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

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I. Budget and Appropriations

Closing Out Fiscal Year 2024

On September 25, the House of Representatives and Senate passed a bipartisan continuing resolution (CR) maintaining government funding at fiscal year (FY) 2024 levels through December 20. The President signed the bill into law on September 26, well ahead of the September 30 deadline, preventing a government shutdown. With the CR now complete, both chambers are on recess until after the November elections, so final FY2025 funding decisions will be delayed until Congress returns for a "lame duck" session in November. Lawmakers will need to either reach an agreement on the FY2025 funding bills before the December 20 deadline or pass another CR extending into the next session of Congress (beginning January 3, 2025), which would further delay agencies receiving FY2025 funding.

As a reminder, FY2024 began on October 1, 2023, but was not officially funded until March 23, 2024, requiring four CRs to keep the government operating while the appropriations process was completed. Ultimately, the National Institutes of Health (NIH) received \$300 million of targeted increases over the FY2023 enacted level, although some expiring or decreasing mandatory funding streams from the 21st Century Cures Act (including Cancer Moonshot funding) were not restored, affecting not only the Moonshot programs but also the All of Us Research Program and the BRAIN Initiative. The \$216 million that the National Cancer Institute (NCI) received for the Moonshot in FY2023 was the last year of the Cures mandatory funding stream, and appropriators did not restore those funds through FY2024 appropriations. This means that although NCI received a \$120 million base budget increase, the overall funding level for FY2024 was \$96 million less than the FY2023 enacted budget.

Status of FY2025 House and Senate Labor-HHS-Education Appropriations

The President's Budget request was released on March 11 and initiated the annual budget and appropriations process. While a new budget request would typically use the prior fiscal year's enacted level as a comparator, the FY2024 numbers were not final when the President's Budget was released, so the FY2025 budget used the FY2023 funding levels as a baseline instead. As outlined in Table 1, the President's Budget Request proposes \$50.10 billion for NIH, and \$7.84 billion for NCI, in discretionary (regular appropriations) funds. The request also proposes Cancer Moonshot funding of \$1.45 billion in mandatory funds for both FY2025 and FY2026.

House and Senate Committees on Appropriations have held hearings with federal agencies to discuss the FY2025 President's Budget Request; more information on this hearing is provided in Section III below. Both the House and Senate Committees have developed FY2025 Labor, HHS, Education, and Related Agencies ("L-HHS") appropriations bills. The House proposal moved forward along party lines during a Subcommittee on L-HHS markup on June 27, and then was passed by the full committee on July 10. The bill would provide an increase of \$651 million for NCI (a total of \$7.8 billion), but would keep funding flat for NIH overall, in part due to the inclusion of a Republican proposal released to restructure several NIH institutes (not NCI; please see Section II of this report for additional information on this proposal). This restructuring proposal is in the early stages of discussion and is unlikely to move forward as part of the appropriations package. During the subcommittee markup, Chairman Cole (R-OK) noted that the bill "starts here but doesn't end here," and acknowledged that they do not expect all of the NIH policy changes to be in the final FY2025 appropriations bill.

The Senate's FY2025 L-HHS appropriations bill would provide an increase of \$266 million for NCI (a total of \$7.49 billion), of which \$216 million is to restore funding for the Cancer Moonshot. The bipartisan bill was approved by the full Senate Appropriations Committee on August 1.

