

March 13, 2024*

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

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I. Budget and Appropriations

Current Status: Continuing Resolution Maintaining Fiscal Year 2023 Federal Funding

The federal government, including the National Cancer Institute (NCI), is operating under a fourth continuing resolution (CR) for fiscal year (FY) 2024 that provides funding for federal agencies at FY2023 levels through March 2024. On Tuesday, February 27, 2024, President Joe Biden and Vice President Kamala Harris met with congressional leadership – Speaker of the House Mike Johnson (R-LA), House Minority Leader Hakeem Jeffries (D-NY), Senate Majority Leader Chuck Schumer (D-NY), and Senate Minority Leader Mitch McConnell (R-KY) – to discuss FY2024 appropriations. A deal was passed by the House and Senate on February 29, 2024, and signed into law by the President on March 1, 2024, to avert a partial government shutdown, extending the laddered deadlines to March 8 and March 22. Six bills are being packaged together for consideration by March 8th. This group includes Agriculture-Food and Drug Administration (FDA), Energy-Water, Military Construction-Veterans Affairs (VA), Transportation-Housing and Urban Development (HUD), Interior-Environment, and Commerce-Justice-Science. There is a March 22nd deadline for the remaining six bills, which include the Labor, Health and Human Services, Education, and Related Agencies (“L-HHS”) bill, which provides funding for the National Institutes of Health (NIH), along with the Department of Defense (DOD), Homeland Security, Financial Services, State-Foreign Operations, and Legislative Branch bills.

FY2024 to date: A series of Continuing Resolutions

After a tumultuous month of unsuccessful attempts to move FY2024 appropriations bills through the legislative process, and the strong threat of a government shutdown, Congress quickly developed and passed the first CR on Saturday, September 30, 2023, that provided appropriations until November 17, 2023. The President signed the bill into law the same evening, just hours before the end of the fiscal year. Congress once again averted a government shutdown by passing another CR in advance of the November 17th deadline. On November 16, 2023, the “laddered” and second CR was signed into law and included two expiration dates for two separate sets of appropriations bills. The first expiration date, January 19, 2024, applied to programs funded by the Agriculture-FDA, Energy-Water, Military Construction- VA, as well as the Transportation-HUD bills. Funding for programs supported by the other eight spending bills, including L-HHS, was slated to expire on February 2, 2024. To prevent a government shutdown in January, Congress passed another laddered CR signed into law on January 19, 2024. The third CR extended the two deadlines for the sets of appropriations bills: it extended the January 19th deadline for four appropriations bills until March 1, 2024, and it extended the February 2nd deadline for the remaining eight appropriations bills, including Labor-HHS, until March 8, 2024.

Due to disagreements over the first FY2024 CR’s passage, among other intra-party issues, for the first time in U.S. history, the House ousted its Speaker on October 3, 2023, with a vote of 216-210 to remove Speaker Kevin McCarthy (R-CA) by approving a motion to vacate brought forward by Rep. Matt Gaetz (R-FL). Three weeks later, following failed Speaker bids by several House Republicans, the House GOP coalesced around Rep. Mike Johnson (R-LA) and elected him as the Speaker of the House on October 25, 2023. The same week, Speaker Johnson released an ambitious schedule to pass the remaining FY2024 appropriations bills through the House, with floor votes proposed on the L-HHS appropriations bill for the week of November 13, 2023.¹ After voting on dozens of amendments to the bill, House leadership postponed the final floor vote due to concerns that the legislation would not pass the chamber due to disagreements over the bill’s inclusion of controversial provisions, including steep spending cuts.

On January 7, 2024, House Speaker Johnson and Senate Majority Leader Chuck Schumer (D-NY) reached an agreement on a topline spending figure of \$1.66 trillion for FY2024, in line with the Fiscal Responsibility Act negotiated last year by then-Speaker Kevin McCarthy and President Joe Biden (see additional information

¹ https://nlihc.org/sites/default/files/Johnson_Speaker-Priorities_102523.pdf

below). The bipartisan deal sets defense funding at \$886 billion and non-defense funding at nearly \$773 billion, a total that includes roughly \$69 billion agreed to in the “side deal” of the debt limit package. House Speaker Johnson secured \$16 billion in additional savings through the acceleration of a \$10 billion Internal Revenue Service (IRS) funding cut from FY2024 – FY2025 and the rescission of \$6.1 billion in COVID-relief funds. After further negotiations, House and Senate Appropriations Committee leaders recently announced they had also agreed on the funding allocations for each of the 12 appropriations bills. This allows the Appropriations Subcommittees to begin drafting the final bills that determine funding levels for individual agencies and programs, including for NIH and NCI, as lawmakers attempt to finalize the FY2024 appropriations bills before the March CR deadlines.

