

July 19, 2023*

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

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I. Budget and Appropriations

The release of the President’s budget request initiates the appropriations process in Congress, which ultimately determines funding levels for federal agencies. President Joe Biden released his fiscal year (FY) 2024 budget request in two phases, in March – the main summary volume on March 9th and the explanatory documents on March 13th. As outlined in Table 1, the request proposes an overall level of \$48.6 billion for the National Institutes of Health (NIH), a \$920 million increase over the FY2023 enacted level. The NIH total includes \$7.8 billion for the National Cancer Institute (NCI), which would continue the ongoing FY2023 level of Cancer Moonshot funding of \$216 million and proposes another \$500 million for FY2024. In addition to funding for NIH, the budget proposes a \$1 billion increase for the Advanced Research Projects Agency for Health (ARPA-H) and notes that the new agency will help lead and advance the goals of the Cancer Moonshot. The budget request also proposes FY2024 Cancer Moonshot funding for the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid, the Health Resources and Services Administration, and the Indian Health Service. ¹

Appropriators on both sides of the Capitol indicated their intentions to begin the FY2024 appropriations process without delay. Top Senate appropriators, Sens. Patty Murray (D-WA) and Susan Collins (R-ME), issued a [joint statement](#) on January 10th announcing their bipartisan commitment to return to regular order by marking up appropriations bills and bringing them to the Senate floor in a timely manner. On March 8th, House Appropriations Committee Vice Chair Tom Cole (R-OK) told reporters² the Committee aimed to hold hearings in April and May, followed by markups in May and June. Department of Health and Human Services (HHS) Secretary Xavier Becerra testified on behalf of the President’s budget request for HHS at hearings before several House and Senate committees. On April 19th, the House Appropriations Labor-Health-Education (L-HHS) Subcommittee held a hybrid budget/oversight hearing on the FY2024 request for NIH, as well as the budget requests for CDC and the Administration for Strategic Preparedness and Response (ASPR). On May 4th, the Senate Appropriations L-HHS Subcommittee held a traditional hearing on the NIH budget.

Since the first days of the 118th Congress, the leadership faced an urgent deadline to raise the debt ceiling, with predictions from the Treasury that it would need to be done by sometime in June. Unfortunately, substantive discussion did not truly get underway until last month due to protracted partisan disagreements between the Administration and the House Majority, with Democrats insisting on a “clean” debt limit bill, without additional provisions, and Republicans insisting that they would not vote to raise the debt limit without associated reductions in spending. Eventually, the parties came to an agreement to raise the debt limit through January 1, 2025, and an associated budget deal that capped discretionary spending for the next two fiscal years. The agreement was completed on May 27th with little time to spare, as Treasury Secretary Janet Yellen informed Congressional leaders that the Treasury would exhaust all “extraordinary measures” to continue paying the debt as soon as June 5th. While there was some GOP opposition that the deal did not go far enough in reducing the debt and future spending, and progressive Democrats objected to the expansion of work requirements for welfare programs and changes to the environmental review process for federal projects, in the end the leaders were able to garner enough support to pass the bill. On May 31st, the House voted 314 – 117 to advance the debt limit package, entitled the *Fiscal Responsibility Act* ([H.R. 3746](#)). The Senate passed the measure on June 1st, and President Biden signed the bill into law on June 3rd.

The agreement caps FY2024 non-defense discretionary spending at FY2023 levels, and allows defense discretionary spending to increase by 3%, the amount proposed in the President’s FY2024 budget request. For

¹ <https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf>

² <https://plus.cq.com/doc/news-7681890?0>

FY2025, both defense and non-defense discretionary spending will increase by 1%. [The bill imposes](#) new work requirements on nutrition assistance programs, [rescinds unspent COVID relief funds](#), limits President Biden’s plan to expand the IRS, and forces the Administration to resume collecting federal student loan payments at the end of the summer. The bill also includes two funding cut triggers to keep the pressure on Congress to get the FY2024 spending bills done this year. First, if Congress does not pass all 12 spending bills by January 1, 2024, an automatic continuing resolution will go into effect with a 1% cut to all defense and non-defense discretionary funding. Second, the 1% cut would become permanent if all 12 spending bills are not completed by April 30, 2024. This agreement serves as a “stick” to force Congress to get the spending bills done, and creates three funding deadlines for FY 2024 appropriations (October 1st, January 1st, and April 30th).

