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

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I. Budget and Appropriations

FY 2022 Appropriations Update

As is customary during the first year of a presidential transition, the release of the President's Budget was delayed beyond the traditional early February release date. The White House released an outline of the FY2022 President's Budget on Friday, April 9th, followed by the release of the full budget on Friday, May 28th. The budget proposes \$51 billion for the National Institutes of Health (NIH), a \$9 billion increase over FY2021 enacted levels. However, \$6.5 billion of this increase would go towards the establishment of a new federal agency, housed within NIH, named the "Advanced Research Projects Agency for Health" (ARPA-H). ARPA-H, modeled after DARPA within the Department of Defense, would include "an initial focus on cancer and other diseases such as diabetes and Alzheimer's," with the goal to "drive transformational innovation in health research and speed application and implementation of health breakthroughs."¹

The President's Budget proposes \$6.73B for NCI, an increase of approximately \$174M over the FY2021 enacted funding level. This increase is part of the \$2.5 billion proposed increase to the NIH base budget.

The House released its version of the FY2022 Labor, Health and Human Services, Education and Related Agencies (L-HHS) Appropriations bill on Sunday, July 11th. The bill would provide \$6.798 billion for NCI's base budget, an increase of approximately \$434 million over the FY2021 enacted level, in addition to \$194 million for the Cancer Moonshot. The total NIH budget would increase by \$6.5 billion, for an overall appropriation of \$49.434 billion, and at least 5% increases for each IC. Notably, the House bill would provide \$3 billion for the establishment of ARPA-H.

The House quickly moved to mark-up appropriations bills, including the L-HHS proposal. The L-HHS Appropriations subcommittee advanced the bill via voice vote on Monday July 12th, and the full Appropriations Committee passed the bill out of committee on Thursday, July 15th, by a partisan vote of 33-25. On Thursday, July 29th, the House passed H.R. 4502, a "minibus" appropriations package containing the FY2022 L-HHS, Agriculture, Energy-Water, Financial Services, Interior-Environment, Military Construction-Veterans Affairs, and Transportation-Housing and Urban Development appropriations bills by a vote of 219-208.

On Thursday, September 30th, Congress narrowly avoided a government shutdown by passing a nine-week continuing resolution (CR, H.R. 5305) to fund federal agencies at FY2021 levels through December 3, 2021. The bill includes language that ensures multiyear funding for all grants issued in FY2016, as one aspect of continued research flexibilities as part of the COVID-19 response. In addition, the legislation provides \$6.3 billion to assist in resettling Afghan refugees and nearly \$29 billion in natural disaster aid.

The Senate released its version of the FY2022 L-HHS appropriations bill on Monday, October 18th. Appropriators proposed \$6.578 billion for NCI, a \$212.6 million increase over FY21 enacted funding levels. The bill provides \$194 million for the Cancer Moonshot, as well as \$2.4 billion for ARPA-H.

Negotiations surrounding the next steps of the appropriations process are occurring against the background of conversations regarding two major infrastructure packages, described in further detail below, and the United States debt limit. On Thursday, October 7th, the Senate passed legislation by a vote of 61-38 that increases the nation's borrowing limit by \$480 billion, which experts believe will allow the country to avoid defaulting on loans until December 16, 2021. The House passed the measure on Tuesday, October 12th, allowing Congressional leaders to consider legislative options to further extend the debt limit.

¹ https://www.whitehouse.gov/wp-content/uploads/2021/05/hhs_fy22.pdf

II. Recent Congressional Events

Congressional Staff Visit to Ft. Detrick (November 3, 2021): 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.

American Association for Cancer Research (AACR) Virtual Briefing (October 13, 2021): AACR hosted their annual briefing for the release of their Annual Progress Report. NCI Director Dr. Ned Sharpless provided pre-recorded remarks, as did Reps. Gwen Moore (D-WI) and House L-HHS Appropriations Subcommittee member Jaime Herrera Beutler (R-WA). Dr. Sharpless also participated in a live panel discussion moderated by AACR President Dr. David Tuveson.

