

# Legislative Update for the Clinical Trials and Translational Research Advisory Committee

Holly Aprea Gibbons, MPP

NCI Office of Government and Congressional Relations

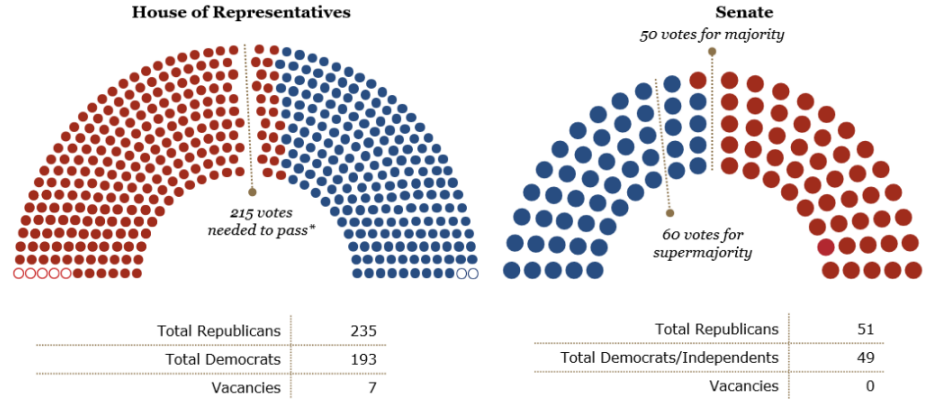
240-781-3410

- 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?

## Current House and Senate divisions



# House Election Results: Democrats Take Control

220

Democrats

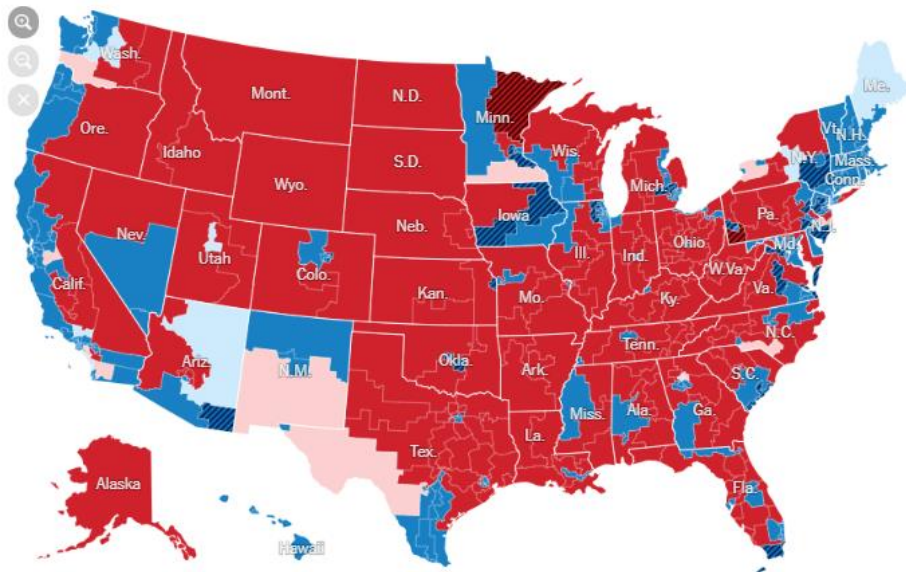
Gained 27 seats  
51,057,697 votes (51.2%)

218  
FOR CONTROL

194

Republicans

Lost 27 seats  
47,054,221 votes (47.2%)