With the debt ceiling crisis averted for now, guidance in place on budgetary caps for FY2024 spending, and appropriation hearings completed, the House and Senate Appropriations Committees have begun to formulate their proposed FY2024 appropriations bills. House Appropriations Committee Chair Kay Granger (R-TX) released the FY2024 subcommittee allocations, which were adopted on June 15th on a party-line vote. The Republican majority wrote FY2024 appropriations bills using FY2022 spending levels, which is below the spending cap agreed upon in the debt limit deal. In her [press release](#), Chair Granger (R-TX) said “The Fiscal Responsibility Act set a topline spending cap – a ceiling, not a floor.” The L-HHS Appropriations allocation is \$147.1 billion, an approximately \$60 billion reduction below the enacted FY2023 level. The House Appropriations L-HHS Subcommittee held a markup of the FY2024 L-HHS spending bill on July 14th and passed the bill without amendments through the subcommittee on a party-line voice vote. The full committee is expected to consider the bill in the coming weeks. As noted in Table 1, the bill proposes a total of \$44.7 billion for NIH, which is approximately a \$3 billion reduction from the current level. The NIH total includes \$7.1 billion for NCI, which does not include continued funding for the Cancer Moonshot, an overall proposed decrease of \$216 million. The bill also proposes that at least a dozen health programs be eliminated, as well as the Agency for Healthcare Research and Quality (AHRQ). The Senate Appropriations Committee approved its FY2024 spending bill allocations on June 22nd, which adhere to the spending level agreed to in the debt limit deal. The discrepancy between the Senate levels and the lower allocations set by the House is expected to cause a contentious battle in the months ahead. Vice Chair of the House Appropriations Committee Tom Cole (R-OK) recently told reporters it is “very likely” that Congress will pass a continuing resolution into November or December to avoid a government shutdown, giving lawmakers more time to pass the FY2024 appropriations bill.

Table 1: Summary of FY2022 and FY2023 Appropriations and President’s FY2024 Budget Request

	FY2023 Enacted Omnibus (passed 12/29/22)	FY2024 President’s Budget Request* (released 3/9/23)	FY2024 House L-HHS Mark 7/14/23 (released 7/13/23)
NCI	\$7.3 B	\$7.8 B (Would continue \$216 M for MS and proposes an additional \$500 M for MS)	\$7.1 B (-\$216 M, does not propose funding for MS)
NIH^	\$47.7 B	\$48.6 B (+\$920 M proposed)	\$44.7 B (approx. -\$3 B proposed)
ARPA-H	\$1.5 B	\$2.5 B (+\$1 B proposed)	\$500 M (-\$1 B proposed)

*The President’s Budget request proposes \$716 million in discretionary funding for the Cancer Moonshot (MS) in FY2024, but also proposed **mandatory funding** for the MS for FY2025 and FY2026. Mandatory funds require authorizing legislation – cannot be provided through the standard appropriations process.

^The NIH enacted and proposed funding noted here do **not** include enacted or proposed funds for ARPA-H within the NIH total, rather ARPA-H funds are presented separately.

II. Special Legislation

Cancer Drug Shortages

Congress is actively engaged in the current cancer drug shortage situation and has held recent hearings on the topic, and Members have introduced several pieces of legislation aimed at addressing the crisis. The Senate Homeland Security and Government Affairs Committee held a hearing on March 22nd entitled, “[Drug Shortage Health and National Security Risks: Underlying Causes and Needed Reforms](#)” and characterized drug shortages as occurring from multiple underlying causes and presenting serious health and national security risks. Similarly, on May 11th, the House Energy & Commerce Committee (E&C) held a hearing entitled “[Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains](#).” Ranking Member Frank Pallone (D-NJ) released a statement addressing the shortages: “*It is both heartbreaking and unacceptable that patients are experiencing delays in access to the lifesaving cancer medications carboplatin and cisplatin due to supply shortages. My Committee staff is working with the Biden Administration and the [FDA] to promptly address these shortages and to implement long-term solutions to prevent these shortages from occurring in the future.*” On July 12th, E&C Chair Cathy McMorris Rodgers (R-WA) announced her plan to release a drug shortages discussion draft legislation soon, which will build on a recent request for information she issued with the Senate Committee on Finance Ranking Member Mike Crapo (R-ID) to external stakeholders. In a recent statement, Chair Rodgers said: “Through our bicameral RFI, we have received more than one hundred substantive responses, most of which agreed we need to think broadly to address underlying economics that have led to devastating and life-threatening drug shortages for patients.”

