Legislative Update

Clinical Trials and Translational Research Advisory Committee (CTAC)

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July 11, 2018
- FY18 Appropriation (March 23, 2018)
- FY19 Appropriation Process & Hearings
- NCI’s Congressional Engagement
- Midterm Elections
FY18 Appropriations Process

1. Budget Deal for FY18 & FY19 (February 8, 2018)
   - Increases including NIH, opioids, infrastructure, veterans, etc.

2. Government Shutdowns

5. Continuing Resolutions
FY18 Appropriation – March 23

+$3 Billion increase for NIH over FY17 enacted

+$275M increase for NCI over FY17 enacted

+$300M to NCI for Moonshot (21\textsuperscript{st} Century Cures)

Targeted increases:
Opioids/Pain $500M, Alzheimer’s $414M, BRAIN $140M, All of Us $60M, Antimicrobial Resistance $50M, Universal Flu Vaccine $40M
FY19 President’s Budget – February 12

- Budget plus addendum* increasing NIH from $25.6B to $34.8B
- $10B HHS request for opioids with $750M for NIH
- Includes full funding for Fogarty International Center
- Consolidates AHRQ and other agencies into NIH
- No changes to current Indirect Cost policies

*Bipartisan budget deal passed Feb. 8 affected totals
“I’m very proud that Congress once again provided a significant increase to NIH of $3 billion...the second highest annual increase in NIH history. And don’t expect that again, by the way!”

Ranking Member
Rosa DeLauro (D-CT)

Labor-HHS Chairman
Tom Cole (R-OK)

Ranking Member
Nita Lowey (D-NY)

Chairman Rodney Frelinghuysen (R-NJ)
“I particularly want to thank Dr. Sharpless for giving me an opportunity to look at the pediatric oncology program and meeting all the tremendous women doctors and Ph.D.s who lead that effort.”
“In a world of frustration and partisanship, what is happening in this room this morning is a welcome exception. You will find more positive feelings, more achievement I hope, and more bipartisanship than in almost any other room on Capitol Hill...

We have established a standard I think and I hope it is one that we can live by of **sustainable, reliable increases in medical research funding** in the United States of America.”
Next steps for FY 2019:

- **Today**: Full House Appropriations Committee Markup for L-HHS
  - L-HHS House Subcommittee bill includes:
    - $1.25 billion increase for NIH
    - $71 million increase to NCI’s base budget
    - $400 million to NCI for the Cancer Moonshot, as authorized in 21st Century Cures
    - No change to indirect costs
  - L-HHS Senate Subcommittee bill includes:
    - $2 billion increase for NIH
    - $82 million increase to NCI’s base budget
    - $400 million to NCI for the Cancer Moonshot, as authorized in 21st Century Cures
    - No change to indirect costs
Senator Jack Reed (D-RI) visit to NCI – May 1, 2018
STAR Act-Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018 (Signed 6/18)
• Provisions directed toward NIH/NCI focus on childhood, adolescent, and young adult biospecimen collection and resources, as well as pediatric cancer survivorship research.
• Addresses inclusion of pediatric oncology expertise.

RACE Act-(Research to Accelerate Cures and Equity for Children Act) (Signed 8/17)
• If molecular targets of a drug under FDA review is “substantially relevant” to the pediatric population, FDA can require a pediatric study plan for dosing and activity-seeking studies.
• The new provisions require FDA, in consultation with NCI, to develop and maintain list of relevant and non-relevant targets by August 2018.
• In April 2018, NCI issued an RFI to collect input in addition to these two meetings. FDA held public meetings in May and June 2018.
Midterms are Disruptive

• History tells us the President’s party usually loses seats

• Midterms flip Majorities - Party in power has lost either the House, the Senate or both in all four of the most recent midterms going back to 2002

• Incumbents are hard to beat, even in wave elections
  • In the last four House wave elections, 59% of incumbents from the president’s party in districts with PVI (partisan voting index) favoring the other party by 0-5 points still won – but when those seats were open, the president’s party only held 6% of them.

Democrats will need to pick up 23 seats in the House and two seats in the Senate to control both chambers of Congress

House of Representatives

<table>
<thead>
<tr>
<th>Total Republicans</th>
<th>235*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Democrats</td>
<td>193*</td>
</tr>
</tbody>
</table>

218 votes needed to pass

Senate

<table>
<thead>
<tr>
<th>Total Republicans</th>
<th>51</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Democrats/Independents</td>
<td>49</td>
</tr>
</tbody>
</table>

50 votes for majority

60 votes for supermajority

*There are currently seven vacancies in the House

Recent midterm wave elections

1994 elections
President: Bill Clinton (D)
Republican gains:
54 seats in the House
8 seats in the Senate

2006 elections
President: George W. Bush (R)
Democratic gains:
31 seats in the House
6 seats in the Senate

2010 elections
President: Barack Obama (D)
Republican gains:
63 seats in the House
6 seats in the Senate

House Republicans are defending 83 competitive seats to only 14 competitive Democratic seats

