

**July 11, 2018\***

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

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

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

## ***I. Budget and Appropriations***

### ***FY2019 President's Budget Proposal and Congressional Appropriation***

The White House released the FY 2019 President's Budget and an accompanying addendum on Monday, February 12, 2018. Taken together, these budget documents reflect a proposed NCI funding level for FY2019 of \$5.626B (including Moonshot funding authorized by the 21<sup>st</sup> Century Cures Act), a less than 1% reduction compared to the FY 2018 omnibus base appropriation. Dr. Sharpless joined NIH Director Dr. Collins and several IC directors at Labor-HHS Subcommittee hearings on the FY19 NIH Budget Request in both the House (April 11, 2018) and Senate (May 17, 2018). *See additional details in Section II below.*

The House Labor-HHS appropriations subcommittee marked up their FY 2019 appropriations bill on June 15, 2018. The draft legislation proposes an appropriation for NCI of \$6.136 billion, an increase of approximately \$71 million to the base appropriation compared to FY 2018 enacted, and the full \$400 million for Cancer Moonshot activities as authorized by the 21<sup>st</sup> Century Cures Act. The full House Appropriations Committee plans to mark up the bill after the July 4<sup>th</sup> recess. The House returns to session on July 10, 2018 and a date has not yet been confirmed for the full committee markup.

The Senate Labor-HHS appropriations subcommittee marked up their FY2019 appropriations bill on June 26, 2018, and the full committee advanced the bill on June 28. The draft legislation proposes an appropriation for NCI of \$6.147 billion, an increase of approximately \$82 million to the base appropriation compared to FY2018 enacted, and the full \$400 million authorized for Cancer Moonshot activities.

### ***FY2018 Omnibus***

Congress reached a budget agreement in February 2018, which provided overall government funding levels through September 2019. The appropriations committees then had the large task of dividing those funds among the 12 appropriations subcommittee bills, and passing the subcommittee bills as one omnibus bill, before funding from the previous continuing resolution expired. Congress managed to pass their omnibus bill (H.R.1625) on March 23, 2018 with mere hours to spare, and President Trump signed the bill into law on the same day. NIH received a \$3B increase in the omnibus, with an additional \$500M for opioids research. NCI's share of the increase was set at approximately \$275M, bringing the FY18 base appropriation to \$5,664,800,000. In addition, NCI received \$300M for the Cancer Moonshot for FY18 (as authorized by the 21<sup>st</sup> Century Cures Act), bringing our total appropriation (base plus Cures) to \$5,964,800,000.

## ***II. Congressional Hearings, Briefings, and Visits***

Congressional Staff Visit to NCI's Pediatric Oncology Branch (May 30): A bicameral, bipartisan group of ten congressional staffers visited NCI to learn about the Institute's childhood cancer research efforts. The visit included staff from the offices of Sens. Jack Reed (D-RI), Roy Blunt (R-MO), Chris Van Hollen (D-MD), Dianne Feinstein (D-CA), and Reps. Michael McCaul (R-TX), Jackie Speier (D-CA), Joe Barton (R-TX), and Steve Cohen (D-TN). The group met with representatives from NCI's Pediatric Oncology Branch (POB) in the Center for Cancer Research, the Division of Cancer Epidemiology and Genetics, and the Division of Cancer Treatment and Diagnosis; visited an NCI lab and a National Institute on Deafness and Other Communication Disorders (NIDCD) lab; met with a patient on a CAR T-cell trial; and joined Dr. Ned Sharpless for a tour of The Children's Inn.

Senate L-HHS FY19 Appropriations Hearing (May 17): Dr. Ned Sharpless (Director, NCI) joined Dr. Francis Collins (Director, NIH), Dr. Walter Koroshetz (Director, NINDS), Dr. Tony Fauci (Director, NIAID), Dr. Richard Hodes (Director, NIA), and Dr. Nora Volkow (Director, NIDA) in serving as a witness at a Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (L-HHS) Hearing on the FY19 NIH Budget.