Legislation recently introduced addressing this topic includes three bills with bipartisan support. The *Patient Access to Urgent-Use Pharmacy Compounding Act of 2023* ([H.R. 167](#)) introduced by Reps. Morgan Griffith (R-VA) and Henry Cuellar (D-TX) on January 9th aims to improve access to compounded drugs during drug shortages or when there is an urgent need for the medication by establishing a regulatory pathway for compounding pharmacies to prepare medications upon provider request after certain requirements are met. On January 27th, the *Essential Medicines Strategic Stockpile Act of 2023* ([H.R. 405](#)) was introduced by Reps. Earl “Buddy” Carter (R-GA) and Lisa Blunt Rochester (D-DE) which if enacted, aims to provide access to generic drugs at risk for shortage through stockpiles. Finally, Reps. Earl “Buddy” Carter (R-GA), Darren Soto (D-FL), Carol Miller (R-WV), Matt Cartwright (D-PA), and eight additional Republican cosponsors, introduced the *MAD E (Manufacturing API, Drugs, and Excipients) in America Act* ([H.R. 2707](#)), on April 19th. This bill aims to make the U.S. pharmaceutical supply chain less dependent on China and other foreign countries by incentivizing the domestic manufacturing of drugs, API, PPE, and diagnostics.

In addition to hearings and legislation, there is a new bipartisan “Domestic Pharmaceutical Manufacturing Caucus” in the House, led by Reps. Earl “Buddy” Carter (R-GA), Elissa Slotkin (D-MI), Chrissy Houlahan (D-PA), and Gus Bilirakis (R-FL), focused on legislation that incentivizes more domestic production for essential medicines to reduce American reliance on foreign adversaries and head off potential supply chain disruptions.

Cancer Public Health Bills

E&C Health Subcommittee advanced 17 public health bills during a [markup](#) held on July 13th, including the *Gabriella Miller Kids First Research Act 2.0* ([H.R. 3391](#)) and the *Firefighter Cancer Registry Reauthorization Act of 2023* ([H.R. 3821](#)). During the markup, members of Congress expressed their strong support for the [Gabriella Miller Kids First Research Act, P.L. 113 – 94](#), which authorized a pediatric research initiative through NIH and is set to expire in FY2024. H.R. 3391 would reauthorize the efforts for 5 years and would authorize an appropriation of \$25 million per year (as compared to the current \$12.6 million per year). However, the version voted out of the subcommittee extends the program at its current funding level of \$12.6 million for FY 2024 – FY

2028. The measure does not propose a specific source of funding, a notable difference compared to the original Act, which leveraged unspent funds for presidential nominating conventions. A similar version of the bill was passed through E&C last Congress but was never considered on the House floor. H.R. 3821 would authorize \$5 million for the voluntary registry for firefighter cancer incidents under the CDC for FY 2024 – FY 2028, which is an increase from the program’s current funding level of \$2.5 million per fiscal year.

III. Recent Congressional Events

Hearings

Senate L-HHS Appropriations Subcommittee Hearing on the FY2024 NIH Budget (May 4, 2023): During the Senate L-HHS [hearing](#), NCI Principal Deputy Director Dr. Doug Lowy joined NIH colleagues Dr. Larry Tabak, NIH Acting Director; NIMH Director Dr. Joshua Gordon; NIA Director Dr. Richard Hodes; and NIDA Director Dr. Nora Volkow. Full Committee Chair Sen. Patty Murray (D-WA), Full Committee Vice Chair Sen. Susan Collins (R-ME), Subcommittee Chair Sen. Tammy Baldwin (D-WI), and Subcommittee Ranking Member Sen. Shelley Moore Capito (R-WV) all expressed support for NIH and biomedical research, with Sen. Capito mentioning the reauthorization of the Childhood Cancer STAR Act and directing [her first question](#) to Dr. Lowy to discuss the most promising advances in pediatric cancer research. Dr. Lowy addressed additional questions from [Sen. Jerry Moran \(R-KS\)](#) on the coordination of cancer research funding across federal agencies and prioritization of NCI-funded research proposals, as well as from Sen. John Boozman (R-AR) on the geographic reach of [NCI-designated cancer centers](#) and [clinical trial recruitment for rural populations](#). Sen. Dick Durbin (D-IL) highlighted groundbreaking research from [Northwestern University](#) on glioblastoma and scientific advances that may enable treatment across the blood-brain barrier, work that is funded in part by NCI.

