

**November 7, 2018\***

**Legislative Update:**

**Clinical Trials and Translational Research Advisory Committee (CTAC)**

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

### ***FY2019 Congressional Appropriation***

#### ***Efforts to Return to Regular Order***

Congressional Appropriators provide funding for the federal government through twelve separate spending bills, developed by twelve appropriations subcommittees. The bills passed out of committee by the Appropriators are not always considered individually by Congress and the President (so-called “regular order”), and in fact in recent years have been frequently combined into one big funding measure (an “omnibus” spending bill). However, for FY19 the House and Senate Appropriators have made a significant and mostly successful effort to return to regular order and move the bills to a vote in small groups of “minibus” bills, which allow additional congressional oversight.

Last month, five of the twelve FY19 spending bills were signed into law before the start of the fiscal year. For the Labor-HHS-Education bill, this has not happened since 1996. Congress advanced the first FY19 bills in a group of three bills – a “minibus” - consisting of the Legislative Branch, the Military Construction-Veteran’s Affairs and Energy and Water spending bills. This minibus was signed into law on September 21. The second minibus, consisting of the Department of Defense and the Labor-HHS-Education spending bills, was signed into law on September 28. Appropriators attached a continuing resolution through December 7<sup>th</sup> to cover outstanding funding bills awaiting an FY19 appropriation. Outstanding bills are the Homeland Security, Commerce/Justice/Science, Financial Services, Interior, Agriculture, Transportation, and Housing and Urban Development bills.

#### ***Defense / Labor-HHS-Education Package***

The Senate made the decision to combine their Defense and L-HHS appropriations bills in July and passed the minibus on August 23, 2018. After conferring with the House through the conference process, the Senate agreed to the Conference Report for the Defense/L-HHS minibus on September 18, 2018, in a 93-7 vote. On September 26, 2018, in a 361-61 vote, the House also agreed to the Conference Report. The bill was sent to the President on September 27, 2018 and signed into law the next day.

The Defense/L-HHS appropriations minibus provides a \$2 billion increase over the FY2018 enacted level for NIH, including an increase of \$79 million to NCI (NCI’s proportional share of the NIH increase). The bill also provides the full \$400 million authorized for the Cancer Moonshot through the 21<sup>st</sup> Century Cures Act. NCI’s FY2019 base appropriation is \$5.74 billion.

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

American Cancer Society Cancer Action Network (ACS CAN) Briefing (October 11): Dr. Meg Mooney, Branch Chief of the Clinical Investigations Branch of the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis, spoke at the ACS CAN congressional briefing. Dr. Mooney and other panelists discussed the barriers to patient enrollment in therapeutic clinical trials for cancer. Dr. Mooney highlighted the importance of NCI’s role in providing infrastructure to clinical trials through the NCI NCTN and NCORP.

One Voice Against Cancer (OVAC) Briefing (October 4): Dr. Ned Sharpless spoke at OVAC’s annual congressional briefing at the Capitol Visitor Center on Thursday, October 4, 2018. Dr. Sharpless joined other panelists in highlighting both recent progress and notable challenges in the fight against cancer. Other speakers included Brittany Avin, Johns Hopkins School Medicine PhD Candidate and childhood

cancer survivor; Dr. Jason Luke, Assistant Professor of Medicine, University of Chicago; and Dr. Raymond DuBois, Dean of the College of Medicine, Medical University of South Carolina. Congressional staff and advocates from across the cancer research community participated in this briefing.

Rep. Yoder Visit to NIH (September 25): Rep. Kevin Yoder (R-KS), co-chair of the House Cancer Caucus, toured the NCI Center for Cancer Research Pediatric Oncology Branch (POB), including visiting the lab of Dr. Jack Shern, Assistant Clinical Investigator in the POB. Rep. Yoder also met with Drs. Ned Sharpless; Dr. Brigitte Widemann, Chief, POB; Dr. Andrea Gross, Solid Tumors Group, POB; and Ms. Trish Whitcomb, Research Nurse, POB.

Congressional Childhood Cancer Caucus (September 14): The Co-Chairs of the Congressional Childhood Cancer Caucus – Congressman Michael McCaul (R-TX), Congresswoman Jackie Speier (D-CA), and Congressmen Mike Kelly (R-PA) and G.K. Butterfield (D-NC) – invited Dr. Ned Sharpless to give the keynote address at their 9<sup>th</sup> annual summit at the Capitol Visitor Center. Dr. Sharpless joined Reps. McCaul and Kelly, congressional staff, and advocates from across the childhood cancer community to share updates on STAR Act implementation and the Cancer Moonshot.

Prostate Health Education Network (PHEN) Annual Summit (September 13): Dr. Damali Martin, Program Director, Genomic Epidemiology Branch, Epidemiology and Genomics Research Program, Division of Cancer Control and Population Sciences, provided an overview of NCI's prostate cancer health disparities research, including the RESPOND Study.