However, several significant conflicts remain on policy provisions as the House and Senate plan to continue their work to determine funding for the remainder of the fiscal year. While Speaker Johnson said in a letter to the Republican conference that the agreement would allow the party to “fight for important policy riders included in our House fiscal 2024 bills,”² Senate Majority Leader Chuck Schumer (D-NY) and House Minority Leader Hakeem Jeffries (D-NY) said in a joint statement that they “will not support including poison pill policy changes in any of the twelve appropriations bills put before Congress.”³

Additional Background: FY2024 Budget and Appropriations Process

The release of the President’s budget request initiates the appropriations process in Congress, which ultimately determines funding levels for federal agencies. President Biden released his FY2024 budget request in March 2023. As outlined in Table 1, the request proposes an overall level of \$48.6 billion for NIH, a \$920 million increase over the FY2023 enacted level. The NIH total includes \$7.8 billion for NCI, which would continue the ongoing FY2023 level of Cancer Moonshot funding of \$216 million, as well as an additional \$500 million for FY2024.

The first several months of this 118th Congress were dominated by an urgent deadline to raise the debt ceiling, given the prediction from Treasury Secretary Janet Yellen that it would need to be done by early June 2023. The parties agreed to raise the debt limit through January 1, 2025, with an accompanying budget deal that capped discretionary spending for FY2024 and FY2025. On May 31, 2023, the House voted 314 – 117 to advance the debt limit package, entitled the *Fiscal Responsibility Act (H.R. 3746)*, referred to as the “FRA.” The Senate passed the measure on June 1, 2023, and President Biden signed the bill into law on June 3, 2023.

The FRA caps FY2024 non-defense discretionary spending at FY2023 levels, while allowing defense discretionary spending to increase by 3% (the amount proposed in the President’s FY2024 budget) and stipulates a 1% increase in FY2025 for both defense and non-defense discretionary spending. The FRA also includes two triggers to keep pressure on Congress to complete FY2024 spending bills. First, it required that if Congress does not pass all 12 FY2024 spending bills by January 1, 2024 (they did not), automatic spending caps with a 1% across-the-board reduction would take effect (i.e., the funding level currently in place for all government programs). Second, this 1% cut would become permanent if all 12 spending bills are not enacted by April 30, 2024. This agreement serves as a “stick” to force Congress to get the spending bills done or risk a full-year CR at a 1% cut to both defense and non-defense funding.

The House and Senate Appropriations Committees formulated their FY2024 appropriations bills with dramatically different approaches to setting the top-level funding amounts. House Republicans announced that

² <https://punchbowl.news/smj-dear-colleague-1-7-24/>

³ <https://democraticleader.house.gov/media/press-releases/jeffries-schumer-joint-statement-bipartisan-topline-appropriations-agreement>

they would write their appropriations bills to the FY2022 funding level, approximately \$130 billion below the FY2023 enacted funding level and \$119 billion less than the agreed-upon FRA level. In a press release formalizing this approach, House Appropriations Committee Chair Kay Granger (R-TX) stated, “The Fiscal Responsibility Act set a topline spending cap – a ceiling, not a floor.”⁴ In contrast, the Senate Appropriations Committee set its FY2024 subcommittee allocations using the \$1.59 trillion spending level agreed to in the debt limit deal and included an additional \$23 billion proposed as a set aside for emergency funding.

The House Appropriations L-HHS Subcommittee held a markup of the FY2024 L-HHS spending bill on July 14, 2023, and passed the bill without amendments through the subcommittee on a party-line voice vote. The bill has not been considered by the full committee. 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 22, 2023, and for the first time in five years, passed all 12 spending bills out of Committee. The L-HHS bill advanced through the committee in a bipartisan manner and is expected to be followed by a bipartisan floor vote when the bill is considered by the full chamber. As indicated in Table 1, the Senate L-HHS bill includes \$47.8 billion for NIH, an increase of approximately \$123.6 million from current funding levels. The bill also proposes \$7.3 billion for NCI, which accounts for the “funding cliff” created by the end of the Cancer Moonshot funding provided through the 21st Century Cures Act. NCI’s appropriation would include a \$276 million increase from the FY2023 enacted level and includes a total increase of \$60 million for cancer research for FY2024, as well as \$216 million that “shall remain available until expended.”

Table 1: Summary of FY2023 and FY2024 Appropriations

	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)	FY2024 Senate L-HHS Mark 7/14/23 (passed 7/27/23)
NCI	\$7.32 B (Includes \$216 M for MS)	\$7.82 B (Proposes \$716 M for MS)	\$7.10 B (-\$216 M, does not include funding for MS)	\$7.38 B (Proposes +\$60 M, and \$216 M for MS)
NIH[^]	\$47.68 B	\$48.60 B (+\$920 M proposed)	\$44.70 B (approx. -\$3 B proposed)	\$47.81 B (approx. +123.6M proposed)
ARPA-H	\$1.50 B	\$2.50 B (+\$1 B proposed)	\$500 M (-\$1 B proposed)	\$1.50 B (level funding)

*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 – that is, they 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.

