November 9, 2022*

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

*Content current as of November 3, 2022

Office of Government and Congressional Relations

National Cancer Institute

Building 31-10A48

NCIOGCR@mail.nih.gov

240-781-3410

Visit the Office of Government and Congressional Relations website at:

https://cancer.gov/about-nci/legislative/

I. Budget and Appropriations

Days after the fiscal year (FY) 2022 omnibus bill, which provided $6.9 billion for the National Cancer Institute (NCI), was signed into law, the White House released the FY2023 President's Budget on March 28th. Due to the delayed finalization of the FY2022 package, administration officials have noted the President's Budget was developed using FY2021 funding levels as a base. Overall, the administration has proposed $127.3 billion in discretionary budget authority for the Department of Health and Human services (HHS), which is a 1.4% increase relative to the FY2022 enacted level.[1] The proposed Budget includes $49 billion for NIH, $4.3 billion above the FY2022 enacted funding level, including $5 billion for the Advanced Research Projects Agency for Health (ARPA-H). The President's Budget also includes $6.7 billion for NCI, an amount $199 million less than the FY2022 enacted level. Final FY2022 funding levels, as well as figures from the FY2023 President's Budget proposal and the proposed House and Senate versions of the FY2023 appropriations bills, are provided in Table 1 below.

Although House and Senate appropriators have both put forward their proposed FY2023 spending bills, disagreements remain about overall defense and non-defense spending levels and controversial policy riders. Because the bills were not completed before the end of FY2022 (September 30), Congress avoided a government shutdown and gave themselves more time by passing a FY2023 Continuing Resolution (CR) to extend FY2022 funding levels through December 16th. The Senate passed the CR on September 29th by a vote of 72-25 followed by the House CR passage by a vote of 230-201 on September 30th. The President signed the CR into law on September 30th.

Passage of the CR was prolonged by debate over whether to attach additional legislative provisions to the bill, including federal energy project permitting, Food and Drug Administration (FDA) user fees, and an Administration request for emergency funding. Ultimately, the CR reauthorized FDA user fees programs without changes (additional information in Section II); the bill also provides funds to the Federal Emergency Management Agency (FEMA) for disaster aid, as well as emergency funding for the war in Ukraine. The package did not provide the Biden Administration's requested supplemental funds to address the ongoing public health emergencies such as COVID-19 and monkeypox, nor did it include a controversial measure to streamline energy project permits that was championed by Sen. Joe Manchin (D-WV).

Congress is expected to finish work on a final FY2023 appropriations package after the mid-term elections during the lame duck session (November – December). Although funding the federal government for the remainder of FY2023 is a top priority for lawmakers, time will also need to be devoted to other must-pass legislation, including the FY2023 National Defense Authorization Act (NDAA). Congress is required to reauthorize Department of Defense (DoD) programs each year, in contrast to other federal agencies, which are typically reauthorized for several years at a time. Notably, the NDAA sets funding levels for the Congressionally Directed Medical Research Programs (CDMRP), which funds DoD-supported research across a number of cancer types.[2]

House FY2023 Appropriations Progress

[1] The NIH appropriation is part of the HHS discretionary budget – that is, funding for HHS agencies that is determined through the appropriations process each year. The remainder of HHS's budget is classified as mandatory, meaning that it is required through legislation. For example, the majority of Medicare funds are mandatory; under law, the federal government must provide certain services to eligible Medicare enrollees, regardless of what the cost is each year.
[2] A list of CDMRP research programs is available at https://cdmrp.health.mil/researchprograms.aspx. Cancers included in the FY2022 CDMRP include breast, kidney, lung, melanoma, ovarian, pancreatic, prostate, and rare. The program also includes funding for neurofibromatosis and disease agnostic, peer reviewed cancer research.

On June 22nd, House appropriators released a $242.1 billion FY2023 Labor, Health and Human Services, Education, and Related Agencies (L-HHS) spending bill. It includes a total of $47.5 billion for NIH, an increase of $2.5 billion over FY2022 and a total $7.4 billion for NCI, which includes $216 million for the Cancer Moonshot, as authorized in the 21st Century Cures Act (Public Law 114-255). This would represent an overall $466 million increase for NCI over the FY2022 enacted level. The bill also proposes $2.75 billion for ARPA-H, an increase of $1.75 billion, and the bill indicates appropriations will be made available provided "[T]hat the President shall appoint in the Department of Health and Human Services a director of advanced research projects for health." On June 23rd, the L-HHS subcommittee favorably reported the bill out of the subcommittee by voice vote. A week later, on June 30th, the House Committee on Appropriations approved the draft bill during a full committee mark-up with a final vote of 32-24. Republican appropriators opposed the draft bill due to the split between domestic and foreign aid and objected to controversial policy riders related to abortion and immigration.