Table 1: Summary of FY2024 and FY2025 Appropriations

	FY2024 Minibus (enacted 3/23/24)	FY2025 President's Budget Request* (released 3/11/24)	FY2025 House L-HHS Mark (passed 7/10/24)	FY2025 Senate L-HHS Mark (passed 8/1/24)
NCI	\$7.22 B (-\$96 M, due to no MS funding and +120 M to base)	\$7.84 B (+\$522 M, would include \$716 M discretionary funding for MS; plus \$1.4 B in mandatory funding)	\$7.88 B (+\$651 M to base)	\$7.49 B (+50 M to base and +216 M for MS funding)
NIH^	\$47.36 B (+\$300 M to base, -\$678M in Cures funds (MS, BRAIN, AoU))	\$50.10 B (+\$2.44 B proposed)	\$48.6 B (level funding, includes \$500 M for ARPA-H)**	\$50.35 B (+2.05 B to base, +127 M in Cures funds, includes \$1.5 B for ARPA-H)
ARPA-H	\$1.50 B (level funding)	\$1.5 B (level funding)		\$1.5 B (level funding)

[^]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. Authorizing Committees and Special Legislation

There has been movement on proposals and legislation relevant to NCI and cancer research and care during this 118th Congress spearheaded by authorizing committees, including the House Energy & Commerce (E&C) Committee, Ways & Means (W&M) Committee, and the Senate Health, Education, Labor, and Pensions (HELP) Committee. These committees have broad legislative jurisdiction over topics including health care, and they consider bills and issues, as well as oversee agencies, programs, and activities within their jurisdictions. Several committee actions are summarized below.

Frameworks Propose Structural and Policy Changes at NIH

There has been bicameral interest among Republican members of Congress to reform NIH. In September 2023, Ranking Member of the HELP Committee, Sen. Bill Cassidy, M.D. (R-LA) released a public request for information on policies Congress could consider to modernize NIH "so it is more transparent, nimble, and forward-thinking." On May 9, the Ranking Member released a white paper entitled, "NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership," summarizing public comments and outlining proposed policy changes for the agency. His proposals aim to address several areas, including research prioritization and portfolio balance, sustaining U.S. competitive advantage in biomedical research, and opportunities to streamline peer review.

In the House, on June 14, E&C Chair Cathy McMorris Rodgers (R-WA) released a proposed <u>framework</u> entitled, "Reforming the National Institutes of Health – Framework for Discussion." While Committee Republicans say they "support NIH and the critical role it plays in serving Americans, furthering scientific discovery, and ensuring

^{*}The President's Budget proposes **mandatory funding** for the MS for FY2025 and FY2026. Mandatory funds require authorizing legislation – cannot be provided through the standard appropriations process.

^{**}The House mark proposes significant restructuring for NIH, including consolidating ARPA-H with several other NIH ICs.

¹ https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-requests-information-on-nih-reform

the U.S. remains the world's leading pioneer in basic science and biomedical research innovation," it emphasizes that reform and restructuring are overdue, and opportunities remain to improve NIH's operations to better support the U.S. biomedical research enterprise. The framework includes structural and policy reforms, including consolidating NIH's 27 ICs into 15 ICs with the goal to "better align the missions of each institute and center and establish more coordinated overarching research goals, agendas, and constituencies." NCI, the National Institute of Mental Health (NIMH), and the National Institute on Aging (NIA) would not be restructured. The proposal also suggests a 5-year term limit for IC Directors, with the ability to serve two consecutive terms, if approved by the NIH Director. The Committee solicited public comment on the framework and asked for feedback and suggestions to be submitted by August 16.

Building on the 21st Century Cures Initiative

On June 6, Reps. Diana DeGette (D-CO) and Larry Bucshon, M.D. (R-IN) released a <u>letter</u> to request information to inform the next generation of the 21st Century Cures initiative. Spearheaded by Rep. DeGette and former Rep. Fred Upton (R-MI), the 21st Century Cures Act was signed into law in 2016. Key provisions for NIH aim to coordinate policies relating to early career investigators, improve loan repayment programs, and streamline procedural requirements for attendance at scientific meetings (additional information on the Act's NIH provisions may be found <u>here</u>). To build on the acceleration of medical research and increased patient access to novel therapeutics, as well as telehealth services, the members introduced the <u>Cures 2.0 Act</u> in 2021. Some provisions of Cures 2.0 have been implemented, such as the establishment of the Advanced Research Projects Agency for Health (ARPA-H). The letter states that the 21st Century Cures initiative is "an ongoing process of reform" that requires continuous input and collaboration from stakeholders. Reps. DeGette and Bucshon sought input from the public by August 2 on ways Congress can support the next generation of treatments.