House L-HHS Appropriations Subcommittee Hearing on the FY2024 CDC, ASPR, and NIH Budget (April 19, 2023): During the [House L-HHS hearing](#), NIH Acting Director Dr. Larry Tabak was the sole witness testifying on behalf of NIH. He was joined by CDC Director Dr. Rochelle Walensky and the Assistant Secretary for Preparedness and Response at ASPR, Dawn O’Connell. Subcommittee Chair Robert Aderholt (R-AL) expressed concern that while basic research is essentially flat-funded in the FY2024 NIH budget request, a large increase is proposed for ARPA-H. Ranking Member Rosa DeLauro (D-CT) emphasized NIH’s important role at the forefront of biomedical research, including the Cancer Moonshot. While several members praised the committee’s long-standing bipartisan support for NIH, they also were critical of low paylines across NIH ICs, high indirect cost rates paid by NIH, NIH’s refusal to use march-in rights to control Xtandi drug pricing, and NIH’s insufficient funding models to support early career researchers and speed scientific breakthroughs. Cancer research was specifically mentioned by [Rep. Chuck Fleischmann \(R-TN\)](#), who inquired about the greatest areas of opportunity in cancer research, and [Rep. Bonnie Watson Coleman \(D-NJ\)](#), who asked about NIH activities to address endometrial cancer rates and the associated health disparities.

Briefings/Events

Congressional Staff Visit to NCI and The Children’s Inn at NIH (June 28, 2023): Staff to Sens. Tammy Baldwin (D-WI), Shelley Moore Capito (R-WV), and Chris Van Hollen (D-MD), as well as staff to Reps. Kathy Castor (D-FL), and Mike Kelly (R-PA), visited NCI for a tour focused on childhood cancer research. The group met with NCI extramural program leaders (Drs. Malcolm Smith, Nita Seibel, Greg Reaman, and Michelle Mollica), as well as leadership of NCI’s Pediatric Oncology Branch (POB, Drs. Brigitte Widemann and Carol Thiele), and participated in two lab tours with POB investigators Drs. Troy McEachron, Zihui Liu, and Rosa Nguyen. The staff also participated in a tour of the NIH Clinical Center and a tour of The Children’s Inn at NIH, which provides free lodging and services for many families with children, adolescents, and young adults participating in clinical trials at NCI and other NIH Institutes and Centers.

Jaguar Health Canine Cancer: Take C.H.A.R.G.E. (Canine Health and ReGistry Exchange) Congressional Briefing (June 8, 2023): Dr. Amy LeBlanc, Director of NCI's Comparative Oncology Program, spoke at this briefing on the status and landscape of canine cancer research, as well as on the promise of comparative oncology research to help advance treatments and potential cures for both canine and human cancers. The event was organized by Take C.H.A.R.G.E. and sponsored by Rep. Steve Cohen (D-TN). Other speakers included Lisa Conte, CEO of Jaguar Health; Dr. Craig Clifford, Take C.H.A.R.G.E. Scientific Advisory Board Co-Chair; Dr. Carol Robertson-Plouch, Canines-N-Kids Foundation Board of Directors; and Dr. Chiara Palmieri, Global Initiative for Veterinary Cancer Surveillance (GIVCS) Co-Coordinator.

Lazarex Cancer Foundation and Medidata 6th Annual Summit (June 6, 2023): NCI Principal Deputy Director Dr. Doug Lowy participated in a discussion panel on genomic sequencing at this event entitled "Disrupting the System VI." Additional speakers in the panel included Dana Dornsife, Chief Mission and Strategy Officer for Lazarex Cancer Foundation; Jo Mary, a cancer patient affiliated with Lazarex; and Dr. Neena Haider, Professor at Harvard Medical School. Dr. Lowy also received a 2023 Disruptor award for his role in developing the HPV vaccine, recognizing him as an individual who is working tirelessly to improve access to cancer care and cancer health outcomes. Reps. Earl "Buddy" Carter (R-GA), Robin Kelly (D-IL), and Pete Sessions (R-TX) also attended the event and participated in a fireside chat entitled "Paving Pathways to Access."