Senate FY2023 Appropriations Progress

Senate appropriators released the chamber's versions of all twelve FY2023 appropriations bills on July 28th and indicated that they will not hold committee markups. The bills represent the majority viewpoint and are not negotiated, bipartisan bills. Senate Committee on Appropriations Ranking Member Richard Shelby (R-AL) stated that "These drafts fail to appropriately allocate resources to our national defense, remove important legacy riders that enjoyed broad, bipartisan support just four months ago, and are filled with poison pills." Given that the bills lack bipartisan support, they serve as a starting point in negotiations. The Senate's FY2023 L-HHS spending bill would provide $216.1 billion to HHS, an increase of $21 billion over FY2022 levels. It includes $47.9 billion for NIH and $7.2 billion for NCI; these funding levels represent an approximately $290 million increase over FY2022 levels for NCI, including $216 million for the Cancer Moonshot. The bill proposes $1 billion for ARPA-H, which matches the FY2022 enacted level.

Table 1: Summary of FY2022 and FY2023 Appropriations

	FY22 Enacted Omnibus Passed 3/15/22	**PB FY23 (3/28/22)**	***House L-HHS Subcomm Mark 6/23/22 & Full Cmt 6/30/22***	***Senate L-HHS Subcomm Draft Posted 7/28***
NIH	**$45.0 B**	**$49.0 B (+ $4.3 B)***	***$47.5 B (+2.5 B)****	***$48.0 B (+2 B, as compared to $46 B after ARPA-H transfer to NIH in FY22)***
ARPA-H	**$1.0 B**	**$5.0 B (+ $4 B)**	***$2.75 B (+$1.75 B)***	***$1.0 B (Flat)***
NCI	**$6.9 B**	**$6.7 B (- $199 M)**	***$7.4 B (+ 466 M)***	***$7.2 B (+ 290 M)***

*Includes $4 B increase for ARPA-H, so non-ARPA-H increase would be $0.3 B
** Does not include ARPA-H (or mandatory request for pandemic preparedness)

II. Special Legislation

Notable Legislative Activities

FDA User Fees Reauthorization

Congress incorporated a 5-year reauthorization of FDA programs to collect user fees for prescription drug, generic drug, biosimilar, and medical device developers in the FY2023 CR. The programs were last reauthorized in 2017 and were set to expire on September 30th. The extension is a "clean" reauthorization that does not include any substantive policy riders that had been considered by Congressional committees in the House and Senate as part of their efforts to reauthorize the user fee programs.

Despite the reauthorization of the core FDA programs, there are provisions that were included in the House and Senate bills that the House Energy and Commerce Committee and the Senate HELP Committee are expected to reconsider after the mid-term elections. In particular, FDA officials noted in October[3] that they are advocating for the passage of the Verifying Accurate Leading-edge IVCT[4] Development (VALID) Act, included in the Senate version of the FDA user fees reauthorization package, before the end of this Congressional session. This bill would allow the FDA to regulate laboratory-developed tests and in vitro diagnostics under one umbrella, thereby requiring premarket review of certain tests that currently do not receive such reviews. Senate HELP Committee Ranking Member Richard Burr (R-NC) has indicated that passing the VALID Act before the end of this session is a top priority, especially as the legislation is not expected to move forward in the next Congress if Democrats lose their Senate majority. FDA officials have indicated that, in the absence of Congressional action, the agency might pursue rulemaking to address the regulation of diagnostics and laboratory-developed tests.