<u>Committee Consideration of Cancer and Public Health Legislative Proposals</u>

Childhood Cancer Therapy Development and Research

The E&C Health Subcommittee met on February 29, in honor of Rare Disease Day, to consider several bipartisan bills that aim to tackle rare diseases. Of note, the panel discussed the Creating Hope Reauthorization Act of 2024 (H.R. 7384) and the Give Kids a Chance Act of 2024 (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 for four years. The law expanded the Food and Drug Administration's (FDA) 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 was set to sunset in September 2024, but there was a provision added to the current CR that extends the program through December. 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 to childhood cancers. Both bills were advanced out of an E&C Health Subcommittee markup on May 16. During the markup, an amendment was approved that would consolidate the Retaining Access and Restoring Exclusivity (RARE) Act (H.R. 7383) and the Creating Hope Reauthorization Act of 2024 into the Give Kids a Chance Act. The consolidated Give Kids a Chance Act passed out of full committee unanimously on September 18 and passed in the House of Representatives on September 23. The Senate has not yet taken up the consolidated bill. It would need to pass in the Senate during the lame duck session of Congress in order to be signed into law, either as a stand-alone bill or added onto another piece of legislation.

The E&C Health Subcommittee advanced 17 public health bills during a markup held on July 13, 2023, including

² https://energycommerce.house.gov/posts/chair-rodgers-unveils-framework-for-nih-reform-requests-stakeholder-input

³ https://d1dth6e84htgma.cloudfront.net/NIH Reform Report f6bbdca821.pdf

the Gabriella Miller Kids First Research Act 2.0 (H.R. 3391), which would reauthorize this NIH research program that is set to expire in 2024. The bill passed the House on March 5 and was sent to the Senate for consideration. However, the Senate has introduced its own version of the reauthorization of the Gabriella Miller Kids First Research Program, and it remains to be seen which version will ultimately provide reauthorization for the program, which is popular among members of both parties. The Senate HELP Committee advanced its version of the Gabriella Miller Kids First Research Act 2.0 (S. 1624) during a markup held on September 21, 2023. The House version would reauthorize the efforts for five years and would authorize 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. The Senate version of the bill would reauthorize the Gabriella Miller Kids First Research Program for a 10-year time period, from FY2024 - 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 White House 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. Both the House and Senate FY2025 L-HHS bills propose continuing to fund the program at \$12.6 million in FY2025.

Cancer Research and Prevention

On February 14, the E&C Health Subcommittee held a legislative hearing to consider a slew of health care 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). Identical companion bills were introduced in the Senate: SCREENS for Cancer (S. 1840) by Sens. Tammy Baldwin (D-WI) and Susan Collins (R-ME), and Women and Lung Cancer Research and Preventative Services Act (S. 2245) by Sens. Marco Rubio (R-FL) and the late Dianne Feinstein (D-CA).

In the House, the SCREENS for Cancer Act was unanimously voted out of the E&C Committee on March 20. In the Senate, the bill was reported favorably out of the HELP Committee on February 1. 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.

The Women and Lung Cancer Research and Preventative Services Act would require the Secretary of HHS, in consultation with the Secretaries of the Department of Veterans Affairs (VA) and the Department of Defense (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. The E&C Committee unanimously voted to send the bill forward for consideration by the full chamber during a committee markup on June 12. The Senate HELP Committee has not yet marked up the bill.

The House W&M Committee held a markup on June 27 to consider the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection (MCED) Screening Coverage Act* (<u>H.R. 2407</u>), which would create a pathway for Medicare to cover blood-based cancer screenings after FDA approval. The bill was voted out of the full committee and is expected to be considered by E&C before it advances to the full House chamber.

