

**July 12, 2017**

**Legislative Update**

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

*\*Content current as of July 5, 2017*

**Activities of the 115<sup>th</sup> Congress-  
First Session**

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

### ***Fiscal Year 2017 Appropriations***

Seven months into fiscal year 2017, an omnibus FY2017 appropriations bill was signed into law by the President on May 5th. The bill cleared the Senate on May 4<sup>th</sup> in a 79-18 vote, following a 309-118 vote in the House the day before. The omnibus funds the government through the end of the fiscal year on September 30. For the second year in a row, the bill provides a \$2 billion increase for the NIH for a funding level of \$34.1 billion, with a total appropriation for NCI of \$5.389 billion. This is an increase of \$174.6 million to NCI over the FY16 enacted level.

In December 2016, Congress passed a continuing resolution (CR) for FY17 that provided an additional \$300 million to fund the Beau Biden Cancer Moonshot, as authorized by the 21<sup>st</sup> Century Cures Act.

### ***Fiscal Year 2018 Budget Proposal***

The Office of Management and Budget (OMB) released its full budget proposal for FY2018 on May 22, 2017. The budget proposal calls for a funding level of \$26.9 billion for NIH. This represents a \$7.2 billion decrease in funding for the NIH in comparison to the FY2017 enacted funding level of \$34.1 billion. The budget proposal calls for a funding level of \$4.474 billion for NCI.

Details regarding the NIH budget can be found at <https://www.hhs.gov/about/budget/fy2018/budget-in-brief/nih/index.html>, and NCI's congressional justification is available at <https://www.cancer.gov/about-nci/budget/congressional-justification/fy2018-nci-congressional-justification.pdf>.

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

Congresswoman Suzan DelBene (D-WA) Visits NIH (June 26): During the NCI portion of her visit, Congresswoman DelBene met with Dr. Bill Dahut, Clinical Director, NCI Center for Cancer Research (CCR), and Dr. Andrea Apolo. Dr. Apolo is Head of the Bladder Cancer Section in CCR's Genitourinary Malignancies Branch and is also an NIH Lasker Clinical Research Scholar. Congresswoman DelBene visited Dr. Apolo and her team in the outpatient clinic, and met with a bladder cancer patient who is participating in a clinical trial evaluating a combination of an immune checkpoint inhibitor and a targeted therapy. The Congresswoman mentioned that as an undergraduate student and biology major, she worked on an NIH-supported research project focusing on immunology, and she was particularly interested in learning more about immunotherapy approaches for cancer treatment.

Senate L-HHS Appropriations Subcommittee NIH Hearing (June 22): Dr. Lowy, Acting Director, NCI, joined Dr. Francis Collins, Director, NIH, and other Institute and Center Directors for a hearing on the NIH FY18 Budget Proposal. Chairman Roy Blunt (R-MO) opened the hearing by recognizing the presence of an NCI patient that several of the subcommittee members had met when they visited NIH on June 5, and thanking her for attending. Chairman Blunt began his remarks by stating that he fundamentally disagreed with the FY18 budget proposal's proposed reduction for NIH, a sentiment that was echoed by Ranking Member Patty Murray (D-WA) and several other subcommittee members. Dr. Lowy answered questions about NCI's efforts in several research areas, including precision medicine for cancer treatments, immunotherapy, and childhood cancer research. Senator Dick Durbin (D-IL) made a point about NIH-funded research leading to the development of pharmaceutical products and medical devices, and asked his colleagues to consider joining him in a bipartisan effort to make sure that "credit is given where it's due so that Americans come to appreciate how [NIH is] at the heart of basic research that really makes their lives an awful lot better." Senator Durbin also thanked Dr. Lowy for visiting the University of Chicago Cancer Center and Lurie Cancer Center at Northwestern, and commended him for his service as acting director of the NCI.

Senate Appropriations Committee Visit to NIH (June 5): Nine members of the Senate Appropriations Committee, including Senators Roy Blunt (R-MO) and Patty Murray (D-WA), the Chairman and Ranking Member, respectively, of the L-HHS Subcommittee, met with Drs. Doug Lowy, Acting Director, NCI, and Steve Rosenberg, of NCI's Center for Cancer Research, as part of a broader NIH visit. The Senators discussed immunotherapy research with Drs. Lowy and Rosenberg, and then had the opportunity to meet a patient who participated in an NCI immunotherapy clinical trial. The Senators also met with Drs. Francis Collins and Larry Tabak, as well as Drs. Richard Hodes (NIA), Tony Fauci (NIAID), James Gilman (CC), and Joshua Gordon (NIMH). In addition to L-HHS Subcommittee Members Sens. Lamar Alexander (R-TN), Dick Durbin (D-IL), John Kennedy (R-LA), James Lankford (R-OK), and Jeanne Shaheen (D-NH), the visit included Sens. John Boozman (R-AR) and Susan Collins (R-ME), who sit on the full committee.