House Committee on Veterans' Affairs Women Veterans Task Force (May 23, 2023): Dr. Stan Lipkowitz, Chief of the Women's Malignancies Branch at NCI's Center for Cancer Research, participated in a closed-door Congressional roundtable hosted by the House Veterans' Affairs Committee (HVAC) Women Veterans Task Force on health issues that uniquely affect women veterans, including cancer research, treatment, and diagnostics. The event provided the Task Force an opportunity to hear directly from experts in the field about ongoing work to address health issues impacting women veterans, as well as learn about challenges and gaps in efforts. Representatives Aumua Amata Radewagen (R-AS), Frank Mrvan (D-IN), Nikki Budzinski (R-IL), and Nancy Mace (R-SC) participated in the Roundtable and were joined by experts from various organizations including the Department of Veterans Affairs (VA), American Cancer Society, Huntsman Cancer Institute, Society of Gynecologic Oncology, Society for Women's Health Research, and several Veteran Service Organizations (VSOs).

Less Cancer 2023 National Cancer Prevention Initiatives Event (February 1, 2023): Dr. Vikrant Sahasrabudde, Deputy Chief, Breast and Gynecologic Cancer Research Group, Division of Cancer Prevention, provided remarks on health disparities in cancer prevention at an event to kick off National Cancer Prevention Day and the National Cancer Prevention Workshop, organized by the Less Cancer Foundation. This year's event included remarks from Reps. Debbie Dingell (D-MI), John James (R-MI), and Terri Sewell (D-AL). Bill Couzens, Founder and Executive Director, Less Cancer; Dr. Danielle Carnival, the White House Cancer Moonshot Coordinator, the White House Office of Science and Technology Policy (OSTP); Dr. Jann Balmer, Vice President, Less Cancer Board of Directors; and Dr. Jolynn Gardner, Associate Chair of the Department of Health Studies, American University also provided remarks.

IV. Recent Legislation of Interest

The following bills were introduced during the 118th Congress, which convened on January 3, 2023, and were selected for inclusion in this update due to anticipated interest among CTAC members. The legislation listed below reflects proposals introduced since the start of the 118th Congress.

Selected Bills – 118th Congress

Cancer and Biomedical Research

Henrietta Lacks Congressional Gold Medal Act (H.R. 4122)

- Rep. Kweisi Mfume (D-MD) introduced the bill on 6/14/23
- The bill would award posthumously a Congressional Gold Medal to Henrietta Lacks, in recognition of her immortal cells which have made invaluable contributions to global health, scientific research, quality of life, and patients' rights.

Counting Veterans' Cancer Act (S. 1994)

- Sens. Mark Kelly (D-AZ) and Sen. Thom Tillis (R-NC) introduced the legislation on 6/14/23
- The legislation would amend Title 38, United States Code, to require medical facilities of the Department of Veterans Affairs to share certain data with State cancer registries, and for other purposes.

Gabriella Miller Kids First Research Act 2.0 (H.R. 3391 / S.1624)

- Reps. Jennifer Wexton (D-VA), Tom Cole (R-OK), Gus Bilirakis (R-FL), and Debbie Dingell (D-MI), as well as Sens Mark Warner (D-VA), Tim Kaine (D-VA) and Jerry Moran (R-KS) introduced the bill on 5/16/23
- The bill would provide a new source of funding for the NIH's Gabriella Miller Kids First Pediatric Research Program (Kids First) by redirecting penalties collected from pharmaceutical, cosmetic, supplement, and medical device companies that break the law to pediatric and childhood cancer research. H.R. 3391 does not propose a specific funding source, rather it reauthorizes the program through FY 2028, and proposes an authorization of appropriations of \$25 million per year for FY2024 – 2028, without a specified source of funds.
- As noted in Section II of this report, a version of H.R. 3391 was passed through the House E&C Health Subcommittee and will next be considered by the full committee.

Companion Animal Release from Experiments (CARE) Act of 2023 (H.R. 2878)

- Reps. Tony Cárdenas (D-CA) and Ken Calvert (R-CA) introduced the bill on 4/26/23
- The legislation would require research facilities that use companion dogs, cats, or rabbits for research purposes and receive funding from NIH to offer such animals for adoption after completion of such research.