Telehealth

With the telehealth flexibilities introduced by Medicare during the COVID-19 pandemic set to expire at the end

of this calendar year, lawmakers are working to pass legislation that would continue to allow patients to virtually attend medical appointments and receive certain types of care at home (i.e., Hospital-at-Home programs). The House is considering two proposals that combine several telehealth bills into larger legislative packages. The *Preserving Telehealth, Hospital, and Ambulance Access Act* (<u>H.R. 8261</u>) was voted out of the W&M Committee on May 8. The *Telehealth Modernization Act* (<u>H.R. 7623</u>) was voted out of the E&C Subcommittee on Health on May 16 and out of full committee on September 18.

The bills are similar in many ways – both extend Medicare flexibilities for telehealth until the end of 2026 and Hospital-at-Home programs until the end of 2029, using pharmacy benefit manager reform to pay for the costs of these programs. Both legislative packages also aim to reduce fraud related to lab tests and durable medical equipment. One key difference is that the E&C proposal would establish payment parity for Federally Qualified Health Centers and Rural Health Clinics for in-person and virtual care. The question of whether to reimburse at the same rate for in-person and virtual care was a topic of debate at a recent House E&C Subcommittee on Health hearing on this topic, titled, "Legislative Proposals to Support Patient Access to Telehealth Services," on April 20. Furthermore, the E&C legislation would vary payment rates based on whether patients receive care via a "telehealth virtual platform" or from a non-physician provider. The W&M's bills do not include these provisions, and differences between the measures would need to be addressed before the full House considers a package on the floor. The proposals do not address cross-state licensure.

The Senate has not yet advanced a telehealth legislative proposal, but members continue to express their desire to extend Medicare flexibilities for telehealth beyond the end of this year. One popular proposal is the *Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2023 (S. 2016)*, which has more than 60 bipartisan cosponsors in the chamber.

III. Recent Congressional Events

Briefings and Visits

Senate Leadership Staff Visit to NIH/NCI (October 31): Staff to Senate Minority Leader Mitch McConnell (R-KY) toured the NCI Molecular Imaging Branch (MIB), housed at the NIH Clinical Center, and met with Drs. Peter Choyke, Chief of the MIB, and Baris Turkey, Senior Clinician. They shared how the MIB works to develop targeted imaging methods that accelerate the creation of cancer therapies, as well as how investigators are leveraging artificial intelligence, novel cancer-fighting agents, radiochemistry, and other technologies to better detect, monitor, and treat a variety of cancers, including prostate cancer. The congressional staffer also toured the National Institute of Diabetes and Digestive and Kidney Diseases Metabolic Clinical Research Unit and met with NIH Director Dr. Monica Bertagnolli; the Director of the National Institute of General Medical Sciences, Dr. Jon Lorsch; and the Director of the National Center for Advancing Translational Sciences, Dr. Joni Rutter.

One Voice Against Cancer (OVAC) Congressional Briefing (September 24): NCI Deputy Director for Data Science and Strategy Dr. Warren Kibbe, FACMI, participated in an OVAC educational briefing focused on the vital role of federal research in advancing cancer innovation, as well as the need for sustained increases to the NIH, NCI, CDC, and ARPA-H budgets. Other speakers included Dr. Christina Annunziata, Senior Vice President, Extramural Discovery Science at the American Cancer Society; Dr. Danielle Carnival, Deputy Assistant to the President for the Cancer Moonshot, OSTP Deputy Director for Health Outcomes; Dr. Robert A. Winn, Director and Lipman Chair in Oncology, Virginia Commonwealth University Massey Cancer Center; and Dr. Luisa Escobar-Hoyos, MSc, Assistant Professor of Therapeutic Radiology, Yale School of Medicine.