## Key Races 80 Total

Dem. favored		Tossup		Rep. favored	
DISTRICT	MARGIN	DISTRICT	MARGIN	DISTRICT	MARGIN
Ariz. 2	✓	Fla. 26	✓	N.Y. 11	✓
Colo. 6	✓	Iowa 3	✓	S.C. 1	✓
Fla. 27	✓	Ill. 14	✓	Minn. 8	✓
Iowa 1	✓	Mich. 8	✓	Pa. 14	✓
Ill. 6	✓	N.J. 7	✓	Alaska	✓
Kan. 3	✓	N.Y. 19	✓	Fla. 6	✓
Mich. 11	✓	Tex. 7	✓	Fla. 16	✓
Minn. 2	✓	Tex. 32	✓	Fla. 18	✓
Minn. 3	✓	Va. 2	✓	Fla. 25	✓
N.J. 2	✓	Va. 7	✓	Iowa 4	✓
N.J. 11	✓	Calif. 25	D+2.6	Ill. 12	✓
Pa. 6	✓	Calif. 48	D+1.4	Ill. 13	✓
Pa. 7	✓	Ga. 6	D+1.0	Mich. 6	✓
Pa. 17	✓	Me. 2	D+0.1	Mo. 2	✓
Va. 10	✓	N.Y. 22	D+0.6	Mont.	✓
Nev. 3	✓	Utah 4	D+2.6	N.C. 2	✓
Nev. 4	✓	Fla. 15	✓	Neb. 2	✓
Ariz. 1	D+6.6	Kan. 2	✓	N.Y. 24	✓
Calif. 49	D+4.8	Ky. 6	✓	Ohio 1	✓
Wash. 8	D+5.8	N.C. 13	✓	Pa. 16	✓
		Ohio 12	✓	Tex. 22	✓
		Pa. 1	✓	Va. 5	✓
		Pa. 10	✓	Wash. 5	✓
		Calif. 10	R+1.2	Wis. 1	✓
		Calif. 39	R+2.6	W.Va. 3	✓
		Calif. 45	R+3.4	Calif. 50	R+8.4
		Minn. 1	R+0.4	Ga. 7	R+0.4
		N.C. 9	R+0.6	N.Y. 27	R+1.1
		N.J. 3	R+0.9	Tex. 23	R+0.3
		N.M. 2	R+1.0	Wash. 3	R+4.6

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

# Senate Election Results: Republicans Keep Majority

45

Democrats\*

23 Democrats not up for election

Lost 2 seats

45,416,724 votes (56.8%)

50



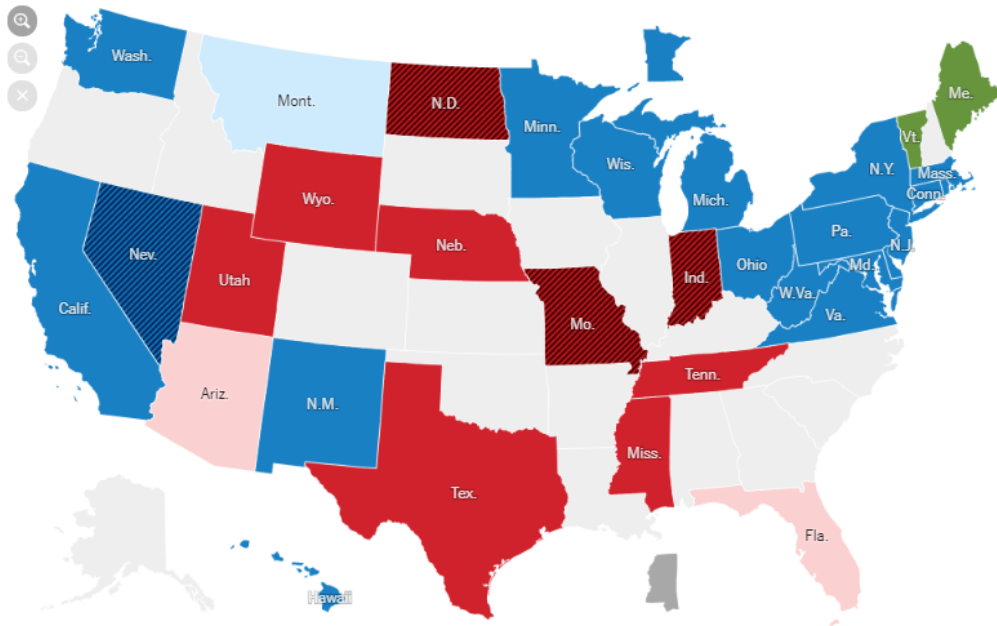
51

Republicans

42 Republicans not up for election

Gained 2 seats

33,196,485 votes (41.5%)