Senate HELP Committee Hearing (August 23): Dr. Ned Sharpless joined Dr. Francis Collins, Director, NIH; Dr. Richard Hodes, Director, National Institute on Aging (NIA); Dr. Tony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID); Dr. Collins, and Dr. Diana Bianchi, National Institute of Child Health and Human Development (NICHD) at the hearing, entitled "Prioritizing Cures: Science and Stewardship at the National Institutes of Health." Dr. Sharpless had the opportunity to address a question from Senator Michael Bennet (D-CO) regarding the Research to Accelerate Cures and Equity (RACE) for Children Act.

House Energy and Commerce Committee Hearing (July 25): Dr. Ned Sharpless joined Dr. Francis Collins, NIH Director; Dr. Stephanie Devaney, Deputy Director of the NIH All of Us Research program; and Dr. Scott Gottlieb, FDA Commissioner, at a hearing of the House Energy and Commerce Committee's Subcommittee on Health. The discussion focused on implementation of the 21st Century Cures Act at NIH and FDA. Dr. Sharpless had the opportunity to address several questions from members of the Subcommittee about research underway through the Cancer Moonshot, as well as other areas of NCI-supported research.

AACR Briefing (July 18): Dr. Rachel Grana Mayne, Program Director, Tobacco Control Research Branch, Behavioral Science Program, Division of Cancer Control and Population Sciences, spoke at an AACR-organized event entitled, "E-Cigarettes: State of the Science and Reducing Youth Uptake." Sen. Dick Durbin (D-IL) provided opening remarks.

### ***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>

#### **Notable Legislative Activity**

##### Advancing Cutting Edge (ACE) Research Act (S. 2406/H.R. 5002)

- The bill would expand the NIH's "other transaction authority" (OTA), giving the NIH Director more flexibility to approve high-impact research projects to address public health threats.
- Introduced in the Senate on February 8, 2018 by Sens. Alexander (R-TN) and Murray (D-WA) and the House on February 13, 2018 by Reps. Dingell (D-MI) and Upton (R-MI).
- The proposal was included in a consolidated package of opioid-related proposals called the SUPPORT (Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment) for Patients and Communities Act (H.R.6). H.R.6 passed in the House on 6/22/18, and in the Senate on 9/17/18. The President signed the bill into law on 10/24/18 (Public Law No.: 115-271).

##### Deferment for Active Cancer Treatment Act of 2018 (H.R.2976/S.3207 – provisions enacted as an amendment to Appropriations Bill)

- The Act aims to amend the Higher Education Act of 1965 to allow patients receiving cancer treatment to defer student loan payments during treatment (and six months following treatment), and without interest accruing during that deferment period.
- H.R.2976 was originally introduced in the House by Rep. Ileana Ros-Lehtinen (R-FL) on 6/21/17, and S.3207 was introduced in the Senate by Sen. Bill Nelson (D-FL) on 7/12/18.
- While the bills did not move forward as stand-alone legislation in the House and Senate, Rep. Betty McCollum (D-MN) introduced an amendment to the FY2019 House Labor-HHS Appropriations Act modeled after H.R.2976. Her amendment was adopted and was included in the Defense/Labor-HHS "minibus" Appropriations Act, effectively amending the Higher Education Act of 1965 to provide for the deferment terms proposed in H.R.2976/S.3207.

##### 21<sup>st</sup> Century Integrated Digital Experience Act (IDEA) (H.R.5759/S.3050)

- The bill would require that any new websites or digital services produced by executive agencies meet modern requirements: 1) accessibility to individuals with disabilities, 2) consistent appearance across pages, 3) lack of overlap with any legacy websites, 4) presence of a search function, 5) standard secure connections, 6) user-centered design, 7) customizable user experience, and 8) mobile device functionality.
- Agencies would have one year to review existing websites and digital services and identify those sites that require modernization.
- Executive agencies would have two years to ensure paper-based forms or in-person government services are made available in digital format (as practicable).
- The bill was introduced by Reps. Ro Khanna (D-CA) and John Ratcliffe (R-TX) on 5/10/18; companion legislation was introduced in the Senate by Sens. Rob Portman (R-OH) and Claire McCaskill (D-MO) on 6/12/18. The House bill has 19 co-sponsors, and the Senate bill has one co-sponsor.
- The bill was approved by the House Oversight Reform Committee and the Senate Homeland Security and Governmental Affairs Committee in September 2018.

#### Federal Advisory Committee Act (FACA) Amendments of 2017 (H.R.70)

- H.R. 70, the Federal Advisory Committee Act Amendments of 2017, seeks to amend the Federal Advisory Committee Act (FACA) by tightening requirements for transparency and imposing new disclosure requirements on advisory committee members.
- HHS and NIH have raised concerns that the bill would be harmful to the NIH peer-review process. The HHS comments, made publicly available through recent reporting, noted that the bill would increase HHS's costs for supporting FACA committees, and that the new requirements would impede the process of appointing and confirming committee members, and possibly deter prospective members from serving on FACA committees. Recent reporting also indicates the bill is unlikely to be considered by the Senate in this Congress.
- The bill was passed by the House in January 2017, and advance through the Senate Committee on Homeland Security and Government Affairs in March 2018.
- The bill was introduced by Rep. William Lacey Clay (D-MO) on 1/3/2017.