Preparing Regulators Effectively for a Post-prohibition Adult-use Regulated Environment (PREPARE) Act of 2023 (H.R. 2598)

- Reps. Dave Joyce (R-OH) and Hakeem Jeffries (D-NY) introduced the bill on 4/14/23
- The legislation would establish a commission on the Federal Regulation of Cannabis to study a prompt and plausible pathway to the Federal regulation of cannabis.

Triple-Negative Breast Cancer Research and Education Act (H.R. 235)

- Rep. Sheila Jackson Lee (D-TX) introduced the legislation on 1/10/23
- This legislation would provide for research and education with respect to triple-negative breast cancer.

Byron Nash Renal Medullary Carcinoma Awareness Act (H.R. 124)

- Rep. Al Green (D-TX) introduced this bill on 1/9/23

- This bill would aim to provide incentives for education on the risk of renal medullary carcinoma in individuals who are receiving medical assistance under such title and who have Sickle Cell Disease.

Telehealth

Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2023 (H.R. 4189 / S. 2016)

- Reps. Mike Thompson (D-CA), David Schweikert (R-AZ), Doris Matsui (D-CA), and Bill Johnson (R-OH), as well as Sens. Brian Schatz (D-HI) and Roger Wicker (R-MS) introduced the bill on 6/15/23
- The legislation would amend Title XVIII of the Social Security Act to expand access to telehealth services, and for other purposes.

Expanded Telehealth Access Act (H.R. 3875)

- Reps. Mikie Sherril (D-NJ) and Diana Harshbarger (R-TN) introduced the legislation on 6/6/23
- The bill would amend Title XVIII of the Social Security Act to expand the scope of practitioners eligible for payment for telehealth services under the Medicare program.

Prostate Cancer Community Assistance, Research and Education Act (H.R. 1315)

- Rep. Gregory Murphy (R-NC) introduced the bill on 3/1/23
- The legislation would establish a Prostate Cancer Coordinating Committee comprised of Federal agencies (e.g., NIH, CDC, DOD, Department of Veterans Affairs (VA)) to monitor, coordinate, and evaluate the activities of Federal prostate cancer research programs.

Federal Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Research Evaluation Act (S. 466)

- Sen. Gary Peters (D-MI) introduced the bill on 2/16/23
- This legislation would direct the Nation Academies of Sciences, Engineering, and Medicine to study and report on a federal research agenda to advance the understanding of PFAS substances.

Humane and Existing Alternatives in Research and Testing Sciences (HEARTS) Act (H.R. 1024)

- Rep. Chris Pappas (D-NH-1) introduced the legislation on 2/14/23
- This bill would direct NIH to provide incentives to researchers to use non-animal methods when feasible and applicable, as well as establish a dedicated center within the NIH devoted to advancing new alternative methods and developing a plan for reducing the use of animals in federally-funded research.

Taxpayer Research and Contributions Knowledge (TRACK) Act (H.R. 885/S. 315)

- Rep. Lloyd Doggett (D-TX-37) and Sen. Jeff Merkley (D-OR) introduced the legislation on 2/9/23
- The bill would direct the secretary of HHS, and other Federal officials, to compile information relating to Federal support for biomedical research and development into a public, searchable database.

Genomics Data Security Act (S. 289)

- Sen. Marco Rubio (R-FL) introduced the bill on 2/7/23
- The legislation would establish requirements and otherwise direct the NIH to take actions to address national security concerns in genomic and other research.

Strengthen the Pediatric Research Initiative Act (H.R. 546)

- Rep. Tom Cole (R-OK) introduced the bill on 1/26/23
- The bill would end taxpayer financing of Presidential Election Campaigns and transfer all remaining funds into the Pediatric Research Initiative Fund.

Cancer Care and Healthcare Access

Women and Lung Cancer Research and Preventative Services Act of 2023 ([H.R. 4534](#))

- Reps. Brendan Boyle (D-PA) and Brian Fitzpatrick (R-PA) introduced the bill on 7/6/23
- This legislation would require the HHS Secretary, in consultation with the secretary of the Department of Defense (DOD) and secretary of the Department of Veterans Affairs (VA), to conduct an interagency review to evaluate research on women and lung cancer, how women are given access to lung cancer preventive services and conduct public awareness campaigns on lung cancer.

