

National Cancer Institute



U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

National Institutes
of Health

NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

November 9, 2011

Susan Erickson

Director, Office of Government and
Congressional Relations



Discussion Topics

Appropriations Status

NCI Interactions with Congress

Topic of Interest



Appropriations Status – FY 2012

Where are we?

- No appropriation bills have passed.
- Government is operating under a Continuing Resolution (CR) that expires November 18

How did we get here?

- Debt ceiling negotiations delayed progress on any Appropriations bills May – July
- Labor-HHS Education bill passed in Senate by Appropriations Committee Sept. 21
- House Labor-H bill finally made public Sept. 29, but no action

Appropriations Status – FY 2012

What Else Happened in the Senate?

☺ Sen. Moran (R-KS) offered amendment to increase NIH funding by \$190 million

☹ NIH increase paid for by across-the-board cut

- Amendment did not pass

Appropriations Status – FY 2012

What Else Happened in the House?

☺ Bill includes higher funding levels for NIH and NCI

☹ Prohibits funding for implementation of health care reform

- Minority objected because they had no input
- Bill unlikely to be voted on

Appropriations Status – FY 2012

What's Next?

- House and Senate leadership needed a strategy to reduce the time it will take to pass all 12 appropriations bills, but still avoid a single catch-all bill.
- Reached agreement to have the Senate combine 2 or more bills into “minibus” packages.
- 1st minibus voted on by Senate next week, others to follow
- Bills must then be passed by House, signed by President
- Labor, HHS, Education bill will be in the last group.
- A new CR that will extend through mid-December will be included in the first minibus bill.



Discussion Topics

Appropriations Status

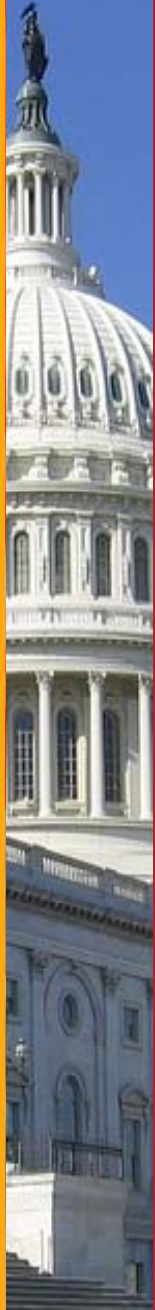
NCI Interactions with Congress

Topic of Interest



NCI Staff Inform Congress

- Cancer Research (Sept. 22)
 - AACR invited RSC members
 - Dr. Varmus
- Ovarian Cancer (Sept. 15)
 - Ovarian Cancer National Alliance sponsored
 - Members and staff attended
 - Dr. Jennifer Loud (DCEG)
- Multiple Myeloma (Oct. 25)
 - International Myeloma Foundation sponsored
 - Rep. Jackie Speier (D-CA) participated
 - Dr. Ola Landgren (CCR)



Members of Congress Visit NIH

- Rep. Jackie Speier (July 29)
 - Drs. Helman and Mackall led tour of CC
 - Discussed pediatric clinical trials
 - Dr. Collins, staff from NIDDK participated
- Sen. Jerry Moran (Sept. 22)
 - Visited lab with Dr. Linehan
 - Toured clinic with Dr. Helman
 - Met Dr. Collins
- Congressional Staff and Advocates (Sept. 27)
 - Research! America sponsored
 - Multiple ICs participated
 - Dr. Linehan (NCI)



Discussion Topics

Appropriations Status

NCI Interactions with Congress

Topic of Interest



Drug Shortage – Legislation

Preserving Access to Life-Saving Medications Act

- S 296 introduced by Klobuchar/Casey Feb. 17
- HR 2245 introduced by Rooney/DeGette June 21
 - ✓ Manufacturers must notify FDA of discontinuance, interruption, disruption that would result in shortage
 - ✓ HHS must implement evidence-based criteria to identify drugs vulnerable to shortages
 - ✓ GAO must study possible causes
 - ✓ HHS must report to Congress



Drug Shortage – Congressional Interest

- House Energy and Commerce Comm. Hearing Sept 23
 - HHS (Dr. Koh) and FDA (Dr. Kweder) testified
- Sen. Schumer held press conference Oct. 9
 - Asked FTC to investigate distributors for price gouging
- Rep. Cummings launched investigation of gray market
 - October - Requested information from 5 companies that sell drugs but do not manufacture them or treat patients
 - November - Expressed concern at some companies lack of cooperation



Drug Shortage – Follow Up

- FDA released “Review of Drug Shortages”
- HHS posted issue brief “Economic Analysis of the Causes of Drug Shortages”
- President Obama issued Executive Order - FDA to:
 - Use existing authorities to require drug manufacturers to provide advance notice of potential shortages
 - Expand current efforts to expedite regulatory reviews
 - Work with DOJ to review certain behaviors by market participants



NATIONAL[®]
CANCER
INSTITUTE
