

March 7, 2018*

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

**Content current as of March 1, 2018*

MK Holohan, J.D.
Director, Office of Government and Congressional Relations
National Cancer Institute
Building 31-10A48
mholoha@mail.nih.gov
240-781-3410

Visit the Office of Government and Congressional Affairs website at:
<http://cancer.gov/about-nci/legislative/current-congress>

I. Budget and Appropriations

A Second Shutdown and a Budget Agreement Plus the Fifth Continuing Resolution for FY2018

Funding for the government ran out at midnight on February 9th, resulting in an overnight government shutdown, the second lapse of funding in FY2018.¹ In the pre-dawn hours of February 9th, Congress passed legislation (HR 1892) that included a two-year budget agreement and a stopgap spending measure to fund the government through March 23. The bill also suspends the debt limit through March 1, 2019. The Senate passed the measure 71-28 at 2 am, the House passed it 240-176 at 5:30 am, and the President signed it into law just before 9 am.

The two-year budget agreement sets new limits on how much the government can spend over the next two years, raising nondefense discretionary spending by \$131 billion and defense spending by \$165 billion, and including \$89 billion in disaster aid. Among other priorities, it also extends the Children's Health Insurance Program through 2027, and provides (over two years) an additional \$6 billion for opioid abuse and mental health, and an additional \$2 billion for NIH. These categories called out for specific funding reflect Congress' intention to reserve funding for bipartisan priorities. The increases reflect a "floor" but do not impose a "ceiling" - the appropriators can augment the levels specified in the budget agreement with additional funds from their subcommittee allocation.

Congress has until March 23 (when the current CR expires) to finalize an FY2018 omnibus spending bill to fund the government. While the budget agreement provides the overall funding levels available, the appropriations committees still need to divide the funds among the 12 appropriations subcommittee bills, which will be complicated because some of the areas targeted for funding increases in the budget agreement cross into the jurisdiction of more than one appropriations subcommittee.

Appropriations Committees - Fiscal Year 2018 Bills

The House Appropriations Committee advanced the FY2018 Labor-HHS-Education spending bill out of Committee in July 2017, allocating \$35.2 billion for NIH, a \$1.1 billion increase for the NIH over the FY2017 enacted level, and \$5.471 billion for the NCI, a \$82 million increase over the FY2017 enacted level. The Senate Appropriations Committee advanced their Labor-HHS spending bills out of Committee on September 7, 2017, including a \$2 billion increase for NIH and a \$169 million increase for NCI over the FY2017 enacted level.

II. Congressional Hearings, Briefings, and Visits

Visit by Senator Maggie Hassan (D-NH) (February 16): Senator Hassan visited the NIH campus and met with NIH Director Francis Collins and several IC directors including Dr. Sharpless. She also met with Dr. Bridgette Widemann and Dr. John Glod of CCR's Pediatric Oncology Branch and visited with one of Dr. Glod's young adult patients. Senator Hassan also toured an NINDS Traumatic Brain Injury Lab, and the NIH Eye Clinic (NEI).

National Cancer Prevention Day Briefing (February 7): Dr. Vik Sahasrabudhe, Program Director, NCI Division of Cancer Prevention, participated in a panel discussion hosted by Less Cancer to recognize

¹ The first shutdown was January 20-22, 2018.

National Cancer Prevention Day. Dr. Sahasrabuddhe described NCI's HPV vaccination research portfolio and answered questions on HPV vaccination uptake. Members in attendance included Rep. Charlie Dent (R-PA), Rep. Barbara Comstock (R-VA), Rep. Debbie Dingell (D-MI), Rep. Don Beyer (D-VA), and Sen. Maggie Hassan (D-NH).

The Children's Inn at NIH Congressional Reception (January 17): Dr. Sharpless, along with several colleagues from the Center for Cancer Research (CCR) Pediatric Oncology Branch (POB) and Urologic Oncology Branch, attended the annual Congressional reception for the Children's Inn at NIH. More than 20 members of Congress attended the reception, including Sens. Blunt (R-MO) and Van Hollen (D-MD), and Reps. Matsui (D-CA), McCaul (R-TX), Dingell (D-MI), Kennedy (D-MA), Jackson Lee (D-TX), DeSaulnier (D-CA), Raskin (D-MD), Hoyer (D-MD), and Joyce (R-OH).