Congressional Staff Visit to NCI's Pediatric Oncology Branch (May 31): A bicameral, bipartisan group of eleven congressional staffers visited NCI to learn about the Institute's childhood cancer research efforts. The visit included staff from the offices of Reps. Michael McCaul (R-TX), Jackie Speier (D-CA), Mike Kelly (R-PA) G.K. Butterfield (D-NC), co-chairs of the Congressional Childhood Cancer Caucus. The congressional staffers were also joined by Ms. Mary-Sumpter Lapinski, Counselor for Public Health and Science in the HHS Office of the Secretary. The group met with Drs. Brigitte Widemann, Kathy Warren, Lori Wiener, Terry Fry, Jack Shern, and Nirali Shah from the NCI Center for Cancer Research Pediatric Oncology Branch, as well as Drs. Malcolm Smith and Nita Siebel, who lead key programs within NCI's extramural childhood cancer research portfolio. The visitors also had the opportunity to meet a family whose child participated in an NCI clinical trial, and to tour The Children's Inn at NIH.

House L-HHS Appropriations Subcommittee NIH Hearing (May 17): Dr. Lowy, Acting Director, NCI, joined Dr. Francis Collins, Director, NIH, and other Institute and Center Directors at a hearing titled "Advances in Biomedical Research." Dr. Lowy fielded a question from Rep. Nita Lowey (D-NY) on early detection of pancreatic and kidney cancer, and Rep. Lucille Roybal-Allard (D-CA) requested an update on the Cancer Moonshot. In his opening statement, Dr. Collins shared the story of a breast cancer patient treated by Dr. Steve Rosenberg of NCI's Center for Cancer Research.

Sen. Shelley Moore Capito (R-WV) Visit to NIH (April 3, 2017): Sen. Capito toured Dr. Steve Rosenberg's lab to learn about NCI's immunotherapy research and met with one of his patients and her family. Sen. Capito also toured a NIDA brain imaging lab and an NIMH suicide prevention research unit. During her visit, she met with Drs. Francis Collins (NIH), Lawrence Tabak (NIH), Nora Volkow (NIDA), and Carlos Zarate (NIMH).

## ***VI. Legislation of Interest***

The following 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 Bills in the 115<sup>th</sup> Congress**

#### RACE for Children Act (H.R.1231/S.456)

- The bill would amend the Federal Food, Drug, and Cosmetic Act to expand requirements for assessing the use of medications in pediatric populations. Applications and supplements to applications for certain drugs and biological products, including orphan drugs, that could be used to treat pediatric cancer must include an assessment of pediatric use.
- H.R. 1231 was introduced by Rep. Michael McCaul (R-TX) on 2/27/17 and referred to the Energy and Commerce Committee. S. 465 was introduced by Sen. Michael Bennet (D-CO) on the same day and referred to the HELP Committee.

- *Additional Information:* Sen. Bennet has also stated that he plans to introduce an amendment to the FDA Reauthorization Act (S. 934), that would propose to incorporate elements of the RACE for Children Act into the broader FDA reauthorization bill as it is considered by the full Senate. The Senate Committee on Health, Education, Labor, and Pensions passed S. 934 out of committee on 5/11/17, and the bill has yet to be scheduled for a vote by the full Senate. S. 934 would provide a reauthorization of the FDA's user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products. The current user-fee programs are authorized through 9/30/17, the end of Fiscal Year 2017.

#### Scientific Integrity Act (S.338)

- The bill would require the Directors of the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) to establish policies to protect scientists and the scientific endeavor, including preventing the intentional and unintentional tampering of data and safeguarding open communication of scientific findings from federally funded research. S. 338 would codify existing policies that extend from a 2009 executive order requiring federal agencies to detail how they would safeguard scientific integrity. Specifically, the legislation would:
  - Reaffirm the principle of open communication of scientific findings and prevent the suppression of scientific findings.
  - Ensure that scientists are free to communicate their findings with the public, press, and Congress.
  - Direct federal agencies to develop scientific integrity policies that include whistleblower protections.
  - Require scientific integrity policies to be posted online and given to all new hires
- The bill was introduced by Senator Bill Nelson (D-FL) on 2/7/2017 and referred to the Committee on Commerce, Science, and Transportation.
- Twenty-Eight Democratic Senators joined Sen. Nelson as cosponsors to this bill. They are Sens. Peters, Udall, Schatz, Blumenthal, Coons, Gillibrand, Merkley, Van Hollen, Whitehouse, Baldwin, Reed, Heinrich, Feinstein, Warren, Hassan, Stabenow, Booker, Cantwell, Warner, Shaheen, Franken, Cardin, Murray, Carper, Cortez Masto, Markey, and Wyden.

