NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

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Discussion Topics

- Recent Congressional Activity
 - Appropriations increases proposed for NIH
 - Authorizing bills 21st Century Cures

114th Congress – Committee Leadership and Priorities

Recent Congressional Activity

Appropriations

Key Issues



Appropriations Status – FY 2016

Budget Caps Limit Possible Options

House LHHS Committee Approved FY 2016 bill on June 24, 2015

- Provides NIH \$31.2 billion, an increase of 1.1 billion above FY2015
- Includes \$200 million for Precision Medicine Initiative, \$70 million to
 NCI
- Targets specific research areas, providing increased funding for Alzheimer's disease research, Clinical Translational Sciences Awards, the BRAIN initiative, among others
- Provides NCI \$5.081 billion, an 2.65 increase over FY2015

Senate LHHS Committee Approved FY 2016 bill on June 25, 2015

- Provides NIH \$32 billion, an increase of \$2 billion above FY2015
- Includes \$200 million for Precision Medicine Initiative, \$70 million to
 NCI
- Targets specific research areas, providing increased funding for Alzheimer's disease research, BRAIN initiative, and the Combating Antibiotic Resistant Bacteria program, among others.
- Provides NCI \$5.204 billion, an 5.12% increase over FY2015

HEALTH CARE

NIH sees reversal of fortune with proposed funding boosts

The medical research agency could potentially receive billions more by 2020.

By **SARAH KARLIN** | 7/7/15 5:18 AM EDT



Appropriations: What to Expect Next

- Both House and Senate appropriations committees plan to finish marking up all 12 bills by mid-July.
- Democrats are threatening a blanket filibuster on all spending bills that reach the Senate floor, because of spending caps.
- Unclear how many spending bills House Leaders will bring to the floor.
- CR(s) likely, followed by an omnibus spending bill.
 Hopefully without a government shutdown in between.

Budget – Reconciliation - Affordable Care Act

- July 24 deadline for budget reconciliation plan
 - "short cut" process (only need 51 votes in Senate not 60)
 - BUT need House and Senate budget agreements to use reconciliation process. And subject matter must be germane
 - GOP dream plan to repeal the ACA... not looking good
 - Supreme Court ruling last month, CBO cost estimates of repeal

Republicans Aim to Hamper Obama's Policies With Spending Bills – New York Times, July 7, 2015

"Frankly, the fall is shaping up to be the most predictable and, really, avoidable — budget crisis in memory." Rep. Nita M. Lowey, Ranking Member House Appropriations Committee

"We all know there's going to have to be a short-term CR to take us from September to December, and I would hope sometime between now and then, we'll have a negotiated budget agreement." Rep. Charlie Dent, MilCon-VA Subcommittee Chairman



"A lot of things are moving toward some kind of a climax..." I think we're asking the pope to do too much, but hey, mood is important to the legislative process."

Rep. Tom Cole

Good Intentions

"This bill prioritizes programs that will provide a significant benefit to all Americans including providing the National Institutes of Health with a \$2 billion increase to focus on advancing medical treatments, Precision Medicine and research to find a cure for Alzheimer's and cancer."

Senate LHHS Subcommittee Chairman Roy Blunt (R-MO) statement in an op-ed published in *The Hill. (June 2015)*

Good Intentions

"It's a good starting point. I always see an initial bill as the opening round of a negotiation... We're just trying to show: here are areas where we can agree. I always call this bill catnip for Democrats. They love everything in it. Nothing can be cut. They have a very hard time prioritizing it. It's sort of like us in defense. I get it. This is something they care deeply about, they are passionate about. They will like the places we plus up. But this is a place where we are freer to make priorities and choices. It's easier for us."

Labor-HHS Appropriations Subcommittee Chairman Tom Cole (R-OK)

More Good Intentions -

"There are promising signs that the status quo for U.S. biomedical research is no longer good enough and that this year is going to be different... Congress is taking a stand for the NIH. Its leaders are demonstrating that they understand it is a good investment for our future. And Congress is making the hard choices to fund cures that will save both lives and health care dollars."

"NIH – A Treasure Worth Investing In"
Published in *Roll Call* (July 2015)



Senate Appropriations Committee



Chair, Thad Cochran (R-MS)



Vice Chair, Barbara Mikulski (D-MD)



Chair, Roy Blunt (R-MO)



Ranking, Patty Murray (D-WA)



Senate HELP Committee





Chair, Lamar Alexander (TN)

Ranking, Patty Murray (D-WA)



House Appropriations Committee



Chair, Hal Rogers (R-KY)



Ranking, Nita Lowey (D-NY)

L-HHS Subcommittee



Chair, Tom Cole (R-OK)



Ranking, Rosa DeLauro (D-CT)



House Energy and Commerce Committee



Chair, Fred Upton (R-MI)



Ranking, Frank Pallone (D-NJ

Health Subcommittee



Chair, Joe Pitts (PA)



Ranking, Gene Green, (D-TX)

Support for NIH

House and Senate Appropriations bills

■21st Century Cures (House)

•Innovation Initiative (Senate)

21st Century Cures Initiative

- Bipartisan effort led by Representatives Fred Upton (R-MI) and Diana DeGette (D-CO).
- Purpose: To accelerate the discovery, development, and delivery of treatments and cures for diseases.
- Draft bills released in January, April, and May 2015.
- On May 21, 2015, unanimously approved by the House Energy and Commerce Committee.
- House vote today

21st Century Cures (cont.)

- Establishes NIH and Cures Innovation Fund within the Treasury of the United States:
 - \$1.75 B for NIH annually from FY2016 FY2020
 - \$110 M for FDA annually from FY2016 FY2020

Strings Attached...

- Funding Allocation Distribution for NIH:
 - \$500 M for Accelerating Advancement Program
 - ICs must match \$1 for each dollar received from the Innovation Fund
 - At least 35% (\$437.5M) for Early Stage Investigators
 - At least 20% (\$250 M) for High-Risk, High-Reward
 Research
 - No more than 10% (\$125 M) for Intramural Research

21st Century Cures (cont.)

- Dems unhappy with reduced NIH funding
- Set for a vote in the House on July 8th
- 29 amendments filed yesterday riders of all types
- CBO score
- Offsets trouble
- Stay tuned...

Innovation for Healthier Americans

- Senate HELP Committee parallel effort to House's 21st Century Cures
- Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to our Nation's Medical Product Discovery and Development, report by Senators Lamar Alexander (R-TN) and Richard Burr (R-NC) released January 29, 2015

"Together, we can take important steps to ensure that America remains the world's leading global innovator in medicine, and in the process also ensure that our nation's patients have access to the most cutting-edge medical products in as timely a manner as possible"

- Senators Alexander and Burr
- Senate legislation expected in early 2017

QUESTIONS?