Lawmakers may also consider additional provisions that were included in House and Senate versions of the FDA user fees reauthorization legislation. The House version of the bill, introduced by Rep. Anna Eshoo (D-CA-18), H.R. 7667, includes several provisions related to diversity in clinical trials, alternatives to animal testing, and FDA's accelerated approval pathway. It incorporates provisions from H.R. 5416, Give Kids a Chance Act, which aims to provide the FDA with additional authorities to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances. The House passed H.R. 7667 on June 8th with a vote of 392-28. The Senate HELP Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) released a draft reauthorization bill on May 17th and advanced the package for the full Senate to consider, after a June 14th mark-up. In addition to the VALID Act, the current Senate bill (S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act [FDASLA]) includes cosmetic and dietary reforms, as well as drug importation and food provisions (e.g., on infant formula).

On September 27th, Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) of the HELP Committee released a joint statement on their commitment to continue deliberation and passage of several other bipartisan FDA-priorities that were not included in the CR, before the end of the calendar year.

Gabriella Miller Kids First Research Act 2.0 and ARPA-H Authorizing Legislation

The Energy and Commerce Committee advanced six bipartisan health care related bills during a markup held on May 18th, including H.R.623, Gabriella Miller Kids First Research Act 2.0; H.R.5585, Advanced Research Project Agency–Health Act; and H.R.7667, Food and Drug Amendments of 2022. During committee engagements, members of Congress expressed their strong support for the Gabriella Miller Kids First Research Act, P.L. 113 – 94. The law authorized a pediatric research initiative through NIH and is set to expire in FY2024; however, the current version of H.R. 623 (version that was voted out of committee) would reauthorize the efforts for 5 years

[3] https://www.politico.com/newsletters/prescription-pulse/2022/10/28/fda-will-overhaul-diagnostics-regulation-if-congress-doesnt-00063921

[4] In vitro clinical tests

and would authorize an appropriation of $25 million per year (as compared to the current $12.6 million per year). The bill does not propose a specific source of funding, a notable difference compared to the original Act, which leveraged unspent funds for presidential nominating conventions.

Members of Congress also expressed their strong support for ARPA-H, while voicing concerns with the current structure. There is a common consensus that the agency should be nimble and dynamic, modeling the spirit of DARPA; however, there are conflicting views regarding where the agency should be housed. Legislation has been introduced in both the House and Senate that provide prescriptive authorizing language for ARPA-H. On June 22nd, the House passed the ARPA-H Act, H.R. 5585, introduced by Rep. Anna Eshoo (D-CA-18) by a vote of 336-85. The House bill would establish the agency within HHS and authorize $500 million annually for FY2023-2027. The bill would require all operations to be moved from NIH to an independent division within HHS no later than 180 days after the bill is enacted into law. A manager's amendment authored by Reps. Anna Eshoo (D-CA-18) and Brett Guthrie (R-KY-02), added prior to House passage, would require no more than 15% of funding be used for administrative expenses. The White House released a Statement of Administration Policy (SAP) on the bill, which supports House passage but urges an approach that would allow ARPA-H to leverage NIH's existing infrastructure. The Senate bill, S.3819, ARPA-H Act, introduced by Sens. Patty Murray (D-WA) and Richard Burr (R-NC), would establish ARPA-H within NIH but physically outside of the Washington, D.C. region. Both bills specify that the ARPA-H director is to be appointed by the President. The Senate bill was included as an amendment to the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act, S. 3799) during a Senate HELP Committee mark-up in March and was advanced out of committee to be considered by the full Senate. The schedule for further consideration in the Senate is yet to be determined, and differences between the House and Senate approaches would need to be resolved.

Honoring Our PACT Act

The President signed the Honoring Our PACT Act into law on August 10th during a White House ceremony attended by family members of veterans. Among other provisions, the bill creates a presumption that certain illnesses, including some cancers, are a result of toxic exposures experienced during veterans' previous military service and expands VA health care and benefits for veterans exposed to burn pits and other toxic substances.

SBIR/STTR Reauthorization

Authorization for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, set-aside federal programs for domestic small businesses to engage in research and development, was set to expire at the end of FY2022. On September 20th, Senate Small Business & Entrepreneurship Committee Chair Sen. Ben Cardin (D-MD) introduced the SBIR and STTR Extension Act (S. 4900), a 3-year reauthorization, which also includes some key programmatic changes. These include requiring the establishment of a due diligence program to assess potential risk posed by foreign ties and obligations, and additional reporting for HHS and NIH to Congress. The Senate passed the bill by unanimous consent on the same day. The House passed S. 4900 on September 29th, with a vote of 415-9, and the bill was signed into law by the President the following day.