15th Annual Childhood Cancer Caucus Summit (September 19): 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 15th Annual Childhood Cancer Summit to raise awareness on childhood cancer. Reps. McCaul, Bera, Kelly, Castor, and Anna Eshoo (D-CA) provided remarks at the event. NCI Director Dr. Kimryn Rathmell provided remarks via a video recording. Childhood cancer research leaders Dr. Doug Hawkins (Chair of the NCI-supported Children's Oncology Group (COG)) and Dr. Will Parsons (Co-Principal Investigator of the NCI-COG Pediatric MATCH Study) and advocates from the childhood cancer community also provided remarks.

Senator Visit to NIH/NCI (September 13): Sen. Jack Reed (D-RI) visited the NIH Clinical Center, where NCI Pediatric Oncology Branch (POB) Chief Dr. Brigitte Widemann led a tour for him and NIH Director Dr. Monica Bertagnolli, highlighting childhood cancer research efforts led by NCI to develop new treatments and improve outcomes for young patients with cancer. Sen. Reed toured the lab of POB Investigator Dr. Christine Heske whose work focuses on novel therapeutic agents for pediatric sarcomas. The senator also met with POB Clinical Director and Senior Clinician Dr. John Glod and a young patient with cancer enrolled in an NCI study. During his visit, Sen. Reed also met with Dr. Bertagnolli, National Institute of Environmental Health Sciences Director Dr. Rick Woychik, and National Human Genome Research Institute Division of Genome Sciences Director Dr. Carolyn Hutter on RNA sequencing.

NCI Director Visit to the University of Kansas Cancer Center (KUCC, July 26): NCI Director Dr. Kimryn Rathmell joined Sen. Jerry Moran (R-KS) on a visit to KUCC. She met with leaders of KUCC and the University of Kansas Health System as well as with scientists, trainees, and community members. Dr. Rathmell toured KUCC's early-phase clinical trials unit and its cellular therapeutics program and observed how NCI is helping to expand the reach of cancer research to rural areas through the NCI Community Oncology Research Program (NCORP), which brings clinical trials and cancer care delivery studies to people in their own communities.

National Brain Tumor Society (NBTS) Reception for Glioblastoma (GBM) Awareness Day (July 24): NCI Director Dr. Kimryn Rathmell provided remarks on NCI's research efforts to address glioblastoma at a reception hosted by NBTS to recognize GBM Awareness Day. Other speakers included David Arons, CEO of the National Brain Tumor Society, researchers, and patient advocates. Sen. John Barrasso (R-WY), as well as Reps. Susan Wild (D-PA) and Roger Williams (R-TX) delivered remarks in support of the bipartisan, bicameral resolution recognizing July 17th as National GBM Awareness Day, emphasized the importance of biomedical research, and shared their personal stories with the disease.

Childhood Cancer Research Congressional Staff Visit to NCI and The Children's Inn (May 29): Staff to Sens. Jack Reed (D-RI), Shelley Moore Capito (R-WV), Chris Van Hollen (D-MD), and John Boozman (R-AR), as well as staff to Reps. Michael McCaul (R-TX), Ami Bera (D-CA), Susan Wild (D-PA), and Bonnie Watson Coleman (D-NJ), 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 Emily Tonorezos), as well as leadership of NCI's POB (Drs. Brigitte Widemann and John Glod), and participated in two lab tours with POB investigators: 1) Drs. Nirali Shah, Christopher Chein, and Victoria Giordani, as well as 2) Drs. Rosandra Kaplan, Anandani Nellan, James Cronk, and Sabina Kaczanowska. The staff also met with NCI Director, Dr. Kimryn Rathmell, as well as participated in 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 ICs.

American Association for Cancer Research (AACR) Cancer Disparities Progress Report Congressional Briefing (May 15): Dr. Sanya Springfield, Deputy Director of Cancer Health Equity and Inclusion in NCI's Office of the Director, provided remarks on NCI's efforts to address cancer health disparities at a briefing marking the release of AACR's third Cancer Disparities Progress Report to Congress and the American public. This 2024 report

features the latest research on why disparities in cancer incidence, diagnosis, treatment, and survival exist, and what can be done to address them. Other panelists included Dr. Margaret Foti, AACR CEO; Dr. Robert Winn, Director, Virginia Commonwealth University Massey Comprehensive Cancer Center; Dr. Brian King, Director, Center for Tobacco Products, FDA; and Dr. Marcia Cruz-Correa, Executive Director, University of Puerto Rico Comprehensive Cancer Center.

