Legislative Update for the Clinical Trials and Translational Research Advisory Committee

Holly Aprea Gibbons, MPP
NCI Office of Government and Congressional Relations
240-781-3410

November 7, 2018
▪ Midterm Elections
▪ Appropriations Recap
▪ Congressional Hearings, Briefings, & Visits
▪ Legislative Implementation
Midterm Elections

- What do we know this afternoon?
- What are we still waiting to find out?
- What does it all mean for NCI and NIH?
House Election Results: Democrats Take Control

Associated Press Results as of 12:30 pm, November 7, 2018
Midterm Elections

- What do we know this afternoon?
- What are we still waiting to find out?

- What does it all mean for NCI and NIH?
  - Any new session of Congress brings new Committee/Subcommittee membership, often changes in leadership (e.g., House Appropriations), changes within cancer and biomedical research caucuses
  - Cancer research and biomedical research remain non-partisan issues
  - NCI appreciates Congress's continued strong bi-partisan support
Labor-HHS + Defense + December 7th CR = 1st on-time Labor-HHS Appropriation since 1996 (FY97)

110 STAT. 3009-245  PUBLIC LAW 104-208—SEPT. 30, 1996

and Human Services, subject to section 1531 of title 31, United States Code: Provided further, That of the amount provided, $23,000,000 is designated by Congress as an emergency requirement pursuant to section 251(b)(2)(D)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended.

In addition, $41,000,000, to be derived from the Violent Crime Reduction Trust Fund, for carrying out sections 40151 and 40261 of Public Law 103–322.

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the Public Health Service Act with respect to cancer, $2,382,532,000.
Also in 1996 . . .

Enhancement of Antitumor Immunity by CTLA-4 Blockade

Dana R. Leach, Matthew F. Krummel, James P. Allison*

One reason for the poor immunogenicity of many tumors may be that they cannot provide signals for CD28-mediated costimulation necessary to fully activate T cells. It has recently become apparent that CTLA-4, a second counterreceptor for the B7 family of costimulatory molecules, is a negative regulator of T cell activation. Here, in vivo administration of antibodies to CTLA-4 resulted in the rejection of tumors, including preestablished tumors. Furthermore, this rejection resulted in immunity to a secondary exposure to tumor cells. These results suggest that blockade of the inhibitory effects of CTLA-4 can allow for, and potentiate, effective immune responses against tumor cells.
Vote in Congress showcases all the forces against (and a few supporting) a government shutdown

By Phil McKeon, CNN
Updated: 12:50 PM ET, Sep 29, 2019

Congress

Pentagon set to win first on-time budget since 2008

$854B funding measure is signed; President’s OK averts shutdown

by Compiled by The Des Moines Register staff from wire reports | Sep 29, 2019 at 4:17 a.m.

Last month, Congress passed legislation funding 75% of the federal government on time - the first time this has happened in 20+ years. Here’s what @HouseGOP members had to say on this critical legislation, which funded @DeptOfDefense and health programs.

Politics

Trump Signs Bill Averting Government Shutdown Before Midterms

By Justin Sink and Erik Wasson
September 28, 2018, 1:14 PM EDT Updated on September 28, 2018, 3:02 PM EDT

➤ Postpones fight over border wall until at least December
➤ Includes $853 billion for defense and domestic programs
FY 2018 and FY19 Appropriations

- FY18 Omnibus Appropriation
  - $3 billion increase for NIH, $275 million increase for NCI
  - $300 million for the Cancer Moonshot

- FY19 Appropriation
  - $2 billion increase for NIH, $79.3 million increase for NCI
  - $400 million for the Cancer Moonshot
Increases Over Time

- NIH increase for the 4th consecutive year

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>NIH Base Appropriation</th>
<th>NCI Base Appropriation</th>
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<td>2015</td>
<td>$30.31 billion</td>
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<tr>
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<tr>
<td>2019</td>
<td>$38.34 billion*</td>
<td>$5.74 billion*</td>
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*Does not include NIH Innovation Fund/Cancer Moonshot Funding
House Energy & Commerce Hearing – July 25, 2018
Implementation of 21st Century Cures Act: Updates from FDA and NIH
Senate Health, Education, Labor & Pensions Hearing – August 23, 2018
Prioritizing Cures: Science and Stewardship at the NIH
Briefings

- **AACR - E-Cigarettes: State of the Science and Reducing Youth Uptake, July 18**
  - Dr. Rachel Grana Mayne, Tobacco Control Research Branch
- **Prostate Health Education Network (PHEN) Annual Summit, Sep. 13**
  - Dr. Damali Martin, Epidemiology and Genomics Research Program
- **Congressional Childhood Cancer Caucus Annual Summit, Sep. 14**
  - Dr. Ned Sharpless
- **Once Voice Against Cancer, Oct. 4**
  - Dr. Ned Sharpless
- **ACS CAN – Overcoming Barriers to Clinical Trial Enrollment, Oct. 11**
  - Dr. Meg Mooney, Cancer Therapy Evaluation Program
Member Visits & Meetings

- Rep. Kevin Yoder (R-KS): Visit to CCR’s Pediatric Oncology Branch, September 25, 2018

- Rep. G.K. Butterfield (D-NC): Meeting with Dr. Sharpless, September 26, 2018
Legislative Implementation

- RACE for Children Act (Research to Accelerate Cures and Equity for Children Act) – Title V of FDA Reauthorization Act of 2017
  - Signed into law in August 2017
  - FDA, in consultation with NCI and other stakeholders, developed a list of relevant molecular targets and a list of non-relevant targets and posted it in August 2018
  - NCI will continue to work closely with FDA on updates

- Childhood Cancer STAR (Survivorship, Treatment, Access, Research) Act
  - Signed into law in June 2018
  - Research provisions directed toward NIH/NCI focus on childhood, adolescent, and young adult cancer survivorship research, as well as biospecimen collection and resources
  - Implementation planning is underway
The National Cancer Act of 1971 directs the National Cancer Institute to present its best professional judgment about scientific opportunities to make rapid progress against cancer and the resources required to pursue this work.

- NCI presents the professional judgment budget to the President, through the Office of Management and Budget.
- NCI's Office of Government and Congressional Relations shares the proposal with each Congressional office and relevant committees of jurisdiction.
Questions?
holly.gibbons@nih.gov
240-781-3410