Men's Health Networking Virtual Briefing (September 30, 2021): Dr. William Dahut, Scientific Director Clinical Research at NCI's Center for Cancer Research, shared an update on NCI-supported prostate cancer research at this briefing, organized in collaboration with the Congressional Men's Health Caucus and Prostate Cancer Task Force. The event was sponsored by Rep. Donald Payne, Jr. (D-NJ) and featured remarks from Ms. Elizabeth Battaglino, CEO of HealthyWomen, and Mr. Armin Brott of Healthy Men.

Childhood Cancer Virtual Briefing (September 24, 2021): Dr. Brigitte Widemann, Chief of the Pediatric Oncology Branch and Deputy Director of NCI's Center for Cancer Research, provided an overview of NCI-supported research on pediatric cancer. This virtual briefing was organized and moderated by Rep. Jennifer Wexton (D-VA). Other speakers included Dr. Adam Resnick, Principal Investigator of the Gabriella Miller Kids First Data Resource Center and Director of the Center for Data Driven Discovery in Biomedicine at Children's Hospital of Philadelphia; Dr. D. Ashley Hill, Chief of the Division of Pathology at Children's National Hospital; and Ellyn Miller, President and Founder of the Smashing Walnuts foundation.

American Association for Cancer Research (AACR) Rally for Medical Research Virtual Hill Reception (September 22, 2021): NCI Director Dr. Ned Sharpless provided pre-recorded video remarks, joining several other NIH Institute Directors, as part of this virtual reception for members of Congress, their staff, and members of the advocacy community.

Sen. Chris Van Hollen (D-MD) Visit to Frederick National Laboratory (FNL) (September 9, 2021): Sen. Van Hollen visited the Frederick National Lab to meet with the Maryland Tech Council. NCI Director Dr. Ned Sharpless attended the visit, which included a tour of a COVID-19 serology laboratory.

Virtual FNL Visit (August 19, 2021): Dr. Kristin Komschlies McConville, Deputy Director, Office of Science Operations at FNL, joined virtually along with colleagues from NIAID, the U.S. Army Medical Research and Development Command, the U.S. Department of Agriculture, National Biodefense Analysis and Countermeasures Centers, the Centers for Disease Control and Prevention, the Naval Medical Research Center, and the Food and Drug Administration, in an Army-led visit to Fort Detrick and FNL to highlight the work of the National Interagency Confederation for Biological Research (NICBR).

Friends of Cancer Research Virtual Briefing (July 29, 2021): Friends of Cancer Research hosted a virtual listening session, entitled "21st Century Cures 2.0 – Harnessing the Power of Collaboration." NCI Director Dr. Ned Sharpless joined Dr. Richard Pazdur, Director, FDA Oncology Center of Excellence, in discussing cancer-specific relevance of the 21st Century Cures Act. The session was chaired by the legislation's lead co-sponsors, Reps. Diana DeGette (D-CO) and Fred Upton (R-MI).

III. Special Legislation

Infrastructure and ARPA-H

Both Democratic and Republican leaders have indicated that developing and passing legislation focused on enhancements to the United States infrastructure is a top priority for this year, as both a remedy to the acute economic challenges caused by the COVID-19 pandemic and the fulfillment of long-standing party goals. However, the parties disagree on the definition of infrastructure, with the GOP urging lawmakers to focus on “traditional” investments, such as transit, clean drinking water, and internet services, and their Democratic colleagues arguing for the inclusion of “social” infrastructure initiatives, such as Medicare expansion, subsidized childcare, and climate change programs.