Medicare Access to Cancer Treatment (MPACT) Act of 2023 ([H.R. 4473](#))

- Rep. Jodey Arrington (R-TX) introduced the legislation on 7/6/23
- This legislation would amend Title XVIII of the Social Security Act to provide for site neutral payment for cancer care services under Part B of the Medicare program.

Comprehensive Cancer Survivorship Act (CCSA) ([H.R. 4363](#) / [S. 2213](#))

- Reps. Debbie Wasserman Schultz (D-FL), Brian Fitzpatrick (R-PA), and Mark DeSaulnier (D-CA), as well as Sens. Amy Klobuchar (D-MN) and Ben Cardin (D-MD) introduced the legislation on 6/28/23
- The bill would aim to address the health of cancer survivors and unmet needs that survivors face through the entire continuum of care from diagnosis through active treatment and post-treatment, including by developing a minimum standard of care for cancer survivorship. The legislation would require HHS to conduct a landscape analysis for an Adult Cancer Survivorship Study modeled after NCI's Childhood Cancer Survivor Study (CCSS) and submit a report on the results to Congress.

Increasing Access to Lung Cancer Screening Act ([H.R. 4286](#))

- Reps. Brian Higgins (D-NY), Brian Fitzpatrick (R-PA), and Rep. Kathy Castor (D-FL) introduced the bill on 6/23/23
- The bill would require state Medicaid programs, Medicare, and private insurers to cover annual screenings for all eligible individuals based on guidance and recommendations from the United States Preventive Services Taskforce without cost-sharing and would prohibit prior authorization for lung cancer screenings.

Cancer Drug Parity Act ([S. 2039](#))

- Sens. Tina Smith (D-MN) and Jerry Moran (R-KS) introduced this legislation on 6/15/23
- 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 health care provider.

The Screening for Communities to Receive Early and Equitable Needed Services (SCREENS) for Cancer Act ([H.R. 3916](#) / [S. 1840](#))

- Reps. Joseph Morelle (D-NY) and Brian Fitzpatrick (R-PA), as well as Sens. Tammy Baldwin (D-WI) and Susan Collins (R-ME) introduced the bill on 6/7/23
- The bill would amend the Public Health Service Act to reauthorize and improve the National Breast and Cervical Cancer Early Detection Program for FYs 2024 – 2028.

Give Kids a Chance Act of 2023 ([H.R. 3433](#))

- Reps. Michael McCaul (R-TX) and Anna Eshoo (D-CA) introduced the bill on 5/17/23
- The legislation would authorize the FDA to direct drug companies to develop pediatric study plans for combinations of targeted therapies when relevant for childhood cancers.

Colorectal Cancer Payment Fairness Act ([H.R. 3382 / S. 1894](#))

- Rep. Donald Payne Jr. (D-NJ) introduced the bill in the House on 5/16/23; Sen. Cory Booker (D-NJ) introduced the bill in the Senate on 6/8/23
- The legislation would eliminate the coinsurance requirement for certain colorectal cancer screening tests furnished under the Medicare program.

Pharmaceutical Research Transparency Act of 2023 ([H.R. 3160](#))

- Rep. Jamie Raskin (D-MD) introduced the bill on 5/9/23
- The legislation would require the disclosure of costs associated with clinical trials and pharmaceutical research and development. If enacted, NIH must create a publicly available repository of cost data from certain clinical trials that test the efficacy of drugs, biological products, and devices in human subjects.

Find It Early Act ([H.R. 3086](#))

- Rep. Rosa DeLauro (D-CT) introduced the bill on 5/5/23
- The legislation would provide for health coverage with no cost-sharing for additional breast screenings for certain individuals at greater risk for breast cancer.

Federal Firefighter Cancer Detection and Prevention Act of 2023 ([H.R. 2852](#))

- Reps. Elissa Slotkin (D-MI) and Don Bacon (R-NE) introduced the bill on 4/25/23
- The legislation would require the Secretary of DOD to provide DOD firefighters with medical testing and related services to detect and prevent certain cancers.