University of Oklahoma Stephenson Cancer Center Dedication Ceremony (May 2): Dr. Ned Sharpless, Director, NCI, provided remarks at an event recognizing the Stephenson Cancer Center's new designation as the nation's 70<sup>th</sup> NCI-Designated Cancer Center. Sen. James Inhofe (R-OK), Sen. James Lankford (R-OK), and Rep. Tom Cole (R-OK) also spoke at the event.

Sen. Reed NIH Visit (May 1): Sen. Jack Reed (D-RI) visited the NIH campus to learn about NCI's childhood cancer research portfolio. His visit began with a roundtable discussion on intramural and extramural activities with Dr. Ned Sharpless, Director, NCI; Dr. Brigitte Widemann, Chief, Center for Cancer Research (CCR) Pediatric Oncology Branch (POB); Dr. Kathy Warren, Chief, Neuro-oncology Section, POB; Dr. Lori Wiener, Chief, Psychosocial Care and Research, POB; Dr. Nirali Shah, Associate Research Physician, POB; Ms. Joanne Derdak, Nurse Practitioner, POB; and Dr. Nita Seibel, Head of Pediatric Solid Tumor Therapeutics in NCI's Clinical Investigations Branch, Cancer Therapy and Evaluation Program, Division of Cancer Treatment and Diagnosis. He then met with a patient on a CD22-targeted CAR T-cell clinical trial led by Dr. Shah and toured the lab of Dr. Jack Shern, Assistant Clinical Investigator, POB. Sen. Reed ended his visit by touring the Children's Inn at NIH, where he met with Dr. Francis Collins, Director, NIH.

House L-HHS FY19 Appropriations Hearing (April 11): Dr. Ned Sharpless (Director, NCI) joined Dr. Francis Collins (Director, NIH), Dr. Diana Bianchi (Director, NICHD), Dr. Tony Fauci (Director, NIAID), and Dr. Nora Volkow (Director, NIDA) in serving as witnesses at a House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (L-HHS) Hearing on the FY19 NIH Budget.

Association of Community Cancer Centers (ACCC) Luncheon (March 14): Dr. Doug Lowy, Deputy Director, NCI, delivered the keynote address at a luncheon for ACCC members. He emphasized the vital role that community cancer centers play in providing care to patients and discussed NCI's latest initiatives, including the Cancer Moonshot, the RAS Initiative, the NCI-MATCH Trial, and NCI's efforts to promote the health of individuals with Lynch Syndrome. Dr. Lowy was introduced by Rep. Mark DeSaulnier (D-CA), co-chair of the House Cancer Survivors Caucus. The event also included remarks from Rep. Brian Higgins (D-NY), co-chair of the House Cancer Caucus.

### ***III. Legislation of Interest***

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

#### **Selected New Laws**

Childhood Cancer STAR (Survivorship, Treatment, Access, Research) Act (Public Law No: 115-180)

- This law 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 encourages that these efforts

focus on cancer types/subtypes (and their recurrences) for which current treatments are least effective, and occur within the context of clinical trials.

- The law also authorizes NIH, with guidance from the NCI Director and in coordination with ongoing research activities, to conduct and support pediatric cancer survivorship research, and includes an emphasis on studying late effects of pediatric cancer treatment, as well as disparities in outcomes and barriers to follow-up care.
- Other provisions specific to NIH and NCI include requiring that at least one member of the presidentially appointed National Cancer Advisory Board be knowledgeable in pediatric oncology; reaffirming reporting requirements for NIH in addressing pediatric oncology research within congressional reporting, including 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 law 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 law focused on pediatric cancer survivorship encourage the HHS Secretary to establish pilot programs to evaluate model systems for monitoring and caring for pediatric cancer survivors, and to conduct efforts identify best practices pediatric cancer survivorship care. The bill would also require HHS to conduct a review of activities related to workforce development for health care providers who treat pediatric cancer patients and survivors.
- President Trump signed the bill (S. 292) into law on June 5, 2018.

#### Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act (Public Law No: 115-176)

- This law allows patients with a terminal illness 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 law does not *require* access to be granted.
- President Trump signed the bill (S. 204) into law on May 30, 2018.