⁴ <https://appropriations.house.gov/news/press-releases/granger-plan-fiscal-year-2024-bills-0>

II. Special Legislation

Cancer Drug Shortages

Congress is actively engaged in the current cancer drug shortage situation, with several members of Congress introducing various pieces of legislation aimed at addressing the crisis, and committees in both chambers convening hearings focused on the issue. Members have not yet coalesced around a single bill or legislative package that would address drug shortages.

Most recently, on January 12, 2024, Ranking Member of the Energy and Commerce (E&C) Health Subcommittee Anna Eshoo (D-CA), along with E&C colleagues Reps. Diana DeGette (D-CO), and Kim Schrier (D-WA) introduced the *Pediatric Cancer Drug Supply Act of 2024* ([H.R. 6963](#)), which directs HHS to establish a program to create a reserve supply of essential pediatric cancer drugs by contracting with drug manufacturers. This legislative proposal echoes similar bills, introduced with bipartisan support, that propose the creation of stockpiles for drugs generally: the *Essential Medicines Strategic Stockpile Act of 2023* ([H.R. 405](#)) and the *RAPID (Rolling Active Pharmaceutical Ingredient and Drug Reserve Act) Reserve Act* ([S. 2510](#)).

Additional legislative proposals with bipartisan support include 1) the *Patient Access to Urgent-Use Pharmacy Compounding Act of 2023* ([H.R. 167](#)), which 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, and 2) the *MADE (Manufacturing API, Drugs, and Excipients) in America Act* ([H.R. 2707](#)), which aims to make the U.S. pharmaceutical supply chain less dependent on China and other foreign countries by incentivizing the domestic manufacturing of drugs, active pharmaceutical ingredients (API), personal protective equipment (PPE), and diagnostics.

The Senate Homeland Security and Government Affairs Committee held a hearing on March 22, 2023, 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 11, 2023, E&C held a hearing entitled "[Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains](#)." On July 28, 2023, E&C Chair Cathy McMorris Rodgers (R-WA) released a [discussion draft](#) of legislation to address drug shortages, which builds on a recent request for information (RFI) she issued with the Senate Committee on Finance Ranking Member Mike Crapo (R-ID) to external stakeholders. The E&C Health Subcommittee held a hearing, "[Legislative Proposals to Prevent and Respond to Generic Drug Shortages](#)," on September 14, 2023, to consider potential solutions to drug supply issues and discuss five bills. The House Ways & Means Committee held a hearing, "[Examining Chronic Drug Shortages in the United States](#)," on February 6, 2024, featuring witnesses with expertise in oncology drug shortages, including American Society of Clinical Oncology (ASCO) Chief Medical Officer and Executive Vice President Dr. Julie Gralow.

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

Drug Pricing

Lawmakers in both the House and Senate have frequently stated their desire to address the rising cost of prescription drugs. [Senate Health, Education, Labor, and Pensions \(HELP\) Committee Chair Bernie Sanders \(I-VT\)](#) has said this is currently his top priority. In April 2023, Chair Sanders and Ranking Member Bill Cassidy (R-LA) announced their bipartisan plan, which includes four bills, to “reform pharmacy benefit managers and expand the availability of low-cost generic drugs through the HELP Committee.”⁵ In May, the HELP Committee voted the four drug pricing bills out of committee. These legislative proposals seek to improve access to generic drugs and increase transparency among pharmacy benefit managers. The HELP Committee is continuing to hold hearings with pharmaceutical companies to further encourage action on drug pricing.

The House has developed its legislative strategy aimed at addressing drug pricing, and in early December, the House E&C Committee voted [21 bills](#) out of committee aimed at lowering drug costs, increasing access to care, and encouraging Medicare innovation. Key strategies in these bills include increasing transparency around the activities of pharmacy benefit managers and limiting out-of-pocket costs for drugs under Medicare Part D. Of particular importance to cancer patients is the *Joe Fiandra Access to Home Infusion Act of 2023* ([H.R. 5397](#)), which would provide Medicare coverage for at-home drug infusions. These bills may now be considered on the House floor individually, although if they do move forward, they would likely do so as a legislative package.

Cancer Public Health Bills

Childhood Cancer Therapy Development and Research

The E&C Health Subcommittee plans to meet on February 29, 2024, in honor of Rare Disease Day, to consider several bipartisan bills that aim to tackle rare diseases. Of note, the panel will consider the *Creating Hope Reauthorization Act of 2024* ([H.R. 7384](#)) and the *Give Kids a Chance Act* ([H.R. 3433](#)). Introduced by Reps. Michael McCaul (R-TX) and Anna Eshoo (D-CA), H.R. 7384 would reauthorize the Creating Hope Act of 2011, which expanded FDA’s priority review voucher (PRV) program with a goal to incentivize pharmaceutical companies to develop new drugs for children with a rare pediatric disease. The Creating Hope Act sunsets in September 2024, and the reauthorization would extend the law for another four years. The same House sponsors introduced the Give Kids a Chance Act, which would authorize FDA to direct drug companies to develop study plans for combinations of molecularly targeted therapies when relevant for childhood cancers. The next legislative step is a committee “markup,” which will provide legislators an opportunity to introduce amendments to the bills, or approve them as written, before sending them to the House floor for a vote.