Inflation Reduction Act of 2022

Following months of negotiations, Democratic Senators reached an agreement on a slimmed-down reconciliation package (H.R. 5376), reflective of several of the Democrats' top legislative priorities. Reconciliation bills are aimed at "reconciling" the federal government's budget by altering mandatory funding and do not require certain parliamentary procedures, eliminating the need for bipartisan support and making them an

attractive legislative vehicle for Senate leadership. Chief negotiators on the Inflation Reduction Act were Senate Majority Leader Chuck Schumer (D-NY), who favored progressive legislation that addressed climate change, social infrastructure, and tax provisions, and Sen. Joe Manchin (D-WV), who favored legislation with a narrower scope.

The Senate passed the Inflation Reduction Act of 2022 on August 7th with no Republican support and a tie-breaking vote from Vice President Kamala Harris. The House passed the legislation on August 12th in a strictly party-line vote, and the President signed the bill into law on August 16th during a White House ceremony. The legislation allows Medicare to negotiate on certain prescription drug prices, extends Affordable Care Act subsidies through 2025, provides more than $300 billion for climate change and clean energy, imposes a 15% minimum tax on large corporations, and institutes a new 1% excise tax on stock buybacks. The bill does not contain any provisions directly related to NIH.

CHIPS & Science Act

On August 9th, the President signed into law the CHIPS & Science Act (H.R. 4346), which includes $52 billion in funding for semiconductor manufacturing grants and semiconductor investment tax credits, as well as several science provisions relating to the National Science Foundation (NSF). It authorizes a total of $81 billion for NSF over 5 years, including $20 billion for a new NSF Directorate for Technology, Innovation, and Partnerships to accelerate domestic development of national and economic security technologies. It also seeks to broaden the geographic diversity of NSF grantees by setting a trajectory that would ensure traditionally underrepresented states[5] receive 20% of the funding from NSF by FY2029.

Clinical Trials

In addition to separate provisions directed toward FDA that were included in the House-passed FDA user fee reauthorization package, on June 29th, the Energy and Commerce Committee Subcommittee on Health held a legislative hearing to consider 11 public health bills, including H.R. 7845, NIH Clinical Trial Diversity Act. Several members of the Subcommittee agreed that diversity in clinical trials needs to be improved, and that H.R. 7845 would take a step in the right direction by requiring researchers, who receive NIH funding, to submit "clear and measurable goals" in their grant applications to recruit and retain clinical trial participants who reflect the race, ethnicity, age, and sex of the patient or general U.S. population. The Energy and Commerce Committee has yet to release a mark-up schedule to further consider the NIH Clinical Trial Diversity Act.

On July 27th, Reps. Jackie Speier (D-CA-14) and Michael McCaul (R-TX-10) introduced H.R. 8546, Clinical Trial Coverage Act of 2022. The legislation would require that Medicare and private insurers cover out-of-network routine care for clinical trial participants if no in-network provider is available. The goal of the legislation is to minimize out-of-pocket costs for adult and pediatric patients on clinical trials.

III. Recent Congressional Events

White House Cancer Moonshot Childhood Cancer Forum (September 23, 2022): The White House Office of Science and Technology Policy (OSTP) hosted a livestreamed community forum, in recognition of September as

[5] A jurisdiction is eligible to participate in the Established Program to Stimulate Competitive Research (EPSCoR) if their most recent five-year level of total NSF funding is equal to or less than 0.75% of the total NSF budget. For more information, see https://beta.nsf.gov/funding/initiatives/epscor/epscor-criteria-eligibility.

Childhood Cancer Awareness Month. The event was moderated by Dr. Danielle Carnival of OSTP, and opening remarks were provided by Dr. Alondra Nelson, OSTP, and Environmental Protection Agency (EPA) Administrator Mr. Michael S. Regan. The event included four panels: 1.) the Research to Accelerate Cures and Equity (RACE) for Children Act (Section 504 of P.L. 115-52); 2.) the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act (P.L. 115-180); 3.) the Childhood Cancer Data Initiative (CCDI); and 4.) patient navigation for pediatric cancer. Panelists included Dr. Stephen Chanock, Director of NCI's Division of Cancer Epidemiology and Genetics, who discussed NCI's ongoing childhood cancer research efforts, including work aligned with the STAR Act, and Dr. Gregory Reaman, incoming CCDI Scientific Director. Other panelists included FDA colleague Dr. Martha Donoghue, advocates, and providers.