#### **Selected New Bills in the 115<sup>th</sup> Congress**

##### Donald Payne Sr. Colorectal Cancer Detection Act of 2018 (H.R.6062)

- The bill proposes to amend the Social Security Act to provide coverage under Medicare for FDA-approved colorectal cancer screening blood-based tests.
- Introduced by Rep. Donald Payne Jr. (D-NJ) on June 8, 2018. Related to H.R. 1578, introduced by Rep. Payne last year.

##### Accelerating Biomedical Research Act (H.R. 5455)

- The bill proposes to amend the Balanced Budget and Emergency Deficit Control Act of 1985 to adjust the budget cap for NIH funding to allow an additional \$5B in FY19, \$7B in FY20, and \$8.4B in FY21.
- Introduced on 4/10/18 by Rep. Rosa DeLauro (D-CT) with no cosponsors.

### Colorectal Cancer Detection Act (S.2523/S.2928)

- This bill would provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests. S. 2523 was introduced on March 8, 2018 by Sens. Shelley Moore Capito (R-WV) and Martin Heinrich (D-NV) and referred to the Senate Finance Committee. S. 2928 was introduced by Sens. Capito and Heinrich on May 23, 2018 and referred to the Senate Finance Committee.
- The Senate bills are identical, and are related to H.R. 1578, the Donald Payne Sr. Colorectal Cancer Detection Act, introduced by Congressman Donald M. Payne, Jr. (D- NJ) last year.

### Cancer Care Planning and Communications Act (H.R. 5160)

- This bill would amend the Social Security Act to allow doctors to bill Medicare for time spent on cancer care planning and coordination services. Introduced by Reps. Mark DeSaulnier (D-CA) and Ted Poe (R-TX) on March 5, 2018 and was referred to the Committee on Energy and Commerce in addition to the Ways and Means Committee. Reps. DeSaulnier and Poe are co-chairs of the Congressional Cancer Survivors Caucus and are advocates of effective doctor-patient communication.

## **Other Selected Bills in the 115<sup>th</sup> Congress**

### 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. Representatives from FDA, NIH/NCI, the patient advocacy community, academia, and industry participated in a public meeting at the FDA's White Oak Campus on April 20, 2018 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 Pediatric Subcommittee of the FDA's Oncologic Drugs Advisory Committee also met on June 20, 2018 to continue to review and discuss the list of molecular targets. 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 supported 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 the First Tuesday in June as "National Cancer Survivor Beauty and Support Day" (HRes 904)

- Expresses support for the designation of the first Tuesday in June as "National Cancer Survivor Beauty and Support Day".
- Introduced on 5/18/18 by Rep. Bradley Scott Schneider (D-IL).

Supporting Quality of Life for Prostate Cancer Patients (HRes 812)

- This resolution expresses support for protecting Medicare and Veterans' Administration benefits for medical device treatments for male incontinence and impotence that result from treatment of prostate cancer, diabetes, cardiovascular disease, Parkinson's disease, or multiple sclerosis.
- Introduced on 4/10/18 by Rep. Paulsen (R-MN) and referred to the House Energy and Commerce, Ways and Means, and Veterans' Affairs Committees.

Recognizing the 100<sup>th</sup> Anniversary of the American Association for Cancer Research (HRes 819)

- Recognizes the 100<sup>th</sup> Anniversary of AACR.
- Introduced on 4/11/18 by Rep. Robert Brady (D-PA)

Designating March 2018 as "National Colorectal Cancer Awareness Month" (SRes 425/HRes 760)

- Expresses support for the designation of March 2018 as "National Colorectal Cancer Awareness Month".
- Introduced in the Senate on 3/7/18 by Sen. Mike Enzi (R-WY) and in the House on 3/1/18 by Rep. Donald Payne (D-NJ).

**Passed**

Designation of May 2018 as "National Bladder Cancer Awareness Month" (SRes 510)

- This resolution expresses support for the designation of May 2018 as "National Bladder Cancer Awareness Month".
- The resolution was introduced on 5/15/18 by Sen. Menendez (D-NJ) and passed/agreed to in the Senate on the same day.