Medicare Multi-Cancer Early Detection Screening Coverage Act ([H.R. 2407 / S. 2085](#))

- Reps. Jodey Arrington (R-TX), Terri Sewell (D-AL), Richard Hudson (R-NC), and Raul Ruiz (D-CA) introduced the legislation on 3/30/23, and Sens. Brian Schatz (D-HI), Michael Bennet (D-CO), Tim Scott (R-SC), and Benjamin Cardin (D-MD) introduced the legislation on 6/21/23
- The bill would amend Title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests.

Verifying Accurate, Leading-edge IVCT Development (VALID) Act ([H.R. 2369](#))

- Reps. Larry Bucshon (R-IN) and Diana DeGette (D-CO) introduced the bill on 3/29/23
- The legislation would create a new framework to verify the accuracy of various medical diagnostic tests.

Right to Try Clarification Act ([H.R. 1825](#))

- Rep. Earl Blumenauer (D-OR) introduced the legislation on 3/28/23
- The bill would clarify that the Federal Right to Try law applies to schedule I substances for which a phase I clinical trial has been completed and to provide access for eligible patients to such substances pursuant to the Federal Right to Try law.

Prostate-Specific Antigen Screening for High-risk Insured Men (PSA Screening for HIM) Act ([H.R. 1826](#))

- Reps. Larry Bucshon (R-IN), Yvette Clarke (D-NY), Neal Dunn (R-FL), and Troy Carter (D-LA) introduced the bill on 3/28/23
- The legislation would amend Title XXVII of the Public Health Service Act to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for prostate cancer screenings without the imposition of cost-sharing requirements.

Colorectal Cancer Detection Act ([S. 892](#))

- Sen. Martin Heinrich (D-NM) introduced the legislation on 3/21/23

- The bill would amend Title XVIII of the Social Security Act to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests, to increase participation in colorectal cancer screening in under-screened communities of color, to offset the COVID-19 pandemic driven declines in colorectal cancer screening.

Reducing Hereditary Cancer Act (H.R. 1526 / S.765)

- Reps. Debbie Wasserman Schultz (D-FL), Mariannette Miller-Meeks (D-IA), Elissa Slotkin (D-NI), and Larry Bucshon (R-IN), as well as Sens. Lisa Murkowski (R-AL) and Ben Cardin (D-MD) introduced the bill on 3/9/23
- The bill would provide Medicare coverage for germline mutation testing for individuals with a history of a hereditary cancer gene mutation or a suspected history of hereditary cancer, as well as for associated coverage of risk-reducing surgeries and screenings.

Finn Sawyer Access to Cancer Testing Act (S. 642 / H.R. 1780)

- Sens. Amy Klobuchar (D-MN) and Roger Wicker (R-MS) introduced the legislation on 3/2/23 in the Senate, and Reps. Gus Bilirakis (R-FL) and Doris Matsui (D-CA) introduced the legislation on 3/24/23 in the House
- The bill would allow patients enrolled in Medicare, Medicaid, and the Children’s Health Insurance Plan to receive molecular diagnostic testing at the time of cancer diagnosis.

Advancing Safe Medications for Moms and Babies Act (H.R. 1117)

- Rep. Kathy Castor (D-FL-14) introduced the bill on 2/21/23
- The legislation would promote the inclusion of pregnant and lactating women in clinical research.

The Metastatic Breast Cancer Access to Care Act (H.R. 549)

- Rep. Andrew Garbarino (R-NY-2) introduced the legislation on 1/26/23
- The bill would amend title II of the Social Security Act to eliminate the waiting periods for disability insurance benefits and Medicare coverage for individuals with metastatic breast cancer.

Protect Funding for Women's Health Care Act (S. 13)

- Sen. Joni Ernst (R-IA) introduced the bill on 1/23/23
- The bill would prohibit federal funding of Planned Parenthood Federation of America. The legislation would aim to make the funding no longer available to Planned Parenthood to be made available to other entities to provide women’s health care services, including cervical and breast cancer screenings.

Advanced Safe Testing at Residence Telehealth Act (H.R. 207)

- Rep. David Schweikert (R-AZ-1) introduced the bill on 1/9/23
- The bill would provide coverage and payment for Medicare beneficiaries to receive telehealth assessments. The bill would require the VA secretary to establish a pilot program that would enable patients to have access to FDA-approved at-home tests to diagnose breast cancer, ovarian cancer, prostate cancer, and other health conditions.