To address these differences, the Senate prepared two legislative vehicles centered on infrastructure. The bipartisan INVEST in America Act (Investing in a New Vision for the Environment and Surface Transportation in America Act, [H.R. 3684](#)) cleared the Senate by a vote of 69-30 on Tuesday, August 10th; the roughly \$1 trillion package includes \$550 billion in new money set aside for roads, bridges, transit, Amtrak, clean drinking water, access to high speed internet, and lower prices for internet service. Climate change is also addressed, with an emphasis on clean energy transmission, electric vehicles, and funds to protect against droughts, wildfires, and floods. Secondly, Senate Democrats paired this bill with a \$3.5 trillion budget resolution ([S. Con. Res. 14](#)) that needs only a simple majority in the House and Senate to pass, due to the rules governed by the budget reconciliation process.² That is, Democrats are able, in theory, to move forward a social infrastructure package without any Republican support, by using budget reconciliation. The Senate adopted the budget resolution on Wednesday, August 11th, by a vote of 50-49, sending instructions to various committees to draft legislation along the terms outlined in the resolution by September 15th. Key priorities identified in the resolution include expanded Medicare, free community college (up to two years), subsidized childcare, certain climate initiatives, paid family and medical leave benefits, and green cards for some immigrants.

The House adopted the budget resolution on Tuesday, August 24th, by a vote of 220-212, allowing the reconciliation process to begin. Committees then set to work, writing details of the budget framework into legislation that has since been passed out of respective committees. The House Energy & Commerce Committee released the details of its draft reconciliation package on Monday, September 13th, and reported the Public Health Subtitle favorably out of the Committee on Wednesday, September 15th. The legislation would provide \$3 billion for ARPA-H, but it does not provide details on where the agency would be housed.

Although House Speaker Nancy Pelosi (D-CA) had originally suggested that a vote on both the bipartisan infrastructure bill and the reconciliation package would occur the week of September 27th, intra-party negotiations derailed the process, with progressive Democrats threatening to vote against the bipartisan package if its vote was decoupled from the reconciliation vote, and moderate Democrats – including Sens. Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ) – demanding a more modest reconciliation package. Votes for both pieces of legislation have been postponed.

Senate Democrats have set to work on preparing a pared-down reconciliation package, in the hope of crafting legislation that will satisfy the entire caucus. On Friday, October 8th, news outlets reported that funding for ARPA-H has been dropped from the Senate legislation, due in part to concerns that the authorization for the new agency falls outside of the Senate’s rules for reconciliation bills. As of Wednesday, November 3rd, the reconciliation package is approximately \$1.75 trillion in scope, and a date for a vote has not been set.

² For more information on the budget reconciliation process, please see the House Budget Committee’s website: <https://budget.house.gov/publications/fact-sheet/budget-reconciliation-basics>.

Despite removing ARPA-H from the reconciliation package, Senate leaders have indicated that they remain supportive of the proposal 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 the 21st Century Cures 2.0 legislative proposal, which is still under development by Representatives Diana DeGette (D-CO) and Fred Upton (R-MI), or a stand-alone bill (H.R. 5585) introduced by Rep. Anna Eshoo (D-CA) on October 15th. Rep. Eshoo’s proposal would authorize \$3 billion in funding for the new agency and would situate ARPA-H within HHS. The ARPA-H Director would be presidentially appointed to a five-year term, with the possibility of being appointed for one additional term.

Telehealth

There continues to be significant interest in Congress as well as the public health and research communities in making permanent changes in support of telehealth flexibilities that were temporarily put in place at the beginning of the pandemic. Several bills introduced in the 116th Congress focused on telehealth, and members have reintroduced many of these bills in the 117th Congress. One of the most popular proposals, the Creating Opportunities Now for Necessary and Effective Care Technologies for Health (CONNECT) Act, was reintroduced in both chambers in April 2021. The effort was led in the Senate by Sen. Brian Schatz (D-HI), a longtime advocate for expanded telehealth, and in the House by Rep. Mike Thompson (D-CA-5). The legislation currently has 59 bipartisan cosponsors in the Senate (S.1512) and 112 bipartisan cosponsors in the House (H.R.2903). In addition to removing certain geographic requirements for telehealth services and waiving certain telehealth requirements during public health emergencies, the legislation would require the Secretary of Health and Human Services to conduct a study on telehealth utilization during the COVID-19 pandemic and test models to examine the use of telehealth under Medicare.