## Key States 13 Total

### Dem. favored

STATE	LEADER	MARGIN
Minn. †	Smith	✓
W.Va.	Manchin	✓

### Tossup

STATE	LEADER	MARGIN
Nev.	Rosen	✓
N.J.	Menendez	✓
Mont.	Tester	D+0.3
Ind.	Braun	✓
Mo.	Hawley	✓
Tenn.	Blackburn	✓
Tex.	Cruz	✓
Ariz.	McSally	R+0.9
Fla.	Scott	R+0.4

### Rep. favored

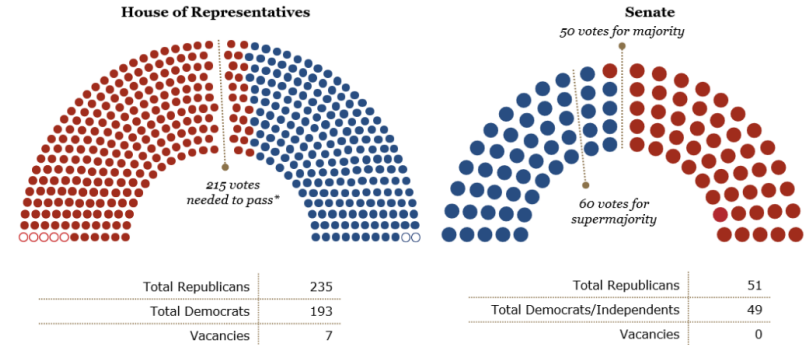
STATE	LEADER	MARGIN
N.D.	Cramer	✓
Miss. †	Runoff	

† Special election

# 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

## Current House and Senate divisions



Labor-HHS + Defense + December 7<sup>th</sup> CR =  
*1<sup>st</sup> 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 . . .



Atlanta 1996



NINTENDO<sup>64</sup>



Science  
AAAS

## 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 Mattingly, CNN  
Updated 12:55 PM ET, Tue September 25, 2018



## \$854B funding measure is signed; President's OK averts shutdown

by Compiled by Democrat-Gazette staff from wire reports | September 29, 2018 at 4:19 a.m.



Following

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 ⚡



**Congress Passes 2nd Minibus, Funding 75% of Federal Government**  
House Appropriations @HouseAppropsGOP  
On September 26, 2018, the House passed the Defense and Labor, Health and Human Services, and Education funding bills. This marks the first time in over 2 decades this much of the federal government...

Moments

2:41 PM - 15 Oct 2018

# Trump Signs Spending Bill to Avert Pre-Election Shutdown

Congress

## Pentagon set to win first on-time budget since 2008

CQ Action Alerts  
Sep. 28, 2018

CQ NEWS ACTION ALERTS  
Sept. 28, 2018 - 1:07 p.m.

## Shutdown Averted as Trump Signs Huge Spending Package

President Donald Trump has signed an \$855.1 billion fiscal 2019 spending bill (HR 6157) including the full-year Defense and Labor-HHS-Education measures, as well as stopgap funding for other agencies through Dec. 7.