13th Annual Congressional Childhood Cancer Caucus Summit (September 22,2022): The Congressional Childhood Cancer Caucus Co-Chairs Reps. Michael McCaul (R-TX-10), Jackie Speier (D-CA-14), G.K. Butterfield (D-NC-01), and Mike Kelly (R-PA-16) hosted the 13th Annual Childhood Cancer Summit at the U.S. Capitol Visitor Center (CVC) to raise awareness on childhood cancer. All current and future co-chairs of the Childhood Cancer Caucus provided remarks: Reps. McCaul, Speier, Kelly, Butterfield, Kathy Castor (D-FL-14), and Ami Bera, M.D. (D-CA-7). NCI Office of Cancer Survivorship Director, Dr. Emily Tonorezos, provided an overview of NCI-supported childhood cancer research, with an emphasis on recent survivorship research initiatives aligned with the Childhood Cancer STAR Act, and how these efforts are advancing research in this field and supporting progress for children with cancer and their families. Also delivering remarks were advocates from the childhood cancer community and Dr. Danielle Carnival, the White House Cancer Moonshot Coordinator.

NCI Webinar on the Implementation of the Childhood Cancer STAR Act (September 12, 2022): NCI subject matter experts participated in a webinar to provide an update on NCI's ongoing efforts to implement the research provisions of the Childhood Cancer STAR Act. The webinar highlighted biospecimen collection and biobanking research projects, as well as childhood and adolescent and young adult (AYA) survivorship research, including recent Requests for Applications and Notices of Special Interests aligned with the Childhood Cancer STAR Act, as well as a collaboration with the Agency for Healthcare Research and Quality (AHRQ). Speakers included Drs. Malcolm Smith, Associate Branch Chief, Pediatrics, Clinical Investigations Branch (CIB) in NCI's Division of Cancer Treatment and Diagnosis ; Nita Seibel, Head, Pediatric Solid Tumor Therapeutics, CIB; Emily Tonorezos, Director, Office of Cancer Survivorship; Sandra Mitchell, Program Director, Outcomes Research Branch in NCI's Division of Cancer Control and Population Sciences (DCCPS); Danielle Daee, Program Director, Genomic Epidemiology Branch, DCCPS; and Paul Jacobsen, Associate Director, Healthcare Delivery Research Program, DCCPS. A recording of the webinar and the slide presentation may be accessed here.

Sec. Becerra and MD Congressional Delegation Visit to NCI-Frederick (July 22, 2022): HHS Secretary Xavier Becerra; Sen. Ben Cardin (D-MD); Sen. Chris Van Hollen (D-MD); Rep. David Trone (D-MD-06), whose district includes NCI-Frederick; and HHS Region 3 Director Dr. Ala Stanford met with NIH and NCI leadership, including from the Frederick facility, to learn about the campus's unique resources. The group participated in a scientific roundtable discussion with NCI Acting Director Dr. Doug Lowy; Dr. Larry Tabak, performing the duties of the NIH Director; NCI Deputy Director Dr. Jim Doroshow; Dr. Jason Yovandich, Chief of the Biological Resources Branch in the Developmental Therapeutics Program (DTP); Dr. Melinda Hollingshead, Chief of the Biological Testing Branch in the DTP; and Dr. Kristin Komschlies, Acting Director, NCI-Frederick Office of Scientific Operations. The group then toured Dr. Hollingshead's lab to learn about the Patient-Derived Models Repository (PDMR).

National Brain Tumor Society Reception (July 20, 2022): Dr. Doug Lowy provided remarks at a reception to recognize Glioblastoma (GBM) Awareness Day. Other speakers included David Arons, CEO of the National Brain Tumor Society, and several patient advocates. Sen. Lindsey Graham (R-NC) and Reps. Jake Auchincloss (D-MA-04) and Salud Carbajal (D-CA-24) delivered remarks providing support of the bipartisan, bicameral resolution

recognizing June 20th as National GBM Awareness Day and emphasized the importance of biomedical research. Pre-recorded remarks were provided by Sens. Ed Markey (D-MA) and Kyrsten Sinema (D-AZ), as well as Rep. Brian Mast (R-FL-18).