The E&C Health Subcommittee advanced 17 public health bills during a [markup](#) held on July 13, 2023, including the *Gabriella Miller Kids First Research Act 2.0* ([H.R. 3391](#)). The Senate HELP Committee also advanced its version of the *Gabriella Miller Kids First Research Act 2.0* ([S. 1624](#)) during a [markup](#) held on September 21, 2023. During the E&C and HELP markups, members of Congress expressed their strong support for the [Gabriella Miller Kids First Research Act, P.L. 113 – 94](#), which reauthorizes a pediatric research initiative through NIH and is set to expire in FY2024. H.R. 3391 would reauthorize the efforts for five 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 E&C Health Subcommittee extends the program at its current funding level of \$12.6 million for FY2024 – FY2028. 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. The Senate version of the bill would

⁵ <https://www.help.senate.gov/chair/newsroom/press/news-sanders-and-cassidy-announce-bipartisan-deal-to-lower-prescription-drug-prices>

reauthorize the Gabriella Miller Kids First Research Program for a 10-year time period, from FY 2024 – FY2033, and the proposed funding levels, as revised during the HELP Committee’s markup, differ from the House. The Senate bill authorizes funding at the current \$12.6 million level for FY2024, gradually increasing funds authorized each year, to a \$25 million authorization for FY2033. At a Childhood Cancer Forum, held on September 22, 2023, the White House Office of Science and Technology Policy (OSTP) voiced the Biden Administration’s support for the Gabriella Miller Kids First Research Program and desire to see the program reauthorized through legislation.

Cancer Prevention

On February 14, 2024, the E&C Health Subcommittee held a legislative [hearing](#) to consider a slew of healthcare bills, including two bipartisan pieces of legislation focused on cancer prevention: the *Screening for Communities to Receive Early and Equitable Needed Services (SCREENS) for Cancer Act* ([H.R. 3916](#)) introduced by Reps. Joe Morelle (D-NY) and Brian Fitzpatrick (R-PA), and the *Women and Lung Cancer Research and Preventative Services Act of 2023* ([H.R. 4534](#)) introduced by Reps. Brendan Boyle (D-PA) and Brian Fitzpatrick (R-PA). The SCREENS for Cancer Act would reauthorize the Center for Disease Control and Prevention’s (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) through 2028. Meanwhile, H.R. 4534 would require the Secretary of HHS, in consultation with the Secretaries of VA and DOD, to conduct an interagency review to evaluate existing research on women and lung cancer, as well as identify opportunities to accelerate research in this area and develop a public awareness campaign on lung cancer screening. These bills may be considered in an E&C legislative markup in the coming months before being brought to the House floor for a vote.

Firefighter Cancer Registry

At its July 2023 markup, the E&C Health Subcommittee advanced the *Firefighter Cancer Registry Reauthorization Act of 2023* ([H.R. 3821](#)). This legislation would authorize \$5 million for the voluntary registry for firefighter cancer incidents under the CDC for FY2024 – FY2028, which is a proposed increase from the program’s current funding level of \$2.5 million per fiscal year.

III. Congressional Retirements and Departures

Fifty-seven members of Congress (49 Representatives and 8 Senators) have announced they would not seek reelection in 2024 or have left office early.⁶ With some members departing before the end of their current term, House Republicans have a slimmer majority over Democrats for passing partisan legislation. Assuming all members are voting and present, to pass legislation along party-lines, there is currently a two-vote margin, as there are 219 Republicans and 213 Democrats.

Notably for the cancer research community, Congressmen Derek Kilmer (D-WA) and Brian Higgins (D-NY), who serve as Co-Chairs of the House Cancer Caucus, will be retiring from the House. Rep. Kilmer plans to serve the remainder of his term, and Rep. Higgins left Congress in January 2024. He was recently named as the President and Chief Executive Officer of the Shea Performing Arts Center in Buffalo, NY. House Appropriations Chair Rep. Kay Granger (R-TX) announced that she will retire from Congress at the end of her term, rather than seek reelection to a 15th term, opening a top position on the committee. Chair Granger shared that “[she is] encouraged by the next generation of leaders in [her] district. It’s time for the next generation to step up and

⁶ https://ballotpedia.org/List_of_U.S._Congress_incumbents_who_are_not_running_for_re-election_in_2024; the total count of members retiring this term or who have left early, does not include those who have died in office, including Sen. Dianne Feinstein (D-CA) and Rep. Donald McEachin (D-VA).

take the mantle and be a strong and fierce representative for the people.”⁷ Longtime House L-HHS Appropriations member Rep. Barbara Lee (D-CA) is running in California’s Senate race, and E&C Health Subcommittee member Rep. Lisa Blunt Rochester (D-DE) is pursuing a Senate seat as well.

