

Legislative Update

Clinical Trials and Translational Research Advisory Committee

M.K. Holohan, J.D.
Office of Government and Congressional Relations

- Presidential Appointments
- Midterm Elections – what do we know?
- Budget and Appropriations (FY23 and FY24)
- Reignited Cancer Moonshot & ARPH-H
- Legislation & the Lame Duck Congress



Midterm Elections – What do we know?

Senate Results

Democrats **48**

50

48 Republicans



36 seats not up for election

29 seats not up for election

★ *Seat flipped* Updated Nov 9, 2022, 8:20 AM

Note: Should an equal number of senators caucus with each party, Democrats will control the chamber due to Vice President Kamala Harris' tie-breaking vote.

House Results

Democrats **172**

218

199 Republicans



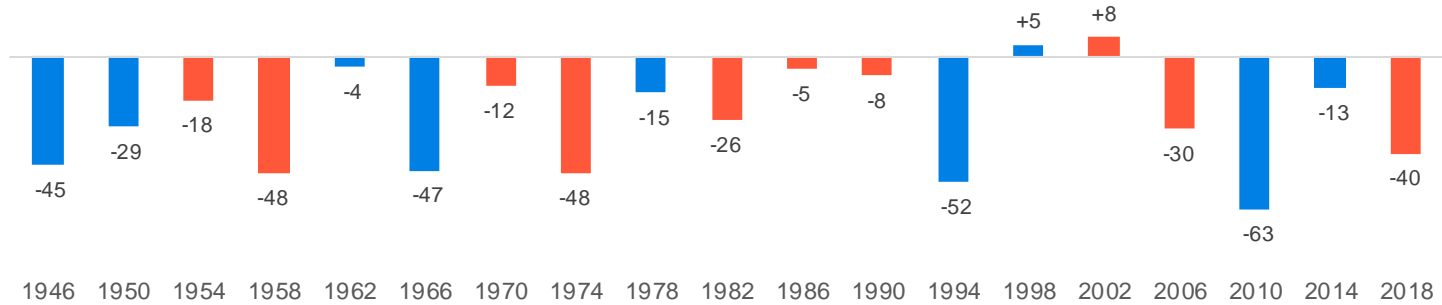
Updated Nov 9, 2022, 8:22 AM

Historically, the president's party loses seats in midterm elections

President's party gain/loss of seats in House

MIDTERM ELECTIONS, 1946-2018

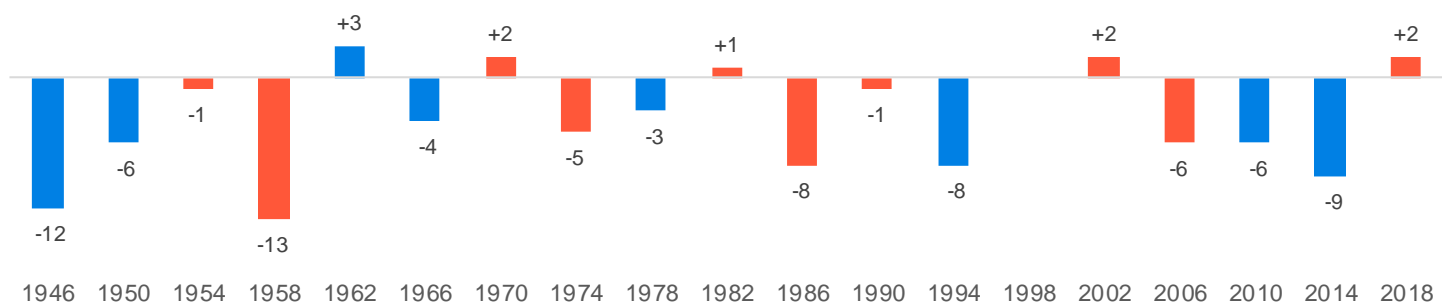
■ Democrats ■ Republicans



President's party gain/loss of seats in Senate

MIDTERM ELECTIONS, 1946-2018

■ Democrats ■ Republicans



SOURCE The American Presidency Project.
SLIDE LAST UPDATED ON 6/4/21

The last four presidents have lost Senate and House majorities; seven of those eight chambers were lost in midterm elections



President Bill Clinton (D)

Republican gains in the 1994 midterms:
52 seats in the House
8 seats in the Senate



President George W. Bush (R)

Democratic gains in the 2006 midterms:
30 seats in the House
6 seats in the Senate



President Barack Obama (D)

Republican gains in the 2010 midterms:
63 seats in the House
6 seats in the Senate

Republican gains in the 2014 midterms:
13 seats in the House
9 seats in the Senate



President Donald Trump (R)

Democratic gains in the 2018 midterms:
40 seats in the House
-2 seats in the Senate

Note: Trump's Senate loss in 2016 was the only loss of a chamber in the past four presidencies to not occur during a midterm.