IV. 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 March 2022.

Selected Bills – 117th Congress

Fighting Cancer in Children Act (H.R. 8786)

- Rep. Ralph Norman (R-SC-5) introduced this legislation on 9/2/2022.
- The bill would transfer funds available for the Office of the Director of NIH to accounts for pediatric cancer research, awareness, and survivorship.

Clinical Trial Coverage Act of 2022 (H.R. 8546)

- Rep. Jackie Speier (D-CA-14) introduced this legislation on 7/27/2022.
- The bill would require out-of-network coverage for qualified individuals participating in approved clinical trials.

Federal PFAS Research Evaluation Act (S. 4492/H.R. 7289)

- Rep. Lizzie Fletcher (D-TX-7) introduced the House bill on 3/30/22, and Sen. Gary Peters (D-MI) introduced the Senate bill on 6/23/22.
- The bill would provide for NASEM to study and report on a federal research agenda to advance the understanding of perfluoroalkyl and polyfluoroalkyl substances, and for other purposes.
- The House passed H.R. 7289 on 7/27/22, with a vote of 359-62, and referred the bill to the Senate.

Screening for Communities to Receive Early and Equitable Needed Services (SCREENS) for Cancer Act (S. 4440/ H.R.8185)

- Sens. Tammy Baldwin (D-WI) and Susan Collins (R-ME) & Reps. Joe Morelle (D-NY-25) and Brian Fitzpatrick (R-PA-1) introduced the legislation on 6/22/2022.
- The bills would reauthorize the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which is a CDC program that provides breast and cervical cancer screening and diagnostic services for women who are low-income, uninsured, and underinsured who do not qualify for Medicaid.

NIH Clinical Trial Diversity Act (H.R.7845)

- Rep. Robin Kelly (D-IL-2) introduced the legislation on 5/19/2022.
- The bill would require NIH to work with clinical trial sponsors to develop clear and measurable recruitment and retention goals based on disease/condition prevalence as well as a rationale for specified goals and a recruitment plan; ensure the availability of less burdensome follow-ups during clinical trials (e.g. fewer follow ups, phone participation, weekend hours) to increase participation of underrepresented populations; the bill would also direct NIH and FDA to launch a public awareness campaign across federal agencies related to research participation opportunities.

Prostate Cancer Community Assistance, Research and Education Act of 2022 (H.R.7750)

- Reps. Greg Murphy (R-NC-3) and Bobby Rush (D-IL-1) introduced this bill on 5/12/2022.
- The legislation would establish a Prostate Cancer Coordinating Committee to monitor, coordinate and

evaluate activities for prostate cancer research programs carried out by Federal agencies.

Childhood Cancer STAR Reauthorization Act (S.4120/H.R.7630)

- Sens. Jack Reed (D-RI), Shelley Moore Capito (R-WV), Chris Van Hollen (D-MD), and Lisa Murkowski (R-AK) & Reps. Michael McCaul (R-TX-10), Jackie Speier (D-CA-14), G.K. Butterfield (D-NC-1), and Mike Kelly (R-PA-16) introduced these bills on 4/28/2022.
- The bills are a five-year reauthorization of the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act, which is currently authorized through FY2023. Provisions directed toward NCI would continue to focus on childhood cancer biobanking efforts and childhood cancer survivorship research.
- On 9/23/22, at the White House Cancer Moonshot Childhood Cancer Forum, Dr. Danielle Carnival, Cancer Moonshot Coordinator, announced that the Biden Harris Administration supports the Childhood Cancer STAR Reauthorization Act.

Additional Pending Legislation

Many legislative proposals continue to be introduced in the 117th Congress with an emphasis on biomedical and/or cancer research and cancer care. Pending legislation listed below were selected for inclusion due to anticipated interest among CTAC members.