E&C Chair Cathy McMorris Rodgers (R-WA) plans to retire at the end of her 10th term in Congress in 2024. E&C Subcommittee on Health Ranking Member Anna Eshoo (D-CA) announced that she will retire from Congress in 2024, at the end of her 16th term in the House. Reps. John Sarbanes (D-MD), Larry Bucshon (R-IN), and Tony Cárdenas (D-CA), also members of the E&C Subcommittee on Health, will not seek reelection. Rep. Bill Johnson (R-OH), another E&C Subcommittee on Health member, resigned from Congress to be the President of Youngstown State University. Reps. Brad Wenstrup, DPM (R-OH) and Michael Burgess, MD (R-TX), Co-Chairs of the GOP Doctors Caucus, also announced their retirement. Rep. Dan Kildee (D-MI), who was diagnosed with oropharyngeal squamous cell carcinoma earlier this year, is retiring at the end of his term, citing his cancer diagnosis as informing his decision.

IV. Recent Congressional Events

Less Cancer 2024 National Cancer Prevention Initiatives Event (February 6, 2024): 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. Dr. Sahasrabudde also highlighted increasing screening access to rural and underserved populations, with some specific references to NCI’s Last Mile initiative. This year’s event included remarks from Reps. Debbie Dingell (D-MI) and Don Beyer (D-VA). Bill Couzens, Founder and Executive Director, Less Cancer; Dr. Catharine Young, Assistant Director for Cancer Moonshot Policy and International Engagement, the White House OSTP; and several local health care advocates also provided remarks.

One Voice Against Cancer Annual Meeting (January 22, 2024): NCI Director Dr. W. Kimryn Rathmell provided brief remarks to the One Voice Against Cancer (OVAC) coalition at their annual meeting. The meeting serves as a platform for OVAC members to discuss priorities amongst their members, and they often invite the NCI director to address their coalition.

Congressional Briefing on Neurofibromatosis (January 12, 2024): Dr. Taylor Sundby, Physician Scientist in NCI’s Pediatric Oncology Branch (POB), joined an annual briefing hosted by the Littlest Tumor Foundation on neurofibromatosis (NF). During his presentation, Dr. Sundby provided an overview of NF and updates on NCI’s research in the field, particularly his work on blood-based early detection of Malignant Peripheral Nerve Sheath Tumors (MPNSTs). The purpose of the briefing was to educate congressional staff about NF and the importance of NF federally funded research. Other speakers included Tracy Wirtanen, Littlest Tumor Foundation; Dr. Theresa Miller, DOD Congressionally Directed Medical Research Programs (CDMRP); Dr. Annette Bakker, Children’s Tumor Foundation (CTF); and Hannah Kim, NF Young Adult.

Nomination of Dr. Kimryn Rathmell to Serve as Director of the NCI: On November 17, 2023, President Biden announced his intention to appoint Dr. Kimryn Rathmell as Director of the NCI. She became the 17th NCI Director on December 18, 2023. A renowned kidney cancer expert, she is the second woman to hold the position of NCI Director. Dr. Rathmell succeeds Dr. Monica Bertagnolli. Dr. Lowy served as NCI’s Acting Director after Dr. Bertagnolli’s departure to serve as NIH Director and has resumed his role as Principal Deputy Director of NCI.

Confirmation of Dr. Monica Bertagnolli to Serve as Director of the NIH: President Biden announced his intent to

⁷ <https://kaygranger.house.gov/2023/11/statement-by-house-appropriations-chairwoman-kay-granger>

nominate Dr. Monica Bertagnolli, NCI Director, as the Director of the NIH on May 15, 2023. The Senate HELP Committee held a hearing on October 18, 2023, to consider her nomination. She faced questions on a wide variety of topics, including childhood cancer, drug pricing, rural health, and NIH's research priorities.⁸ The Committee voted 15-6 to advance her nomination to the Senate floor. Committee Chair Bernie Sanders (I-VT) voted against the nomination, citing what he considered to be an insufficient commitment from Dr. Bertagnolli to lower drug prices, but five Republicans, including Ranking Member Bill Cassidy (R-LA), voted in favor of her nomination. The Senate voted on November 7, 2023, to confirm Dr. Bertagnolli's nomination to serve as NIH Director, in a vote of 62-36, and she was sworn in as the 17th Director of the NIH on November 9, 2023.

Congressional Cancer Survivors Caucus Visit to NIH (October 20, 2023): Rep. Mark DeSaulnier (D-CA), founder and co-chair of the Congressional Cancer Survivors Caucus, visited NIH and joined a roundtable discussion with staff from the NCI Office of Cancer Survivorship (Drs. Emily Tonorezos and Michelle Mollica) and NCI's My Pediatric and Adult Rare Tumor (MyPART) network (Dr. Abby Sandler). Rep. DeSaulnier also toured an NCI lab (Dr. Marston Linehan) and a National Institute on Deafness and Other Communication Disorders (NIDCD) lab (Dr. Lisa Cunningham) to learn more about research underway to improve the quality of life of cancer survivors.