Hearings

Senate L-HHS Appropriations Subcommittee Hearing on the FY2025 NIH Budget (May 23): During the Senate L-HHS hearing, NCI Director, Dr. Kimryn Rathmell, joined NIH colleagues Dr. Monica Bertagnolli, NIH Director; NIAID Director, Dr. Jeanne Marrazzo; NIDA Director, Dr. Nora Volkow; NIA Director, Dr. Richard Hodes; and NHLBI Director, Dr. Gary Gibbons. Members on both sides of the aisle, including L-HHS Subcommittee Chair Sen. Tammy Baldwin (D-WI) and Ranking Member Shelley Moore Capito (R-WV), expressed their strong support for NIH's mission and their enthusiasm for biomedical research but acknowledged the difficult overall budget environment expected for FY2025. Dr. Rathmell received questions on access to clinical trials in rural states that do not have an NCI-Designated Cancer Center, which provided opportunities for her to share information regarding NCORP, a recently created ad hoc working group on community-connected cancer research, and the Virtual Clinical Trials Office pilot program.

IV. 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 March 2024.

Selected Bills – 118th Congress

<u>Uterine Cancer Study Act (H.R. 9782)</u>

- Rep. Yvette Clarke (D-NY) introduced the legislation on 9/24/24.
- The bill would direct the Secretary of Health and Human Services to study and report on the relationship between hair straighteners and uterine cancer, particularly among women of color.

Find it Early Act (S. 5141)

- Sens. Amy Klobuchar (D-MN) and Roger Marshall (R-KS) introduced the legislation on 9/23/24.
- The bill would provide for ensure all health insurance plans cover screening and diagnostic breast imaging, including mammograms, ultrasounds, MRIs, molecular imaging, and other technologies, with no cost-sharing for certain individuals at greater risk for breast cancer.

Stomach Cancer Prevention and Early Detection Act (H.R. 9304)

- Reps. Yadira Caraveo (D-CO) and Joe Wilson (R-SC) introduced the legislation on 8/6/24.
- The bill would require the NCI Director to conduct a review of the current state of stomach cancer incidence, prevention, screening, awareness, and future public health importance.

Innovation in Pediatric Drugs Act (S. 4905)

- Sens. Jack Reed (D-RI) and Shelley Moore Capito (R-WV) introduced the bill on 7/31/24.
- The legislation would require drugs for rare diseases to be studied in children and would grant the FDA authority to penalize companies that do not complete required pediatric studies on time.

American Cures Act (S. 4879)

- Sen. Richard Durbin (D-IL) introduced the legislation on 7/31/24.
- The legislation would increase mandatory federal spending each year at a rate of medical inflation plus five percent for biomedical research conducted at NIH, CDC, DoD, and VA.

Better Care for Per- and Poly-fluoroalkyl Substances (PFAS) Patients Act (S. 4774)

- Sens. Jeanne Shaheen (D-NH) and Susan Collins (R-ME) introduced the bill in on 7/25/24.
- The bill would ensure the Agency for Toxic Substances and Disease Research regularly assesses and updates clinical guidance regarding the health effects from exposures to PFAS.

Bolstering Research and Innovation Now (BRAIN) Act (S. 4739 / H.R. 9113)

- Sens. Richard Blumenthal (D-CT), John Barrasso (R-WY), Jack Reed (D-RI), and Mike Rounds (R-SD) introduced the legislation in the Senate, and Reps. Susan Wild (D-PA), Brian Fitzpatrick (R-PA), Lori Trahan (D-MA), and John Joyce (R-PA) introduced the legislation in the House on 7/23/24.
- The bill aims to address the spectrum of challenges facing the brain tumor community, from basic scientific research to early-phase drug discovery and development, clinical trials, diagnosis and treatment planning, and care and quality of life for those living with and surviving brain tumors.