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

##### Liver Illness Visibility, Education, and Research Act (H.R. 7063)

- The bill includes several provisions directed toward NCI, the Centers for Disease Control and Prevention (CDC), and the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK), to encourage expanded research and public education efforts regarding liver cancer and other liver disease.
- The section of the bill directed toward NCI includes the following provisions:
  - Directs NCI to expand and intensify research on the etiology of liver cancer; clinical research related to liver cancer prevention, detection, and treatment; liver cancer control research, including a focus on underserved populations; and related public education efforts.
  - Directs NCI to issue targeted calls for liver cancer research proposals and establish a special emphasis panel to review such proposals.
  - Directs NCI to establish an inter-Institute working group to focus on liver cancer and related diseases, including Hepatitis B.
- The bill also encourages the HHS Secretary to make awards and enter into cooperative agreements to study conditions known to increase risk of developing liver cancer and other liver diseases, and to support additional research on liver cancer prevention and treatment.
- The bill was introduced by Rep. Nydia Velasquez (D-NY) on 10/12/2018 and was referred to the Committee on Energy and Commerce. The bill currently has 14 co-sponsors, including 12 original co-sponsors who supported the bill's introduction with Rep. Velasquez.

##### Breast Cancer Patient Equity Act (H.R.6980)

- The bill aims to amend the Social Security Act to provide coverage under Medicare for custom fabricated breast prosthesis following a mastectomy.
- The bill was introduced by Rep. Rod Blum (R-IA) on 9/28/18 and was referred to the Committees on Energy and Commerce and on Ways and Means.

##### Metastatic Breast Cancer Access to Care Act (H.R.6114)

- This bill would amend the Social Security Act to eliminate the waiting periods for disability insurance benefits and Medicare coverage for individuals with metastatic breast cancer.
- The bill was introduced by Rep. Peter King (R-NY) on 6/26/18, and referred to the House Ways & Means Committee, Subcommittee on Health.
- The bill currently has 94 co-sponsors.

#### 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.

#### Advancing Access to Precision Medicine Act (H.R. 5062)

- This bill would instruct the HHS Secretary to enter into an agreement with the National Academy of Medicine to study:
  - How the federal government can help to reduce barriers to genetic and genomic testing (including encouraging the expansion of health insurance coverage of testing)
  - The extent to which coverage provisions in the Medicare and Medicaid programs may restrain the use of genetic and genomic testing; and
  - How CMS may make coverage determinations that better suit a precision medicine approach to treatment.
- In addition, the bill would amend the Social Security Act to allow a state to apply for exceptions to Medicaid payment rules to cover whole genome sequencing clinical services for eligible children (children under the age of 21, referred or admitted to an ICU for a chronic or undiagnosed disease, and are suspected to have a genetic disease). States, in turn, will be required to submit a report to CMS detailing the effect of whole genomic sequencing services on reducing health disparities.
- The bill was introduced on February 15, 2018 by Rep. Eric Swalwell (D-CA) and referred to the Energy and Commerce 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.

#### 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 supplement, not supplant discretionary appropriations for NIH and FDA.
- 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.

## **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**

Raising awareness of the lifesaving role of three-dimensional (3D) digital breast tomosynthesis screening in detection and treatment of breast cancer (HRes1135)

- Introduced by Rep. Erik Paulsen (R-MN) on 10/26/18 and referred to the Committee on Energy and Commerce.

Expressing support for the designation of July as National Sarcoma Awareness Month (HRes1103)

- Introduced by Rep. Sean Duffy (R-WI) and Rep. Gene Green (D-TX) on 9/28/18 and referred to the House Committee on Oversight and Government Reform.

A Resolution Designating September 2018 as “National Ovarian Cancer Awareness Month” (SRes 659/HRes 1095)

- Introduced by Sen. Debbie Stabenow (D-MI) on 9/27/18 and referred to the Committee on the Judiciary. The resolution has 6 Senate co-sponsors.
- Introduced by Rep. Rosa DeLauro (D-CT) on 9/27/18 and referred to the Committee on Oversight and Government Reform. The resolution has 29 House co-sponsors.

A Resolution Designating July 15, 2018, as “National Leiomyosarcoma Awareness Day” and the month of July 2018 as “National Sarcoma Awareness Month” (SRes 561/HRes973)

- Introduced by Sen. Debbie Stabenow (D-MI) on 6/28/18.
- Introduced by Rep. Sander Levin (D-MI) on 6/28/18.

### **Passed**

A Resolution Designating September 2018 as “National Prostate Cancer Awareness Month” (SRes 645)

- Introduced by Sen. Robert Menendez (D-NJ) on 9/24/18; the resolution also had 9 co-sponsors.
- The resolution was agreed to by unanimous consent on 9/24/18.