III. Legislation of Interest

The following bills and resolutions were selected for inclusion in this update due to anticipated interest among the NCAB membership. More detailed information about these bills and others are available on our website: <http://cancer.gov/about-nci/legislative/current-congress>

Selected New Bills in the 115th Congress

National Biomedical Research Act (S. 2212)

- The bill would establish a Biomedical Research Innovation Fund, directing the Secretary of the Treasury to transfer \$5 billion per year from the Treasury's general fund to the Biomedical Research Innovation Fund for ten years. Funds would be disbursed to NIH and FDA, proportional to each agencies' discretionary appropriations.
- The bill directs NIH and FDA to use the funds to support specific research efforts, including basic research and support of early-career scientists.
- This new funding would be available in addition to discretionary appropriations, and only in years that NIH and FDA receive discretionary appropriations that meet or exceed a minimum threshold – the bill defines this minimum as “equal to the greatest amount of discretionary appropriations appropriated to such entity for a fiscal year during the period beginning with fiscal year 2017 and ending with the fiscal year before the applicable fiscal year.”
- The bill was introduced on 12/7/2017 by Sen. Elizabeth Warren (D-MA) along with 15 original cosponsors and referred to the HELP Committee

Women and Lung Cancer Research and Preventive Services Act (H.R. 4897/S. 2358)

- The bill would direct the HHS Secretary, in consultation with the Secretary of Defense and Secretary of Veterans Affairs, to conduct an interagency study to evaluate the status of, and make recommendations for increased:
 - Research on women and lung cancer;
 - Access to lung cancer preventive services; and
 - Strategic public awareness and education campaigns on lung cancer.
- H.R. 4897 was introduced by Rep. Frank LoBiondo (R-NJ-2) on 1/30/18 and was referred to the Committee on Energy and Commerce. S. 2358 was introduced by Sen. Marco Rubio (R-FL) on 1/30/18 and was referred to the HELP Committee.

Other Selected Bills in the 115th Congress

Right to Try Act (S. 204/H.R. 878)

- This bill would allow patients with a “terminal illness” (H.R. 878) or “life-threatening disease or condition” (S. 204) to request access from drug manufacturers to experimental treatments that the Food and Drug Administration (FDA) has not yet approved, without going through the FDA’s compassionate use program. While the federal government must *allow* access (in so far as patients may request the use of drugs), the legislation does not *require* access to be granted.
 - To be eligible for the program, the patients must have a physician’s certification that they have exhausted treatment options and are unable to participate in a clinical trial involving the agent.
 - The bill also limits the liability of a sponsor, manufacturer, prescriber, or dispenser that provides, or declines to provide, an eligible investigational drug to a patient.
- The Senate easily passed their Right to Try bill in August 2017, but after being sent to the House for consideration, the bill has not moved out of committee. According to recent reporting, House Energy and Commerce Chairman Greg Walden (R-OR) is consulting with the FDA to develop a revised proposal.
- Vice President Pence has been a vocal supporter of right-to-try legislation, which he also signed into state law during his tenure as Governor of Indiana. President Trump also voiced his support during his 2018 State of the Union address, saying he believes, “patients with terminal conditions, terminal illness, should have access to experimental treatment immediately that could potentially save their lives.”

Childhood Cancer STAR (Survivorship, Treatment, Access, Research) Act (H.R. 820/S. 294)

- H.R. 820 was introduced by Reps. Michael McCaul (R-TX), Jackie Speier (D-CA), Mike Kelly (R-PA), and G.K. Butterfield (D-NC), co-chairs of the Congressional Childhood Cancer Caucus, on 2/2/2017 and was referred to the Committee on Energy and Commerce. The House bill has 359 co-sponsors as of 3/1/18. The Senate companion version of this bill, S. 292, was introduced by Sens. Jack Reed (D-RI), Shelley Moore Capito (R-WV), Chris Van Hollen (D-MD), and Johnny Isakson (R-GA) on 2/2/2017 and was referred to the Committee on Health, Education, Labor, and Pensions. The Senate bill has 45 co-sponsors as of 3/1/18 and was passed out of the Senate Health, Education, Labor and Pensions (HELP) Committee on 2/28/18.
- The bill is in part a consolidation of legislative proposals introduced in past sessions of Congress focused on childhood cancer research and care (including biorepositories and biospecimen research, and survivorship research), as well as childhood cancer surveillance. An identical bill passed the House in the 114th Congress with broad bipartisan support, but did not receive a vote in the Senate.
- The bill authorizes NCI to support and expand collection of biospecimens from children, as well as adolescents and young adults (AYAs), diagnosed with cancer to build upon biorepositories and biospecimen research already underway with NCI support.
- The bill also authorizes NIH, with guidance from the NCI Director and in coordination with ongoing research activities, to support grants focusing on the cause of health disparities in pediatric cancer survivorship; and focusing on late effects and follow-up care for pediatric cancer survivors.
- Other provisions specific to NIH and NCI include requiring that at least one member appointed to the National Cancer Advisory Board be knowledgeable in pediatric oncology; establishing specific reporting requirements for NIH in addressing pediatric oncology research within its annual Pediatric Research Initiative Report to Congress; and expressing the sense of Congress that the NCI Director

should ensure that all applicable study sections, committees, advisory groups, and panels at NCI should include one or more qualified pediatric oncologists, as appropriate.