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

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# 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 4<sup>th</sup> consecutive year

Fiscal Year	NIH Base Appropriation	NCI Base Appropriation
2015	\$30.31 billion	\$4.95 billion
2016	\$32.31 billion	\$5.21 billion
2017	\$34.23 billion*	\$5.39 billion*
2018	\$36.59 billion*	\$5.66 billion*
2019	\$38.34 billion*	\$5.74 billion*

\*Does not include NIH Innovation Fund/Cancer Moonshot Funding

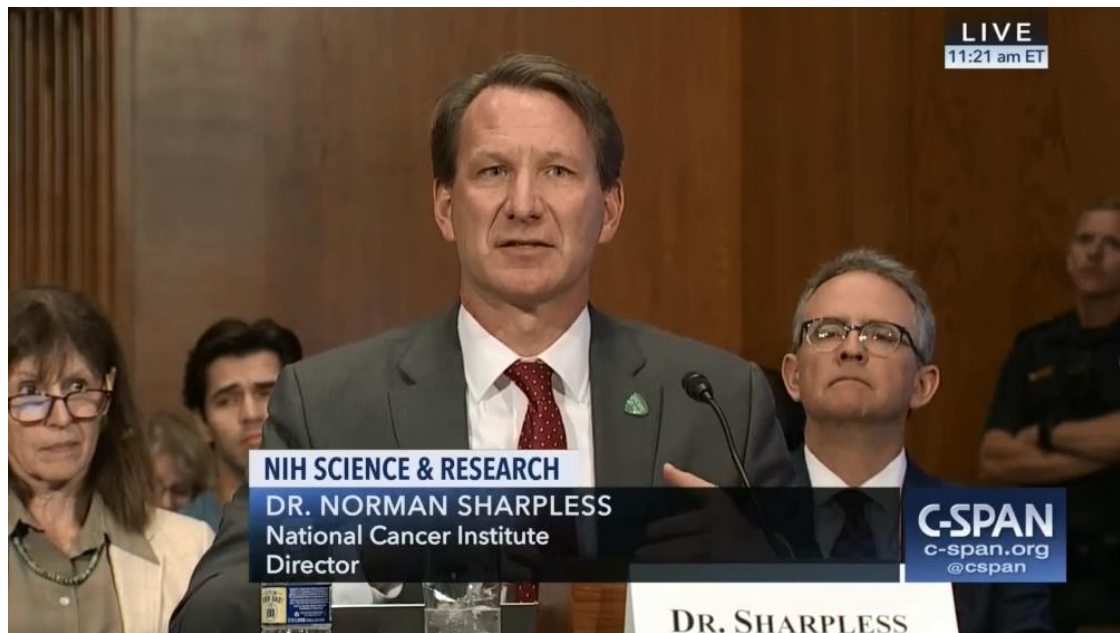
# House Energy & Commerce Hearing – July 25, 2018

## Implementation of 21<sup>st</sup> 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**

# NCI Annual Plan and Professional Judgment Budget



## Annual Plan & Budget Proposal For FY 2020

At a Glance

### DIRECTOR'S MESSAGE: A TIME OF GREAT HOPE AND GREAT CHALLENGE

As director of the National Cancer Institute (NCI), I am pleased to share our *Annual Plan and Budget Proposal for Fiscal Year 2020*. Having been sworn in to my position a little less than a year ago, this marks my first opportunity to present, in this form, the promising results of our country's investments in biomedical research. This plan directs attention to areas where additional support has unique potential to improve cancer prevention, detection, and treatment.

To place the plan's focus squarely on those most likely to benefit from NCI research, we have included stories of patients. While each story is unique, they are not that different from that of Mike, a patient I treated for acute leukemia.

Mike started feeling poorly in 2016, and a bone marrow biopsy revealed acute myeloid leukemia (AML). I began his initial treatment with aggressive chemotherapy, which caused difficult side effects and required him to spend more than a month in the hospital. After further therapy, Mike fully recovered,



Norman E. Sharpless, M.D., with former patient Mike, whom he treated for acute leukemia in 2016.

- 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?

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240-781-3410



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CANCER  
INSTITUTE**

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[www.cancer.gov/espanol](http://www.cancer.gov/espanol)