearly $25 billion in emergency relief funds for federal science agencies, including $10 billion for the NIH.
- Triple-Negative Breast Cancer Research and Education Act of 2021 (H.R.113, Introduced 1/4/21): This legislation would provide for research and education with respect to triple-negative breast cancer.

Telehealth

- Protecting Access to Post COVID-19 Telehealth Act (H.R.366, Introduced 1/19/21): The bill would allow for the expanded use of telehealth after the Coronavirus public health emergency by eliminating restrictions on telehealth services in Medicare.
- The Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S.168 & H.R.708, Introduced 2/2/21): The bill would provide temporary licensing reciprocity for all practitioners and health professionals for all types of services (in-person and telehealth) during the COVID-19 response and for future national emergencies.
- Telehealth Modernization Act (S.368 & H.R. 1332, Introduced 2/23/21 & 2/26/21): The bill would revise the originating site requirements (geographic and site of service) after the public health emergency to mean any site at which the beneficiary is located, including the home of the beneficiary. It would also provide the HHS Secretary the authority to expand the types of practitioners who are eligible to furnish telehealth, among other provisions.
- Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2021 (H.R. 2903 & S.1512, Introduced 4/28/21 & 4/29/21): The bill would permanently remove geographic restrictions on telehealth services and provide the HHS Secretary with the permanent authority to waive telehealth restrictions, a provision currently in place due to the pandemic but on a temporary basis.

Cancer Care and Healthcare Access

- Cancer Patient Equity Act of 2021 (H.R.5377, Introduced 9/29/21): The bill would mandate coverage for molecular diagnostics and genetic counseling at the time of diagnosis for patients on Medicare, Medicaid & CHiP.
- Expanding Access to Palliative Care Act (S.2565, Introduced 7/29/21): The legislation would amend the Social Security Act to provide for the testing of a community-based palliative care model.
- Cancer Care Planning and Communications Act (H.R.4414, Introduced 7/13/21): The legislation would amend the Social Security Act to provide for coverage of cancer care planning and coordination under the Medicare program.
- Cancer Drug Parity Act of 2021 (H.R.4385, Introduced 7/9/21): This legislation would amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide for cost sharing for oral anticancer drugs on terms no less favorable than the cost sharing provided for anticancer medications administered by a healthcare provider.
- Reducing Hereditary Cancer Act (H.R.4110 & S.3656, Introduced 6/23/2021 & 2/16/22): The bill would amend the Social Security Act to provide hereditary cancer genetic testing for individuals with a history of a hereditary cancer gene mutation in a blood relative or a personal or ancestral history suspicious for hereditary cancer.
- Katherine's Law for Lung Cancer Early Detection and Survival Act (H.R.3749 and S.1966, Introduced 6/8/21): This bill would expand the availability of coverage for lung cancer screenings without the imposition of cost sharing for high-risk individuals by removing limitations on screening for people over the age of 80 and for individuals who quit smoking more than 15 years ago.

- Timely Access to Cancer Treatment (TACT) Act of 2021 (H.R.3258, Introduced 5/14/21): The bill aims to improve patient access to anti-cancer oral medications and prevent any undo delay in the initiation of the patient's cancer treatment.
- Metastatic Breast Cancer Access to Care Act (S.1312 & H.R.3183, Introduced 4/22/21 & 5/13/21): The legislation would amend the Social Security Act to eliminate the waiting periods for disability insurance benefits and Medicare coverage for individuals with metastatic breast cancer.
- Colorectal Cancer Payment Fairness Act (H.R.2594, Introduced 4/15/21): This legislation would amend the Social Security Act to eliminate coinsurance requirements for certain colorectal cancer screening tests furnished under the Medicare program.
- Access to Breast Cancer Diagnosis Act of 2021 (S.1067 & H.R.5769, Introduced 4/12/21): This bill prohibits private health insurance plans from imposing higher cost-sharing requirements on breast cancer diagnostic examinations than initial breast cancer screening examinations. Diagnostic examinations are generally required after an initial screening detects an abnormality and typically require additional mammogram images (e.g., x-rays).
- Jeanette Acosta Invest in Women's Health Act (S. 1063 & H.R. 2216, Introduced 3/25/21): This bill establishes, or authorizes to be established, a series of programs relating to cancer screenings for women.
- Donald Payne Sr. Colorectal Cancer Detection Act of 2021 (H.R.1655 & S.2149, Introduced 3/8/21 & 6/21/21): The bill would require Medicare to cover FDA-approved blood-based screening tests for colorectal cancer.
- Promoting Resources to Expand Vaccination, Education, and New Treatments (PREVENT) for HPV Cancers Act of 2021 (H.R. 1550, Introduced 3/3/21): The bill aims to increase human papillomavirus (HPV) vaccination rates and otherwise prevent and treat cervical cancer and other cancers associated with HPV.
- Prostate-Specific Antigen Screening for High-risk Insured Men (PSA Screening for HIM) Act (H.R.1176, Introduced 2/18/21): The bill would waive deductibles, copayments, and coinsurances for prostate cancer screenings for men who have a family history of prostate cancer or who are African American.
- Comprehensive Breast Reconstruction Act of 2021 (H.R.469, Introduced 1/25/21): The bill would provide for Medicare, Medicaid, and private health insurance coverage of certain tattooing services in connection with post-mastectomy breast reconstruction, and aligns the scope of Medicare and Medicaid coverage of such breast reconstruction with that of private health insurance.
- Lung Cancer Screening Registry and Quality Improvement Act of 2021 (H.R. 107, Introduced 1/4/21): The bill aims to provide funds for FY2022-FY2026 for grants to help entities establish free lung cancer screening registries and requires registries to be interoperable in order to receive federal funds.