- The bill also authorizes HHS, through the Centers of Disease Control and Prevention, to award grants to state cancer registries to expand surveillance infrastructure to track the epidemiology of cancer in children and AYAs.
- Additional provisions in the bill focused on pediatric cancer survivorship encourage the HHS Secretary to establish pilot programs to evaluate model systems for monitoring and caring for childhood cancer survivors, and carry out a 3-year demonstration project to improve quality and coordination of childhood cancer survivorship care as survivor's transition to adult care. The bill directs the HHS secretary to establish a task force on long-term follow-up services for pediatric cancer survivors and requires the Government Accountability Office (GAO) to submit recommendations to Congress regarding barriers to obtaining and paying for childhood cancer survivorship care.

FDA Reauthorization Act of 2017 (H.R. 2430 / S. 934; Public Law No: 115-52)

The FDA Reauthorization Act of 2017 (FDARA) amends the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products. H.R. 2430 was introduced by Rep. Greg Walden (R-OR) on 5/16/2017 and was signed into law on 8/18/2017, becoming Public Law No: 115-52. The Act includes several provisions relevant to NCI as described below:

The Research to Accelerate Cures and Equity (RACE) for Children Act

The RACE for Children Act was introduced as stand-alone legislation in both the House and Senate earlier this year, and key provisions of the bill were included in FDARA as Section 504, *Development of drugs and biological products for pediatric cancers*. These provisions amend current study requirements under the Pediatric Research Equity Act (PREA) so that requirements for pediatric studies are based on relevant molecular targets rather than the current requirements, based on cancer site of origin. Additionally, the provisions amend PREA by ending the exemption of PREA obligations for cancer drugs with orphan designations if the molecular target of their drug is relevant to a pediatric cancer.

The Act includes two provisions specifically relevant to NCI, and NCI is currently coordinating with the FDA to begin planning and implementation of these efforts:

- The Act directs the HHS Secretary to consult with both FDA and NCI to develop a list of relevant molecular targets. The Act describes this as “a list of molecular targets considered, on the basis of data the Secretary determines to be adequate, to be substantially relevant to the growth and progression of a pediatric cancer, and that may trigger the requirements under this section.”
- The Act directs the HHS Secretary to consult with FDA and NCI and in convening a public meeting within one year after the Act is signed into law to solicit feedback from physicians, researchers, patients, and other stakeholders regarding various aspects of implementation, including development of the list of relevant molecular targets.

Additional Background and Implementation: Implementation of the provisions described above is underway, and representatives from FDA, NIH/NCI, the patient advocacy community, academia, and industry will be participating in a public meeting on 2/20/18 to discuss several considerations to define the best approaches for the creation of a list of molecular targets considered substantially relevant in pediatric cancers. The RACE for Children Act was originally

introduced as H.R. 1231 by Reps. McCaul (R-TX), Duffy (R-WI), and Clarke (D-NY) on February 27, 2017, and as S. 456 Sens. Bennet (D-CO), Rubio (R-FL), Van Hollen (D-MD), and Gardner (R-CO) on February 27, 2017.

Enhanced Clinical Trial Design Act of 2017

The Enhanced Clinical Trial Design Act of 2017 was also introduced as stand-alone legislation in the Senate. The bill aims to expand patient access to experimental treatments in clinical trials, including by providing updated guidance on eligibility criteria. Several aspects of this bill are relevant to NCI and were included in the FDA Reauthorization Act of 2017 as well.

- The Act requires the FDA and the NIH to convene a public meeting to discuss clinical trial criteria, including: barriers to participation, alternative clinical trial designs, and potential impact of changes to clinical trial inclusion and exclusion criteria.
- The Secretary is required to issue a public report on the topics discussed at the meeting as well as guidance documents regarding eligibility criteria for clinical trials.
- In addition, the Secretary is required to issue guidance to streamline the institutional review board (IRB) review process for individual pediatric and adult patient expanded access protocol and how the IRBs may facilitate the use of the protocols.

Additional Background and Implementation: Implementation of the provisions described above are underway, and FDA is supporting a public meeting on 4/16/18 to bring the stakeholder community together to discuss a variety of topics related to eligibility criteria in clinical trials, their potential impact on patient access to investigational drugs, and how they might facilitate the enrollment of a diverse patient population. The Enhanced Clinical Trial Design Act of 2017 was originally introduced as S. 1048 by Sens. Orrin Hatch (R-UT), Michael Bennet (D-CO), Richard Burr (R-NC), and Bob Casey (D-PA) on 5/4/2017.

Selected Resolutions (115th Congress)

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

Introduced

Designation of “National Cancer Prevention Day” (H.Res. 721)

- This resolution expresses support for the designation of February 4, 2018 as National Cancer Prevention Day.
- H.Res. 721 was introduced by Rep. Debbie Dingell (D-MI), Co-Chair of the Cancer Prevention Caucus, on 2/2/18.

Designation of a “Women’s Health Research Day” (H. Res. 706/S. Res. 383)

- This resolution expresses support for the designation of a Women’s Health Research Day.
- H. Res 706 was introduced by Rep. Jan Schakowsky (D-IL) on 1/22/18. S. Res 383 was introduced by Sen. Tammy Duckworth (D-IL) on 1/25/18.