Cook Political Report ratings

COMPETITIVE 2018 HOUSE RACES

- Democrat held seats
- Republican held seats

<table>
<thead>
<tr>
<th>Likely Democrat</th>
<th>Lean Democrat</th>
<th>Toss Up</th>
<th>Lean Republican</th>
<th>Likely Republican</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZ-9 Sinema*</td>
<td>AZ-1 O’Halleran*</td>
<td>MN-1 Walz*</td>
<td>AR-2 Hill</td>
<td>PA-15 Rothfus/Lamb</td>
</tr>
<tr>
<td>CA-7 Bera</td>
<td>NH-1 Shea-Porter*</td>
<td>MN-8 Nolan*</td>
<td>CA-45 Walters</td>
<td>AZ-9 Schweikert</td>
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<tr>
<td>CT-5 Esty*</td>
<td>NV-3 Rosen*</td>
<td>CA-10 Denham</td>
<td>FL-18 Mast</td>
<td>CA-4 McClintock</td>
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<tr>
<td>FL-7 Murphy</td>
<td>AZ-2 McSally*</td>
<td>CA-25 Knight</td>
<td>GA-6 Handel</td>
<td>CA-21 Valadão</td>
</tr>
<tr>
<td>MN-7 Peterson</td>
<td>CA-29 Royce*</td>
<td>CA-39 Rose-Lee-Ver*</td>
<td>IA-3 Young</td>
<td>FL-15 Ross*</td>
</tr>
<tr>
<td>NH-2 Kuster</td>
<td>CA-48 Rohrabacher</td>
<td>CO-6 Coffman</td>
<td>IL-14 Hultgren</td>
<td>FL-16 Buchanan</td>
</tr>
<tr>
<td>NJ-5 Gottheimer</td>
<td>FL-27 Ros-Lehtinen*</td>
<td>FL-26 Curbelo</td>
<td>KS-2 Jenkins*</td>
<td>FL-25 Diaz-Balart</td>
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<tr>
<td>NV-4 Kihuen*</td>
<td>NJ-11 Frelinghuysen*</td>
<td>IA-1 Blum</td>
<td>KS-3 Yoder</td>
<td>GA-7 Woodall</td>
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<tr>
<td>PA-8 Cartwright</td>
<td>PA-7 VACANT (Dent)</td>
<td>IL-6 Roskam</td>
<td>ME-2 Poliquin</td>
<td>IL-13 Davis</td>
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<tr>
<td>NJ-2 LoBiondo*</td>
<td>VA-10 Comstock</td>
<td>IL-12 Bost</td>
<td>MI-8 Bishop</td>
<td>IN-2 Walorski</td>
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<tr>
<td>PA-5 VACANT (Meehan)</td>
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<td>KY-6 Barr</td>
<td>NC-9 Pittenger*</td>
<td>MI-1 Bergman</td>
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<tr>
<td>PA-6 Costello*</td>
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<td>MI-11 Trot*</td>
<td>NC-13 Budd</td>
<td>MI-6 Upton</td>
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<td></td>
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<td>MN-2 Lewis</td>
<td>NE-2 Bacon</td>
<td>MI-7 Walberg</td>
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<td>MN-3 Paulsen</td>
<td>NJ-3 MacArthur</td>
<td>MO-2 Wagner</td>
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<td>NJ-7 Lance</td>
<td>NM-2 Pearce*</td>
<td>MT-AL Gianforte</td>
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<td>NY-19 Faso</td>
<td>NY-11 Donovan</td>
<td>NC-2 Holding</td>
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<td>NY-22 Tenney</td>
<td>OH-1 Chabot</td>
<td>NC-8 Hudson</td>
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<td>OH-12 VACANT (Tiberi)</td>
<td>TX-23 Hurd</td>
<td>NY-1 Zeldin</td>
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<td>PA-1 Fitzpatrick</td>
<td>UT-4 Love</td>
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<td>PA-17 Rothfus/Lamb</td>
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<td>TX-7 Curberson</td>
<td>VA-5 Garrett*</td>
<td>OH-14 Joyce</td>
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<td>TX-32 Sessions</td>
<td>VA-7 Brat</td>
<td>OH-15 Stivers</td>
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<td>WA-8 Reichert*</td>
<td>WA-5 McMorris</td>
<td>PA-10 Perry</td>
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<td>Rodgers</td>
<td>PA-16 Kelly</td>
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<td>WI-1 Ryan*</td>
<td>SC-1 Sanford</td>
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<td>WV-3 Jenkins*</td>
<td>TX-21 Smith*</td>
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<td>TX-31 Carter</td>
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<td>WA-3 Beutler</td>
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<td></td>
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<td>WV-6 Grothman</td>
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</table>

*Incumbent not seeking reelection, seeking other office, or lost primary election

Source: Cook Political Report.

June 21, 2018  | Presentation Center
Control of the Senate will depend on the eight “Toss Up” seats

Breakdown of 2018 Senate races
THE COOK POLITICAL REPORT

Solid
Democrat
Feinstein (CA)
Murphy (CT)
Carper (DE)
Hirono (HI)
Warren (MA)
Cardin (MD)
King (ME)
Klobuchar (MN)
Heinrich (NM)
Gillibrand (NY)
Whitehouse (RI)
Kaine (VA)
Sanders (VT)
Cantwell (WA)

Likely
Democrat
Stabenow (MI)
Tester (MT)
Menendez (NJ)
Casey (PA)
Baldwin (WI)

Lean
Democrat
Smith (MN)
Brown (OH)

Toss Up

Lean
Republican
Nelson (FL)
Donnelly (IN)
McCaskill (MO)
Heitkamp (ND)
Manchin ( WV)
Flake (AZ)*
Heller (NV)
Corker (TN)*

Likely
Republican
Hyde-Smith (MS)
Fischer (NE)
Cruz (TX)

Solid
Republican
Wicker (MS)
Hatch (UT)*
Barrasso (WY)

* Announced retirement

Source: The Cook Political Report, 2018
Democrats, Republicans will take turns playing defense in upcoming elections

Senate seats in play, by election year

<table>
<thead>
<tr>
<th>Year</th>
<th>Republican seats</th>
<th>Democrat seats</th>
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<tbody>
<tr>
<td>2018</td>
<td>26</td>
<td>9</td>
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<tr>
<td>2020</td>
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