White House Cancer Moonshot Childhood Cancer Forum 2023 (September 22, 2023): The White House Office of Science and Technology Policy (OSTP) hosted a livestreamed community forum, in recognition of September as Childhood Cancer Awareness Month. The event was moderated by Dr. Catharine Young, OSTP, and included a panel discussion on progress made this past year on childhood cancer research and advocacy, and where the Administration and the community are headed. Dr. Gregory Reaman, Scientific Director of the Childhood Cancer Data Initiative (CCDI), served as a panelist. Remarks were also provided by advocates who shared their personal stories of childhood cancer. Dr. Danielle Carnival, Deputy Assistant to the President for the Cancer Moonshot and Deputy Director for Health Outcomes, OSTP, as well as Mayor Stephen Benjamin, Senior Advisor and Director of the White House Office of Public Engagement, also shared remarks.

14th Annual Congressional Childhood Cancer Caucus Summit (September 21, 2023): The Congressional Childhood Cancer Caucus Co-Chairs Reps. Michael McCaul (R-TX), Ami Bera (D-CA), Mike Kelly (R-PA), and Kathy Castor (D-FL) hosted the 14th Annual Childhood Cancer Summit to raise awareness on childhood cancer. Reps. McCaul, Bera, and Castor provided remarks at the event. Dr. Carol Thiele, Deputy Chief of NCI's POB, as well as Dr. Anandani Nellan, Physician-Scientist Early Investigator and NIH Distinguished Scholar in the NCI POB, represented NCI at the event and provided remarks. Dr. Thiele highlighted innovative intramural/extramural childhood cancer research collaborations, and Dr. Nellan discussed her experience as an NIH-supported trainee, and her ongoing work to translate promising preclinical findings to the clinic for children and young adults with central nervous system tumors. Advocates from the childhood cancer community, a representative from DOD CDMRP, and a pediatric oncology extramural researcher also provided remarks.

OVAC Congressional Briefing (July 20, 2023): Dr. Doug Lowy participated in an OVAC educational briefing focused on the importance of sustained increases in federal funding for cancer research with a focus on NCI. Other speakers included Lisa Lacasse, President, American Cancer Society Cancer Action Network; Dr. Danielle Carnival, Deputy Assistant to the President for the Cancer Moonshot and Deputy Director for Health Outcomes, OSTP; Dr. Adam Sonabend, Associate Professor of Neurological Surgery, Northwestern University; Dr. Christina Annunziata, Senior Vice President for Extramural Discovery Science, American Cancer Society.

⁸ <https://www.help.senate.gov/hearings/nomination-of-monica-bertagnolli-to-be-director-of-the-national-institutes-of-health>

New Democrat Coalition Visit to NIH (July 17, 2023): Nine Congressional representatives, who are part of the New Democrat Coalition, visited NIH and met with NIH Leadership (Drs. Lawrence Tabak, Tara Schwetz, Alfred Johnson, and Marie Bernard), who provided the members with an overview of NIH. The Representatives also visited three labs: an NCI lab with Drs. Doug Lowy, Brigitte Widemann, and Jack Shern; as well as a National Institute of Mental Health (NIMH) lab and a National Institute of Drug Abuse (NIDA) lab to learn more about NIH's research on cancer, mental health, and substance abuse. As part of the visit, Dr. Lowy welcomed the group at the NCI lab where the members heard about the work being done by NCI's POB from Drs. Brigitte Widemann, Special Advisor to the NCI Director for Childhood Cancer, and Jack Shern, Center for Cancer Research Physician Scientist within the POB.

V. Recent Legislation of Interest

The following bills were introduced during the 118th Congress and were selected for inclusion in this update due to anticipated interest among CTAC members. The legislation listed below reflects proposals introduced since the last CTAC meeting in July 2023.

Selected Bills – 118th Congress

Creating Hope Reauthorization Act of 2024 (H.R. 7384)

- Reps. Michael McCaul (R-TX), Nanette Barragán (D-CA), Gus Bilirakis (R-FL), Anna Eshoo (D-CA-16), Michael Burgess (R-TX), and Lori Trahan (D-MA) introduced the legislation on 2/15/24
- The bill would reauthorize the Creating Hope Act of 2011, which expanded the FDA priority review voucher program to incentivize pharmaceutical companies to develop new drugs for children with rare pediatric diseases.

Harley Jacobsen Clinical Trial Participant Income Exemption Act (H.R. 7090)

- Reps. Mike Kelly (R-PA) and Chrissy Houlahan (D-PA) introduced the legislation on 1/25/24
- The bill would amend the Internal Revenue Code of 1986 to exempt all payments received by participants in clinical trials from being counted towards their gross income.