Cannabis Research Act (H.R. 8901)

- Reps. Scott Peters (D-CA) and Dave Joyce (R-OH) introduced the bill in the House on 6/28/24.
- The bill would provide legal certainty to researchers studying state-legal cannabis products, create a National Cannabis Research Agenda, and authorize funding for 10 Centers of Excellence in Cannabis Research.

Airborne Hazards and Open Burn Pit Registry 2.0 (S. 4624/ H.R. 2472)

- Sen. Peter Welch (D-VT) introduced the bill in the Senate, and Reps. Gus Bilirakis (R-FL) and Raul Ruiz (D-CA) introduced the bill in the House on 6/20/24.
- The legislation aims to improve, expand, and enhance protections for veterans under the PACT Act in addition to eliminating burn pits to prevent future toxic exposure cases.

Clinical Trial Modernization Act (H.R. 8412)

- Reps. Raul Ruiz, M.D. (D-CA) and Larry Bucshon, M.D. (R-IN) introduced this bill on 5/15/24.
- The legislation aims to modernize clinical trials and remove barriers to participation in clinical trials by enabling HHS to issue grants or enter into contractual arrangements to support education, outreach, and recruitment for clinical trials for diseases that have a disproportionate impact on underrepresented populations. The bill also aims to change the tax code to exclude remuneration for participation in clinical trials from taxable income.

Future of Artificial Intelligence Innovation Act of 2024 (S. 4178)

- Sens. Maria Cantwell (D-WA), Todd Young (R-IN), John Hickenlooper (D-CO), and Marsha Blackburn (R-TN) introduced this bill on 4/18/24.
- The legislation would establish artificial intelligence standards, metrics, and evaluation tools, to support
 artificial intelligence research, development, and capacity building activities in an effort to promote
 innovation in the artificial intelligence industry by ensuring companies of all sizes can succeed and
 thrive.

RECA Extension Act of 2024 (S. 4175 / H.R.8097)

- Sens. Mike Lee (R-UT) and Mitt Romney (R-UT) introduced the legislation in the Senate on 4/18/24, and Rep. Celeste Maloy (R-UT) introduced it in the House on 4/19/24.
- The bill would reauthorize the Radiation Exposure Compensation Act for an additional two years.

Aviator Cancer Examination (ACES) Act (S. 4111)

- Sens. Mark Kelly (D-AZ) and Tom Cotton (R-AR) introduced this bill on 4/11/24.
- The legislation would provide for a study by the National Academies of Sciences, Engineering, and Medicine on the prevalence and mortality of cancer among individuals who served as active-duty aircrew in the Armed Forces.

Women and Underrepresented Minorities in STEM Booster Act of 2024 (S. 4028 / H.R. 7790)

- Sen. Mazie Hirono (D-HI) along with 10 other senators introduced this legislation in the Senate, and Reps. Marilyn Strickland (D-WA) and Shontel Brown (D-OH) introduced the bill in the House on 3/21/24.
- The bill would authorize the National Science Foundation to provide grants for activities focused on
 professional development, training, mentoring, and outreach activities of women and minorities in
 science, technology, engineering, and mathematics (STEM) fields, with the goal of increasing
 participation of historically underrepresented demographic groups in STEM fields.

Colorectal Cancer Early Detection Act (H.R. 7714)

- Reps. Yadira Caraveo (D-CO), Donald Payne (D-NJ), Terri Sewell (D-AL) and Haley Stevens (D-MI) introduced the bill on 3/19/24.
- The legislation would authorize the Secretary of HHS, acting through the Director of the CDC, to make
 grants to States to increase awareness and education for colorectal cancer and improve early detection
 of colorectal cancer in young individuals.