NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

March 13, 2013

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Discussion Topics

Appropriations Status

- Sequestration
- FY 2013 Replacing the CR

Legislation of Interest

Recalcitrant Cancer Research Act



Appropriations Status – FY 2013

Where are we?

- Government is operating under a Continuing Resolution (CR) that expires March 27, 2013
 - Terms of CR funded NIH at 0.62% above FY 2012
- Sequestration took effect March 1, 2013
 - Reduces each budget line by 5.1% in 2013
 - Cuts \$109 billion per year through 2021



Activities Related to Sequestration

Feb. 8

• Sen. Cardin visits NIH; holds Town Hall meeting with staff

Feb. 12

• White House issues, "The President's Plan for a Strong Middle Class and a Strong America" advocates cutting the deficit in a balanced way

Feb. 13

House Appropriations Committee Democrats release report,
 "Discretionary Appropriations will Reach Historic Lows"

Feb. 20

• Sen. Mikulski visits NIH; holds press conference



Early Action by Appropriators

Senate

- Feb. 14: Full Appropriations Committee held hearing, "The Impact of Sequestration"
 - All witnesses were Cabinet Secretaries, Sebelius did not attend but submitted letter

House

- March 5: Labor, HHS, Education Subcommittee held hearing, "Public Health Research"
 - HHS Division Heads testified (including NIH Director)



CR Expires March 27 – Unless...

House Bill – HR 933

- Full Year CR and Defense Appropriations
 - Within Defense and Military Construction-VA bills, adjusts individual finding levels to increase funding for priority programs
 - All other appropriations, maintains current funding levels with subsequent reduction due to sequestration
 - Passed House March 6 (267-151)

Senate Proposal – Compromise CR

- House bill + 3 bills (Agriculture, C-J-S, Homeland Security)
 - Introduced jointly by Sens. Mikulski and Shelby
 - Will help selected agencies manage spending cuts
 - Sen. Coburn to delay consideration of bill



What They Said

Mikulski, optimistically

"We must prevent a government shutdown. My Vice-Chairman and I worked together on this bipartisan agreement that avoids a shutdown, complies with the Budget Control Act, improves the House CR for many critical priorities, and lets us wrap up 2013 so we can get to next year's budget and find a balanced solution to sequester"

Shelby, proudly

"Chairwoman Mikulski and I began this process with three shared goals: prevent a government shutdown; provide as much flexibility as possible for the remainder of this fiscal year; produce a bill that both parties in both Houses can support. I believe that we have achieved all three goals"



Possible Amendments

<u>Harkin</u> amendment, modeled on Labor, HHS, Education bill negotiated with House in December, would increase NIH funding by \$211 million, also increase education programs, child care programs, and Ryan White AIDS program.

Cruz would delay funding for ACA

Nelson/McCaskill would reduce salary of lawmakers

Heller would restore White House tours

McCain would strip out pork in Defense bill



Discussion Topics

Congressional Priorities

Legislation of Interest



How the Pancreatic Cancer Research Act Became the Recalcitrant Cancer Research Act

House Action – **September 2012**

- HR 733 amended replaced text and changed title
- Passed House on Sept. 19

Senate Action – 2012

- S 3566, which included the new text of HR 733 was introduced by Sen. Harkin on Sept. 19
- Reported to the Senate on Sept. 19



How the Recalcitrant Cancer Research Act Became Law

HR 733/S 362/S 3566

- Sept. 20 Dec. 17: No Activity
- Dec. 18 Sen. Whitehouse proposed amendment to Defense Authorization adding provisions of HR 733
- Sen. Coburn spoke out against amendment but did not block vote and amendment passed
- House passed Dec. 20; Senate passed Dec. 20
- President signed Jan. 2 (Public Law 112-239)



Recalcitrant Cancer Research Act

Key Provisions

- NCI develop scientific framework to conduct and support research for recalcitrant cancers
 - Recalcitrant cancer defined as cancer for which the 5-year survival is < 50%
 - Criteria to form group: 5-year survival < 20 % and mortality must be > 30,000 per year
 - NCI convene working group to provide expertise, assistance in developing framework
 - Frameworks must be submitted to Congress and made publicly available



Recalcitrant Cancer Research Act

Specific Requirements

NCI must identify 2 or more recalcitrant cancers (i.e. 5-year survival < 20%; mortality > 30,000 per year) not more than 6 months after enactment

NCI must develop scientific frameworks not later than 18 months after enactment

Frameworks must be submitted to Congress and made publicly available on DHHS website not later than 30 days after framework completed



Recalcitrant Cancer Research Act

Implementation

- PDAC Working Group established
 - Preliminary report presented to CTAC in Nov.
 - Finalizing report

- Small Cell Lung Cancer Working Group forming
- Chair Appointed
- Identifying Participants







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