Legislative Update

Clinical Trials and Translational Research Advisory Committee

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Appropriations Update – FY17

- Congress passed an Omnibus appropriations bill in early May, and the President signed it into law on May 5, 2017.
- \$2 billion increase for NIH (total includes the \$352 million provided by the 21st Century Cures legislation)

- For NCI:
 - \$174 million increase
 - \$300 million for the Cancer Moonshot provided through the December 2016 Continuing Resolution

A New Foundation For American Greatness

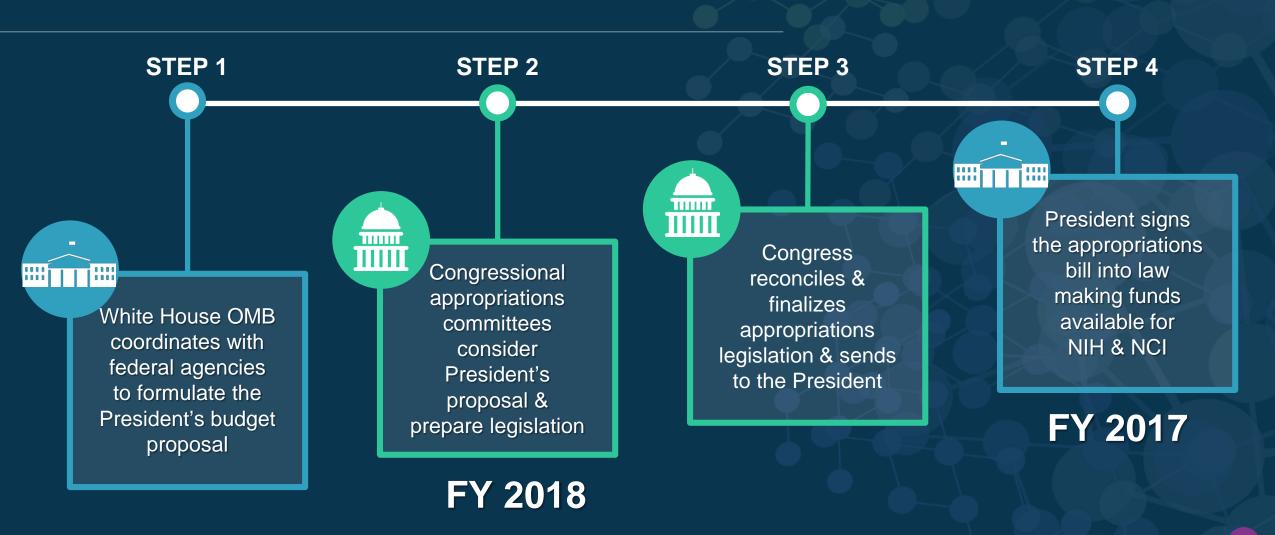
Fiscal Year 2018

Appropriations Update - FY18

- The President's Budget was released on May 23, 2017, and includes more than a 20% cut to NIH's budget compared to the FY17 appropriated level
- House L-HHS Appropriations Subcommittee Hearing May 17, 2017
- Senate L-HHS Appropriations Subcommittee Hearing June 22, 2017
- Dr. Lowy in attendance at both hearings to answer questions



NCI/NIH BUDGET PROCESS FOR REGULAR APPROPRIATION



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



"As outlined in the Constitution, the Congress, not the Executive Branch, has the 'power of the purse.' My Committee takes this responsibility very seriously.

It is our job to analyze the request, go through each and every budget line, question every witness, and demand spending justifications on behalf of the taxpayers who are footing the bill.

Only then can Congress put forward our own plan to fund the federal government."