Counting Veterans' Cancer Act of 2024 (H.R. 7091/ S.1994)

- Rep. Jennifer Kiggans (R-VA) introduced the bill in the house on 1/25/24, and the bill was introduced in the Senate in June 2023 by Sen. Mark Kelly (D-AZ)
- The legislation would require medical facilities of VA to share certain data with state cancer registries.

Pediatric Cancer Drug Supply Act of 2024 (H.R. 6963)

- Reps. Anna Eshoo (D-CA), Diana DeGette (D-CO), and Kim Schrier (D-WA) introduced the bill on 1/11/24
- The bill would direct the Secretary of HHS to enter into agreements with drug manufacturers to establish reserve supplies of covered pediatric cancer drugs.

Knock Out Cancer Act (H.R. 6807)

- Reps. Brian Fitzpatrick (R-PA) and Debbie Dingell (D-MI) introduced the legislation on 12/14/23
- The bill proposes providing additional funding to NCI of an amount equal to 25 percent of NCI's FY 2022 appropriation (a proposed increase of approximately \$1.73 billion) for each year FY 2024 through FY 2028, to remain available until expended. If enacted, the bill also would call for a report to Congress on cancer drug shortages.

Lung Cancer Screening and Prevention Act (H.R. 6693)

- Reps. Vern Buchanan (R-FL) and Derek Kilmer (D-WA) introduced the bill on 12/11/23

- The legislation would amend Title XVIII of the Social Security Act to authorize the coverage of additional lung cancer screening tests under the Medicare program.

Grant Reform and NIH Transparency (GRANT) Act ([H.R. 6483](#))

- Rep. Bill Huizenga (R-MI) introduced the legislation on 11/28/23
- The bill would amend the Public Health Service Act to require greater transparency and accountability within the grant-making process of NIH.

Veterans' Cancer Care Coordination Act of 2023 ([H.R. 6338](#))

- Rep. Sylvia Garcia (D-TX) introduced the bill on 11/9/23
- The legislation would direct the Secretary of VA to establish a pilot program for gynecologic cancer coordination at VA.

Cancer Drug Parity Act ([H.R. 6301](#) / [S. 2039](#))

- Reps. Glenn Grothman (R-WI), Suzanne Bonamici (D-OR), Gus Bilirakis (R-FL), Joe Morelle (D-NY), Brian Fitzpatrick (R-PA), Brian Higgins (D-NY), as well as Doris Matsui (D-CA) introduced the legislation on 11/8/23, and 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.

Data for Pediatric Brain Cancer Act of 2023 ([H.R. 6288](#))

- Reps. Ami Bera (D-CA) and Mike Kelly (R-PA) introduced the legislation on 11/8/23
- The bill aims to create a registry of real-world data for children with atypical teratoid rhabdoid tumors, and it aims to strengthen and expand activities related to the collection, sharing, and use of real-world data for children with brain tumors.

Breast Cancer Patient Equity Act ([S. 3069](#) / [H.R. 4779](#))

- Sens. Tammy Duckworth (D-IL) and Lisa Murkowski (R-AK) introduced the bill in the Senate on 10/18/23, and Reps. Judy Chu (D-CA) and Mariannette Miller-Meeks (R-IA) introduced the bill in the House on 7/20/23
- The legislation would amend Title XVIII of the Social Security Act to provide coverage for custom fabricated breast prostheses following a mastectomy.

Ovarian and Cervical Cancer Awareness Act ([H.R. 5858](#))

- Reps. Nydia Velazquez (D-NY), Joe Morelle (D-NY) and Jonathan Jackson (D-IL) introduced the bill on 9/29/23
- The bill would amend the Public Health Service Act to support activities that would aim to increase the awareness and knowledge of health care providers and women with respect to ovarian, endometrial, and cervical cancers.

Childhood Cancer Clinical Trials Act ([H.R. 5647](#))

- Reps. Michael McCaul (R-TX), Ami Bera (D-CA), and Mike Kelly (R-PA) introduced the legislation on 9/21/23
- The bill would require out-of-network coverage for qualified individuals diagnosed with a rare pediatric disease participating in approved clinical trials.

Give Kids a Chance Act ([S. 2897](#) / [H.R. 3433](#))

- Sens. Michael Bennet (D-CO) and Marco Rubio (R-FL) introduced the bill in the Senate on 9/21/23, and Reps. Michael McCaul (R-TX) and Anna Eshoo (D-CA) introduced the bill in the House 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.

Protecting Patient Access to Cancer and Complex Therapies Act ([H.R. 5391](#))

- Rep. Michael Burgess (R-TX) introduced the bill on 9/12/23
- The bill would provide for a rebate by manufacturers for selected drugs and biological products subject to maximum fair price negotiation.