HOW NCI RECEIVES ITS FUNDING

NCI receives its funding, or appropriation, from Congress as part of the overall federal budget process.

FY24
PJB




STEP 1

The White House Office of Management & Budget (OMB) coordinates with federal agencies to formulate the President's Budget, which covers all federal agencies, including the National Cancer Institute (NCI) and National Institutes of Health (NIH), and reflects the President's priorities. The President submits the budget to Congress, which must pass appropriations legislation that funds federal agencies.



STEP 2

The Congressional appropriations committees consider the President's Budget as they prepare appropriations legislation for the next fiscal year.

You Are Here
FY 23 Appropriations



STEP 3

The appropriations committees finalize their legislative proposals, and the House and Senate consider the proposed legislation. Once passed and reconciled into a unified bill, Congress sends the legislation to the President.



STEP 4

The President signs the appropriations bill into law, making funds available to executive agencies, including NCI and NIH.

NCI Professional Judgment Authority

The National Cancer Act of 1971 gives the NCI Director special authority to submit an annual professional judgment budget directly to the President for review and delivery to Congress. This budget reflects NCI cancer research priorities and identifies areas of potential investment in cancer research.

Power of the Purse

“All Bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with amendments as on other Bills.”

— U.S. Constitution, Article I, section 7, clause 1

“No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time.”

— U.S. Constitution, Article I, section 9, clause 7

“It is the duty of the President to propose, and it is the privilege of the Congress to dispose.”

Franklin D. Roosevelt

FY 2023 Appropriations Hearings

National Institutes of Health



House Hearing, May 11, 2022



Senate Hearing, May 17, 2022

FY 2023 Appropriations

	FY 22 Enacted	FY 23 President's Budget	FY 23 House Committee Passed	FY 23 Senate Draft	FY 23 House less FY22 Enacted	FY 23 Senate Less FY22 Enacted
NCI	\$6.91 B	\$6.71 B	\$7.38 B	\$7.20 B	\$466.1 M	\$290.5 M
ARPA-H	\$1.0 B	\$5.0 B	\$2.75 B	\$1.0 B	\$1.75 B	0
NIH	\$45.2 B	\$45.5 B	\$47.7 B	\$47.2 B	\$2.5 B	\$2.0 B

- Continuing Resolution through December 16

PROFESSIONAL JUDGMENT BUDGET PROPOSAL FOR FISCAL YEAR 2024

(DOLLARS IN MILLIONS)

Prior (FY 2023) Professional Judgment Budget Proposal	\$7,550*	
Proposed Budget Increase for FY 2024 to Seize Opportunities for Progress	\$1,166	<ul style="list-style-type: none"> \$354 Cancer Biology Research \$247 Cancer Prevention Research \$192 Cancer Detection & Diagnosis Research \$227 Cancer Treatment Research \$86 Public Health & Cancer Control Research \$60 Training & Infrastructure
Funding to Revolutionize Cancer Clinical Research [†]	\$1,272	
FY 2024 TOTAL	\$9,988	

*This proposal includes \$50 million for the Childhood Cancer Data Initiative, a 10-year initiative that began in FY 2020.

†This proposed funding will be used to achieve the goals of reducing cancer death rates by 50% over the next 25 years and ending cancer as we know it for all.

ADVISORY COMMITTEE TO THE DIRECTOR

Advanced Research Projects Agency for Health (ARPA-H)

*A New Paradigm for Propelling Use-Driven, High
Impact Biomedical and Health Research*

Tara A. Schwetz, PhD
Acting Principal Deputy Director
National Institutes of Health



June 9-10, 2022

https://www.acd.od.nih.gov/documents/presentations/06092022_ARPA-H.pdf

- \$1B appropriation in FY 22
- \$5B requested for FY 23
 - House - \$2.75B
 - Senate - \$0
- April 2022 – Sec. Becerra transfers ARPA-H and its funding to NIH
- Plan to recruit 100 FTEs this year
- No further action on authorizing legislation (yet)
- Renee Wegrzyn, PhD appointed as Director in September 2022

2022 CONGRESSIONAL CALENDAR

■ House only in session
 ■ House committee work only
 ■ House committee work only / Senate in session
 ■ Both chambers in session
 ■ Senate only in session

November

Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
		1	2	3	4	5
6	7	8 Election Day	9	10	11 Veterans Day	12
13	14	15	16	17	18	19
20	21	22	23	24 Thanksgiving Day	25	26
27	28	29	30			