The Temporary Reciprocity to Ensure Access to Treatment “Treat” Act (S.168) was reintroduced by Sen. Christopher Murphy (D-CT) on February 2, 2021, and would allow healthcare providers to use telehealth to treat patients in any state during the coronavirus pandemic; the bill currently has six cosponsors. Other recently introduced bills aimed at making telehealth expansions permanent are the Advancing Connectivity during the Coronavirus to Ensure Support for Seniors (ACCESS) Act, introduced by Sens. Shelley Moore Capito (R-WV) and Amy Klobuchar (D-MN); Protecting Access to Post-COVID-19 Telehealth Act, introduced by Rep. Mike Thompson (D-CA-5); the Ensuring Telehealth Expansion Act, introduced by Rep. Roger Williams (R-TX-25); the Advancing Telehealth Beyond COVID-19 Act of 2021, introduced by Rep. Liz Cheney (R-WY-At Large); and the Increasing Rural Telehealth Access Act of 2021 introduced in the House by Rep. Dan Newhouse (R-WA-4) and in the Senate by Sen. John Kennedy (R-LA).

Other Legislation of Interest

The following bills were selected for inclusion in this update due to anticipated interest among CTAC members.

Selected Bills – 117th Congress

Companion Animal Release from Experiments (CARE) Act (H.R.5726)

- Rep. Tony Cardenas (D-CA-29) introduced the CARE Act on 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)

- Rep. Anna Eshoo (D-CA-18) introduced this legislation on 10/15/21. There bill has 19 co-sponsors.
- 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”
- Proposes \$3 billion in funding for ARPA-H, which would be separate and distinct from other HHS funding.

Cancer Patient Equity Act of 2021 (H.R.5377)

- Reps. G.K. Butterfield (D-NC) and Gus Bilirakis (R-FL) introduced this legislation on 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. Medicare and Medicaid already reimburse molecular diagnostics for recurrent and metastatic cancers; this Act would extend that coverage of molecular diagnostics to all cancer patients at the time of diagnosis, upon recurrence, and as necessary for monitoring progression.

Give Kids a Chance Act (H.R.5416)

- Reps. G.K. Butterfield (D-NC) and Mike McCaul (R-TX) introduced this bill on 9/29/21 with one additional cosponsor: Rep. Susan Wild (D-PA).
- This legislation would authorize the FDA to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances.

DIVERSE Trials Act (H.R.5030)

- Rep. Raul Ruiz (D-CA) introduced this legislation on 8/13/21 with one cosponsor: Rep. Larry Bucshon (R-IN).
- The legislation seeks to improve diversity in clinical trials and data collection for COVID-19 and future public health threats to address social determinants of health. Among other provisions, it would require the FDA Commissioner to issue draft guidance on how to conduct decentralized clinical trials with meaningful demographic diversity.

The Children’s Program of All-Inclusive Coordinated Care (ChiPACC) Act of 2021 (H.R.4952)

- Reps. Diana DeGette (D-CO) and Michael McCaul (R-TX) introduced the bill on 8/6/21. It has been referred to the House Committee on Energy & Commerce.
- The legislation would amend the Social Security Act to provide States an option to cover a children’s program of all-inclusive coordinated care (ChiPACC) under Medicaid. The bill aims to provide coverage for palliative care, including hospice care.

Pediatric Access to Critical Health Care Act (S.2762)

- Sen. Alex Padilla (D-CA) introduced the legislation on 9/20/21, along with Sen. Amy Klobuchar (D-MN). IT was referred to the Senate HELP Committee.
- The bill would amend the Public Health Service Act to direct HRSA to award grants to eligible entities to carry out construction or modernization projects designed to strengthen and increase capacity within the specialized pediatric health care infrastructure.