House Appropriations Chairman Rodney Frelinghuysen (R-NJ)

Strong Bipartisan Support for NIH and NCI



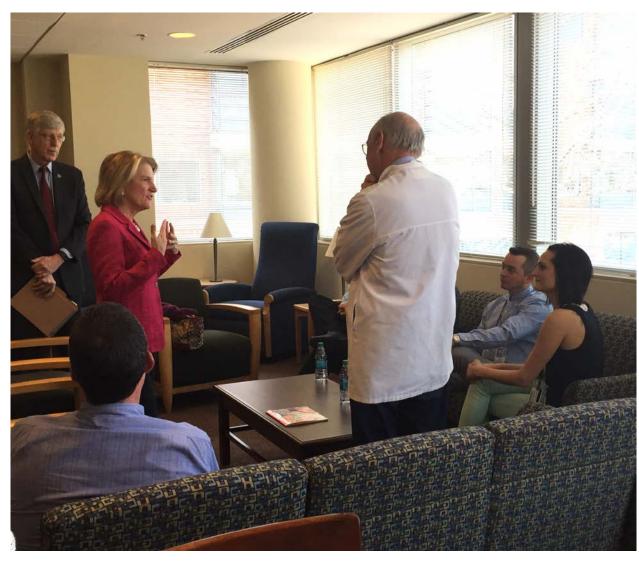


House Labor-HHS Appropriations Subcommittee – February 2017





Third Annual Visit of House Labor-HHS Appropriations Subcommittee



Senator Shelley Moore Capito (R-WV) visits with NCI's Dr. Steve Rosenberg and a patient (April 2017)

Congressional Staff Visit to NCI's Pediatric Oncology Branch – May 2017



Bipartisan group of Nine Senate Appropriators visit NIH – June 5, 2017

Labor-HHS Appropriations Subcommittee Chairman Roy Blunt (R-MO)

Ranking Member Patty Murray (D-WA)

Lamar Alexander (R-TN)

Richard Durbin (D-IL)

James Lankford (R-OK)

John Kennedy (R-LA)

Jean Shaheen (D-NH)

Susan Collins (R-ME)

John Boozman (R-AR)



Dr. Lowy with Senators Lamar Alexander and Patty Murray







Outlook for FY18

Time is short

Only 25 days with <u>both chambers</u> in session between now and end of FY17

It's Complicated

- Senate Majority Leader Mitch McConnell just extended the Senate session into the first two weeks of August recess
 - health care repeal/replace, debt ceiling vote, nominations, tax reform
 - Still negotiating topline budget numbers

Many other political distractions

Absent new legislation, budget caps are back in FY18 ("sequestration")

Congress has yet to allow the full effect of budget caps put in place by 2011 Budget Control Act legislation

2015 Bipartisan Budget Act delayed impact scheduled for FY16 and FY17 by raising the caps, but without further action by Congress, caps are back in place for FY18

Bipartisan support for raising budget caps ("cap enhancement") – but also opposition

July 11: Still Without a Budget, House Appropriators Proceed with Subcommittee Allocations

Proposal to divide \$1.14 Trillion for FY18 across the 12 spending bills

Defense spending increases, non-defense decreases

Exceeds caps put in place by Budget Control Act (max of \$1.065 Trillion for FY18)

Funding plan requires a change in budget law to avoid automatic spending cuts ("Sequester")

House Budget Committee – struggling to craft a budget resolution

Government Shutdown Talk Begins

16-day shutdown in 2013

Costly

No political winners

Majority of members do NOT want a shutdown

No way to predict



Several Paths Forward for FY18

- 12 bill Omnibus
- Full year Continuing Resolution maintaining current funding levels
- A combination of "minibuses" potentially a "cromnibus"

- All hinge on a budget deal for FY18
- A budget deal requires 60 votes in the Senate

Questions?

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FDA Reauthorization

The House will be voting today on H.R. 2430, the FDA Reauthorization Act of 2017.

- The FDA User Fee Reauthorization is a "must-pass" bill current authorization is through September 30.
- The House bill includes provisions based on the RACE for Children Act (introduced earlier this session by Reps. Mike McCaul (R-TX) and G.K. Butterfield (D-NC), and Senators Michael Bennet (D-CO) and Marco Rubio (R-FL).
- The provision is intended to amend the study requirements under the 2003 Pediatric Research Equity Act (PREA) that requires companies to develop a plan for how they will test experimental drugs in children.
- The RACE language would require companies to apply the PREA standards to any therapy with a molecular target relevant to both adult and childhood diseases, as opposed to the current organ site classification.