December

Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19 Hanukkah (begins)	20	21	22	23	24
25 Christmas Day	26 Xmas (observed) Hanukkah (ends)	27	28	29	30	31

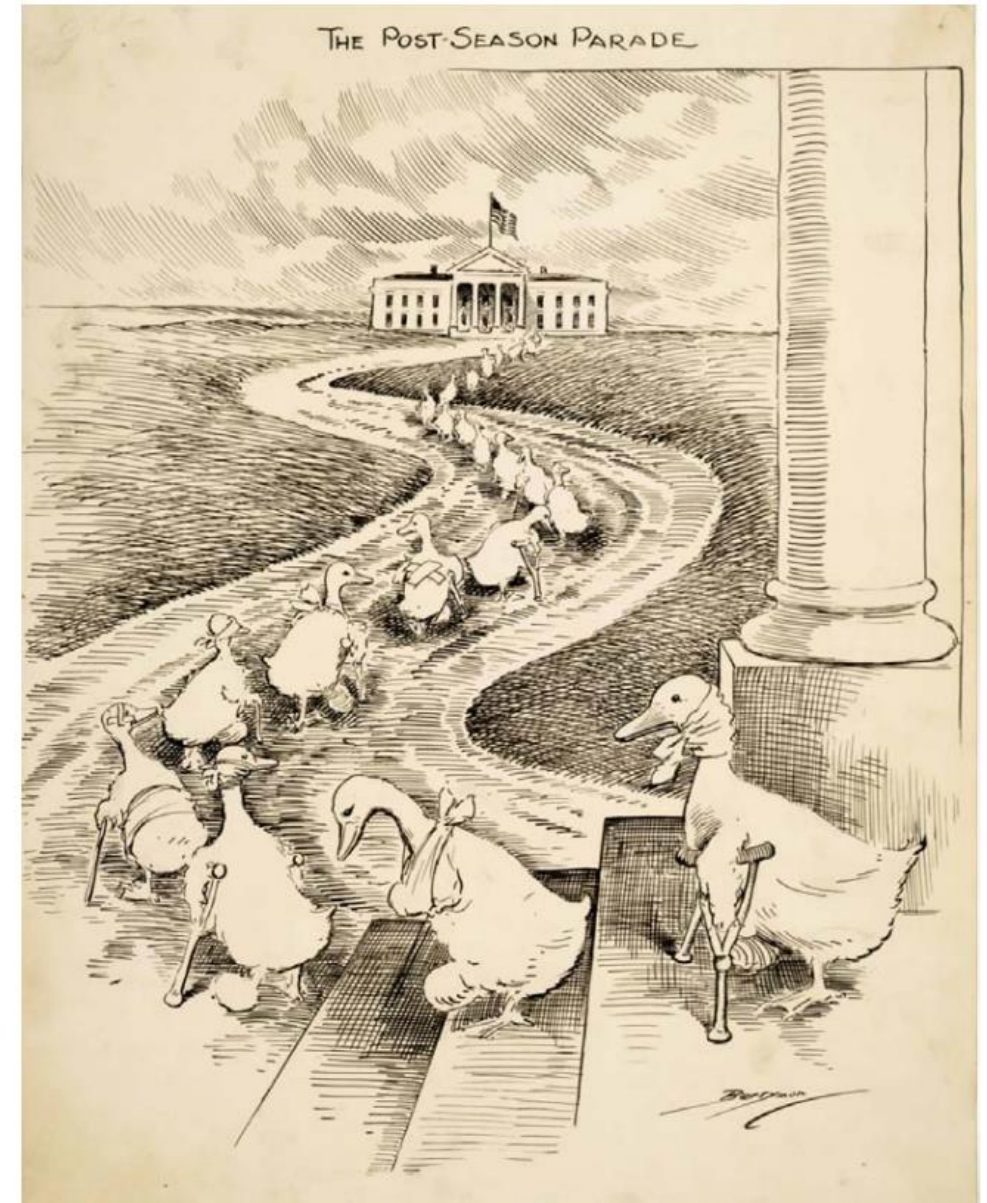
What to watch for in the Lame Duck Congress

Must Pass

- ✓ FDA Reauthorization (5-yr, enacted 9/30 – attached to CR)
- ✓ SBIR Reauthorization(3-yr, enacted 9/30 – S.4900)
- FY2023 Appropriations
- National Defense Authorization Act (NDAA)

May Pass

- Health Omnibus
 - Suspend Medicare payment cuts, allow for Medicare coverage of telehealth after PHE expires, pandemic preparedness funding
 - Authorize FDA regulation of LDTs
- ARPA-H authorizing legislation



Questions?

MK.HOLOHAN@NIH.GOV