Expanding Access to Palliative Care Act (S.2565)

- Sen. Jacklyn Rosen (D-NV) introduced the bill on 7/29/21; lead cosponsors included Sens. John Barrasso (R-WY), Tammy Baldwin (D-WI), and Deb Fischer (R-NE).
- 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)

- Reps. Mark DeSaulnier (D-CA) and Buddy Carter (R-GA) introduced the bill on 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)

- Rep. Brian Higgins (D-NY) introduced this legislation on 7/9/21; the bill currently has five bipartisan cosponsors.
- The bill 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)

- Rep. Debbie Wasserman Schultz (D-FL) introduced this legislation on 6/23/2021 with 3 cosponsors.
- 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. It would also provide coverage of certain cancer screenings or preventive surgeries that would reduce the risk for individuals with a germline mutation associated with a high risk of developing a preventable cancer.

Katherine's Lung Cancer Early Detection and Survival Act (H.R.3749 and S.1966)

- This legislation was introduced in the House by Rep. Brendan Boyle (D-PA-2) and in the Senate by Sen. Tina Smith (D-MN) on 6/8/2021. The House bill has 2 cosponsors.
- 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. It would also allow screening coverage with referral from a specialist for those who have a high risk of lung cancer due to genetic, occupational, family history, or other exposures.

Pediatricians Accelerate Childhood Therapies (PACT) Act of 2021 (H.R.3773 & S.1367)

- Rep. John Joyce (R-PA-13) introduced this legislation in the House on 6/8/2021 with 1 cosponsor; Sen. Joni Ernst (R-IA) introduced the legislation in the Senate on 4/22/2021 with 5 cosponsors.
- The legislation would amend the Public Health Service Act to authorize the Director of the National Institutes of Health to make awards to outstanding scientists, including physician-scientists, to support researchers focusing on pediatric research, including basic, clinical, translational, or pediatric pharmacological research, and for other purposes.

Selected Resolutions – 117th Congress

This section highlights resolutions introduced to raise awareness about specific diseases or issues. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Recognizing October 2021 as Liver Cancer Awareness Month (H.Res.740).

- This resolution was introduced by Rep. Nydia Velazquez (D-NY-7) on 10/21/2021 and has 2 cosponsors.

A resolution designating September 2021 as "National Childhood Cancer Awareness Month" (S.Res.400)

- This resolution was introduced by Sen. Joe Manchin (D-WV) on 9/30/21. It has 6 bipartisan cosponsors.

A resolution designating September 2021 as “National Ovarian Cancer Awareness Month” (S.Res.367 & H.R.687)

- Sen. Debbie Stabenow (D-MI) introduced the resolution on 9/20/21; It has three cosponsors: Sens. Tammy Duckworth (D-IL), Alex Padilla (D-CA), and Gary Peters (D-MI).
- Rep. Rosa DeLauro (D-CT) introduced the resolution in the House on 9/28/2021; it has five bipartisan cosponsors.

Supporting the designation of the week of September 19 through September 25, 2021 as “Telehealth Awareness Week” (H.Res.660)

- The resolution was introduced by Rep. John Curtin (R-UT) on 9/20/21.
- It has two cosponsors: Reps. Peter Welch (D-VT) and Bill Johnson (R-OH).

Expressing support for the designation of September 2021 as “National Prostate Cancer Awareness Month” (H.Res.633 & S.Res.378)

- Rep. Donald Payne, Jr. (D-NJ) introduced the resolution on 9/10/21. It has nine bipartisan cosponsors.
- Sen. Robert Menendez (D-NJ) introduced the resolution in the Senate on 9/22/21. It has twelve bipartisan cosponsors.

Expressing support for the designation of July 2021 as National Sarcoma Awareness Month (S.Res.319)

- Sen. Ron Johnson (R-WI) introduced the resolution on 7/26/21.

A resolution recognizing the 25th anniversary of the Foundation for the National Institutes of Health (S.Res.281)

- Sen. Patty Murray (D-WA) and Sen. Richard Burr (R-NC) introduced the resolution on 6/22/21.