Cancer and Biomedical Research

- Patient Navigator Enhancement Act (S. 4790 Introduced 9/6/22): The bill would provide funding for the Patient Navigator Research Program of the NCI by using funds originally allocated for the "Provider Relief Fund" (coronavirus related funding).
- Give Kids a Chance Act (H.R.5416/S.4215, Introduced 3/8/22 & 5/12/22): This legislation would authorize the FDA to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances.
- ARPA-H Act (S.3819, Introduced 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, D.C. area. The bill would also authorize "such sums as may be necessary for each of fiscal years 2023 through 2027."
- Diverse and Equitable Participation in Clinical Trials (DEPICT) Act (H.R.6584, Introduced 2/3/22): The bill would require the FDA to issue regulations aimed at improving reporting standards for clinical trials, including requiring a diversity action plan for how the sponsor will meet enrollment targets. Provisions would also require NIH to conduct additional community engagement and outreach, and would direct the Health Resources and Services Administration, in consultation with NIH, to support community health center grants to improve access to clinical trials in underrepresented communities.
- KO (Knock Out) Cancer Act (H.R. 6342, Introduced 12/23/21): The bill calls for additional funds to NIH, from FY2023 – FY2027, in an amount equal to 25 percent of what was allocated to the NIH for cancer research in FY2021 to support cancer research.
- Cures 2.0 Act (H.R. 6000, Introduced 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, among other provisions.
- 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 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

- Greater Access to Telehealth Act (H.R.8489, Introduced 7/26/2022): This bill would modify the extension of certain Medicare telehealth flexibilities after the end of the COVID-19 public health emergency and would allow certain flexibilities to continue until 12/31/26, if the emergency period ends before that date.
- Advancing Telehealth Beyond COVID–19 Act of 2021 (H.R. 4040, Introduced 6/22/21): This bill would amend the Social Security Act to telehealth flexibilities under the current Medicare program beyond the COVID-19 pandemic, until the end of 2024. The bill passed in the House on 7/27/22, 416-12.
- 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.
- Telehealth Extension and Evaluation Act (H.R.7573, Introduced 4/26/2022): The bill would extend certain telehealth services covered by Medicare and would also evaluate the impact of telehealth services on Medicare beneficiaries.
- 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.
- 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.

- 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.

Cancer Care and Healthcare Access

- Medicare Coverage of Multimarker Testing for Ovarian Cancer (H.R. 9090, Introduced on 9/30/22): This bill would treat certain multimarker testing relating to ovarian cancer as reasonable and necessary for coverage under the Medicare program.
- Health Equity and Accountability Act (H.R.7585, Introduced on 4/26/22): This bill would address social determinants of health, improve access for underserved communities, address maternal health and mental health crises, gun violence and more.
- Preventive Care Awareness Act of 2022 (H.R.7617/S.3098, Introduced on 4/28/22 & 10/28/21): The bill aims to encourage Americans to get screened for cancer and other preventable diseases by creating a national public health education campaign, grant program, and task force for recommended preventive health care services during the COVID-19 pandemic and future pandemics.
- 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.
- Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (S.1873 & H.R.1946, Introduced on 5/27/21 & 3/16/22): The bills propose 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.
- Reducing Hereditary Cancer Act (S.3656/H.R.4110, Introduced 2/16/22 & 6/23/21): This bill would expand Medicare to cover screening for hereditary cancer for individuals with a family history of hereditary cancer, as well as provide Medicare coverage for risk-reducing surgeries and increased preventative screening frequency.
- 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.
- 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 & 10/28/21): 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 & 3/26/21): 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.

Resolutions

- National Childhood Cancer Awareness Month (S.Res.804, Introduced 9/28/22): The resolution recognizes the impact of cancer on the lives of children, urges stakeholders at every level of government to increase public awareness about the risks of cancer and reminds Americans of the bravery of children who are diagnosed with and recover from cancer.
- Telehealth Awareness Week (H.Res.1352, Introduced 9/14/22): The resolution supports the designation of Telehealth Awareness Week.
- National Prostate Cancer Awareness Month (H.Res.1336 & S.Res.776, Introduced 9/9/22 & 9/20/22): The resolution expresses support for the designation of September 2022 as National Prostate Cancer Awareness Month.
- National Sarcoma Awareness Month (S.Res.694, Introduced 6/23/22): The resolution expresses support for the designation of July 2022 as National Sarcoma Awareness Month.
- National Brain Tumor Awareness Month (H.Res.1150 & S.Res.648, Introduced 5/31/22 & 5/24/22): The resolution expresses support for the designation of May 2022 as National Brain Tumor Awareness Month.
- Diffuse Intrinsic Pontine Glioma (DIPG) Pediatric Brain Cancer Awareness Day (S.Res.642/H.Res.404, Introduced 5/17/22 & 5/17/21): The resolution expresses support for the designation of May 17 as "DIPG Awareness Day" to raise awareness and encourage research into cures for DIPG.