NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

March 7, 2012

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Discussion Topics

FY12 Appropriations
President’s Budget Request FY2013
Appropriations Hearings
NCI Interactions with Congress
Topic of Interest
FY12 Appropriations

Omnibus bill signed into law on December 23

- $30.69 billion for NIH
- $5.071 billion for NCI
  - 0.2% increase over FY11 (1% cut from FY10)

- House bill – increase NIH $1 billion
- Senate bill – cut NIH $190 million
FY12 Appropriations

- Creation of National Center for Advancing Translational Sciences (NCATS)
- Reduction in maximum salary support (from $199K to $179K) for extramural grantees for grants issued on/after 12/23/11
- Pilot study of viability of 3rd party reimbursement for clinical center patients
- Review of trans-NIH applicability of the IOM recommendations re: NCI clinical trials
President’s Budget Request FY2013

Announced February 13, 2012

- Flat funding for NIH and NCI
  - $5.07 billion ($2.7 million over FY12 enacted level)
- Increase for NSF
- More cuts for CDC, SAMSHA
FY13 Appropriations Hearings

➢ House – March 20th (9:30 am)
Subject: NCATS
(Collins & Insel, Industry)

➢ Senate – March 28th (9:30 am)
Subject: NIH
(Collins, Varmus, Fauci, Rodgers)
FY13 Appropriations - Issues

- No “Regular” Order (again)
- Continuing Resolution (CR) late September
- Looming issues:
  - Budget Control Act
  - Failure of Super Committee to agree on savings of $1.2 trillion over 10 years
  - Sequestration “across the board cuts”
Our calculations show that a non-defense sequestration of $54.7 billion in 2013 would result in cuts of approximately 9.1 percent in non-exempt non-defense discretionary programs and 8.2 percent in non-exempt mandatory programs.

NIH = 9.1% cut in January 2013
FY13 Appropriations - Issues

Sequestration – harsh consequences

- Even split “defense” & “non-defense”
- Minimal exemptions (Pell grants, VA medical care)

A way around sequestration?

- Five sequesters between 1986-1991, but for much smaller amounts
- 4 out of 5 reversed or reduced by later laws
Can Congress find a way around sequester (again)?

Different reality now

- Much bigger target to hit
- Downgrade financial rating - concerns
- Loudest voices re: protecting defense

“If we don’t do it, we’re going to start to look a lot like Greece.”
FY13 Appropriations - Issues

November Uncertainty…
“Mother of all Lame Ducks”

Sequestration

FY13 budget

Expiration of Bush tax cuts

AMT
Appropriations Proceeds

Have to ignore threat of sequester...

Hearings:
House March 20
Senate March 28

Markup:
House May/June
Senate June/July
FY13 Appropriations Hearings

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Discussion Topics

Appropriations Status

NCI Interactions with Congress

Topic of Interest
NCI Staff Inform Congress

House Appropriations Labor-H Chairman Denny Rehberg (R-MT) and staff visited NIH on November 28, met with NCI, NIAID, NINDS and NHGRI researchers

Senator Scott Brown (R-MA) visited on December 13, toured CRC and met with NCI and NHGRI researchers
Discussion Topics

Appropriations Status

NCI Interactions with Congress

Topic of Interest
Preserving Access to Life-Saving Medications Act

- S 296 introduced by Klobuchar/Casey Feb. 17
- HR 2245 introduced by Rooney/DeGette June 21

✓ Similar

✓ 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
Drug Shortage Prevention Act

• HR 3839 Reps. John Carney (D-DE) and Larry Bucshon (R-IN)

• Establishing “national critical drug list”
• Expedited review of generic applications by FDA
• Feasibility study of “national contingency plan”
Drug Shortage – Congressional Interest

• House Energy and Commerce Comm. Hearing Sept 23
  – HHS (Dr. Koh) and FDA (Dr. Kweder) testified

Drug Shortage

• 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
Drug Shortage

• Ben Venue Laboratories shutdown exacerbates shortages (doxil, methotrexate)

• FDA working on importation

• No obvious immediate solution – e.g., increase reimbursement, incentives to manufacturers

• Efforts to increase FDA funding, inspections?

• PDUFA, GDUFA – “must pass” bills in the fall