#### Firefighter Cancer Registry Act of 2017 (S. 382)

- The bill directs the Centers for Disease Control and Prevention to establish a voluntary registry of firefighters to collect relevant history and occupational information and to link the voluntary registry to available cancer registry data collected by state cancer registries.
- S. 382 was introduced by Sen. Robert Menendez (D-NJ) on 2/15/2017 and was referred to the Committee on Health, Education, Labor, and Pensions.

#### Removing Barriers to Colorectal Cancer Screening Act of 2017 (H.R. 1017/S.479)

- The bill would require a waiver of coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening.
- H.R. 1017 was introduced by Rep. Charlie Dent (R-PA) on 2/13/2017 and was referred to the Committees on Energy and Commerce; and Ways and Means. S.479 was introduced by Sen. Sherrod Brown (R-OH) on 3/1/2017 and was referred to the Finance Committee.

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

- 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 114<sup>th</sup> 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.
- 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 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.

#### Radiation Exposure Compensation Act Amendments of 2017 (S. 197)

- The bill would amend the Radiation Exposure Compensation Act to extend the Radiation Exposure Compensation Trust Fund until 19 years after enactment of this Act.
- Among other provisions, the bill would expand the downwind exposure area eligible for RECA compensation to include Colorado, Idaho, Montana, and New Mexico, as well as any county in Arizona, Nevada, or Utah.
- The bill would make miners, core drillers, and ore transporters who suffer renal cancer or any other chronic renal disease, including nephritis and kidney tubal tissue injury, eligible for compensation due to exposure to radiation while on the job.
- The bill also directs the National Institute of Environmental Health Sciences, to establish a program of grants to institutions of higher education to study the epidemiological impacts of uranium mining and milling among non-occupationally exposed individuals, including family members of uranium miners and millers.
- S. 197 was introduced by Sens. Mike Crapo (R-ID) and Tom Udall (D-NM) on 1/24/2017 and referred to the Judiciary Committee.

#### USPSTF Transparency and Accountability Act of 2017 (H.R. 539)

- This bill would amend the Public Health Services Act to revise the operations of the United States Preventive Services Task Force (USPSTF).
- The bill would require the Task Force to publish research plans to guide the review of scientific evidence and new science related to the effectiveness of clinical preventive services in consultation with other Federal agencies including the NIH and NCI.
- In addition, the bill would require the Task Force to convene a preventive services advisory board to advise the Task Force on developing, updating, publishing, and disseminating evidence-based recommendations on the use of clinical preventive services. The advisory board is to include representatives of patient groups; providers of clinical services; and Federal departments and agencies, including NIH and NCI.

- The bill would require the GAO to submit a report that includes a listing of the current Task Force recommendations; a comparison of those recommendations to those of other Federal health agencies; and an analysis of the impact of the Task Force’s recommendations on insurance coverage, access, and outcomes, including the impact on morbidity and mortality.
- H.R. 539 was introduced by Rep. Marsha Blackburn (R-TN) on 1/13/2017 and was referred to the Energy and Commerce and Ways and Means Committees.

Byron Nash Renal Medullary Carcinoma Awareness Act of 2017 (H.R. 148)

- This bill would amend the Social Security Act to provide incentives for education on the risk of renal medullary carcinoma to Medicaid recipients with sickle cell disease.
- H.R. 148 was introduced by Rep. Al Green (D-TX) on 1/3/2017 and was referred to the Energy and Commerce 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.*

Designating the week of July 9 through July 15, 2017 as "Sarcoma Awareness Week" and designating July 15, 2017 as "Leiomyosarcoma Awareness Day" (S. Res. 207/H. Res. 420)

- These resolutions express support for designating a Sarcoma Awareness Week and Leiomyosarcoma Awareness Day in July 2017.
- S. Res. 207 was introduced by Sen. Debbie Stabenow (D-MI) on 6/28/2017 and was referred to the Committee on the Judiciary.
- HR. Res. 420 was introduced by Rep. Sander Levin (D-MI) on 6/28/2017 and was referred to the Energy and Commerce Committee.

Designating February 4, 2017 as National Cancer Prevention Day (H. Res. 84)

- This resolution expresses support for designating February 4, 2017 as National Cancer Prevention Day.
- H. Res. 84 was introduced by Rep. Debbie Dingell (D-MI) on 2/2/2017 and was referred to the Committee on Energy and Commerce.

Designating May 17<sup>th</sup> as "DIPG Awareness Day" (H. Res. 69)

- This resolution would designate May 17<sup>th</sup> as "DIPG Awareness Day" to raise awareness and encourage research into cures for diffuse intrinsic pontine glioma (DIPG) and pediatric cancers in general.
- H. Res. 69 was introduced by Rep. Stephen Knight (R-CA) on 1/30/2017 and was referred to the Energy and Commerce committee.