Fairness to Kids with Cancer Act of 2023 ([H.R. 5405](#))

- Rep. Brian Fitzpatrick (R-PA) introduced the bill on 9/12/23
- The bill would require a certain percentage of federal cancer research funds be used for pediatric cancer research.

Cancer Care Planning and Communications (CCPC) Act ([H.R. 5183](#))

- Rep. Mark DeSaulnier (D-CA) introduced the legislation on 8/11/23
- The bill would provide for coverage of cancer care planning and coordination under the Medicare program.

Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act ([S. 2510](#))

- Sens. Gary Peters (D-MI) and Marsha Blackburn (R-TN) introduced the legislation on 7/26/23
- The bill would improve supply chain resiliency for critical drug products with vulnerable supply chains and ensure that reserves of critical drugs and active pharmaceutical ingredients are maintained to prevent supply disruptions in the event of drug shortages or public health emergencies.

Access to Breast Cancer Diagnosis Act of 2023 ([S. 2464](#) / [H.R. 3851](#))

- Sens. Jeanne Shaheen (D-NH) and Katie Britt (R-AL) introduced the bill in the Senate on 7/25/23 and Reps. Debbie Dingell (D-MI), Brian Fitzpatrick (R-PA), Debbie Wasserman Schultz (D-FL) and Colin Allred (D-TX) introduced it in the House on 6/6/23
- The bill would prohibit group health plans and health insurance issuers offering health insurance coverage from imposing cost-sharing requirements with respect to diagnostic and supplemental breast examinations.

Helping Tobacco Users Quit Act ([H.R. 4775](#))

- Reps. Lisa Blunt Rochester (D-DE) and Brian Fitzpatrick (R-PA) introduced the bill on 7/20/23
- The legislation would amend Title XIX and XXI of the Social Security Act to provide coverage of comprehensive tobacco cessation services under such titles.

Breast Cancer Patient Equity Act ([H.R. 4779](#) / [S. 3069](#))

- Reps. Judy Chu (D-CA) and Mariannette Miller-Meeks (R-IA) introduced the bill in the House on 7/20/23, and Sens. Tammy Duckworth (D-IL) and Lisa Murkowski (R-AK) introduced the bill in the Senate on 10/18/23
- The legislation would amend Title XVIII of the Social Security Act to provide coverage for custom fabricated breast prostheses following a mastectomy.

Access to Infertility Treatment and Care Act ([S. 2386](#))

- Sen. Cory Booker (D-NJ) introduced the bill on 7/19/23
- This legislation would require health insurance coverage for the treatment of infertility, including fertility preservation for cancer patients.

Downwinders Parity Act of 2023 ([H.R. 4754](#) / [S. 463](#))

- Rep. Greg Stanton (D-AZ) and Sen. Kyrsten Sinema (I-AZ) introduced the bill on 7/19/23
- This bill would amend the Radiation Exposure Compensation Act to include certain communities.

Worldwide Animal Testing Compliance and Harmonization (WATCH) Act of 2023 ([S. 2397](#))

- Sens. Eric Schmitt (R-MO) and Jeff Merkley (D-OR) introduced the legislation on 7/19/23

- The bill would require inspections of foreign laboratories conducting biomedical and behavioral research to ensure compliance with applicable animal welfare requirements.

Securing Gene Synthesis Act ([H.R. 4702](#) / [S. 2400](#))

- Rep. Anna Eshoo (D-CA) and Sen. Ed Markey (D-MA) introduced the bill on 7/18/23 & 7/19/23
- The bill would require the Secretary of HHS to prescribe a regulation reducing the risks in gene synthesis products and require a report to Congress describing the policies and procedures adopted by all agencies funding or conducting life science research involving gene synthesis products or gene synthesis equipment.

Health Impacts of Nuclear War Act of 2023 ([S. 2398](#))

- Sen. Ed Markey (D-MA) introduced the legislation on 7/19/23
- The bill would require research into the health consequences of the environmental impacts of nuclear war.

Cease Animal Research Grants Overseas (CARGO) Act of 2023 ([H.R. 4757](#))

- Reps. Dina Titus (D-NV) and Troy Nehls (R-TX) introduced the bill on 7/19/23
- The bill would prohibit NIH from awarding any support for an activity or program that uses live animals in research unless the research occurs in the U.S.

Pediatricians Accelerate Childhood Therapies Act 2023 ([H.R. 4714](#) / [S. 2345](#))

- Sens. Joni Ernst (R-IA) and Chris Coons (D-DE), as well as Reps. John Joyce (R-PA) and Kim Schrier (D-WA) introduced the bill on 7/18/23
- The legislation would authorize the Director of NIH to make awards to outstanding scientists, including physician-scientists, to support researchers focusing on pediatric research, including basic, clinical, translational, or pediatric pharmacological research.

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 7/11/23
- This legislation would require the HHS, DOD, and VA Secretaries to evaluate research on women and lung cancer, access to lung cancer preventive services, and conduct public awareness campaigns on lung cancer.