NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

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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
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
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

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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)
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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 disontinuance, 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