



NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

March 7, 2012

M.K. Holohan, J.D.

Deputy Director, Office of Government and
Congressional Relations



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”

FY13 Appropriations - Issues



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



FY13 Appropriations - Issues

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...



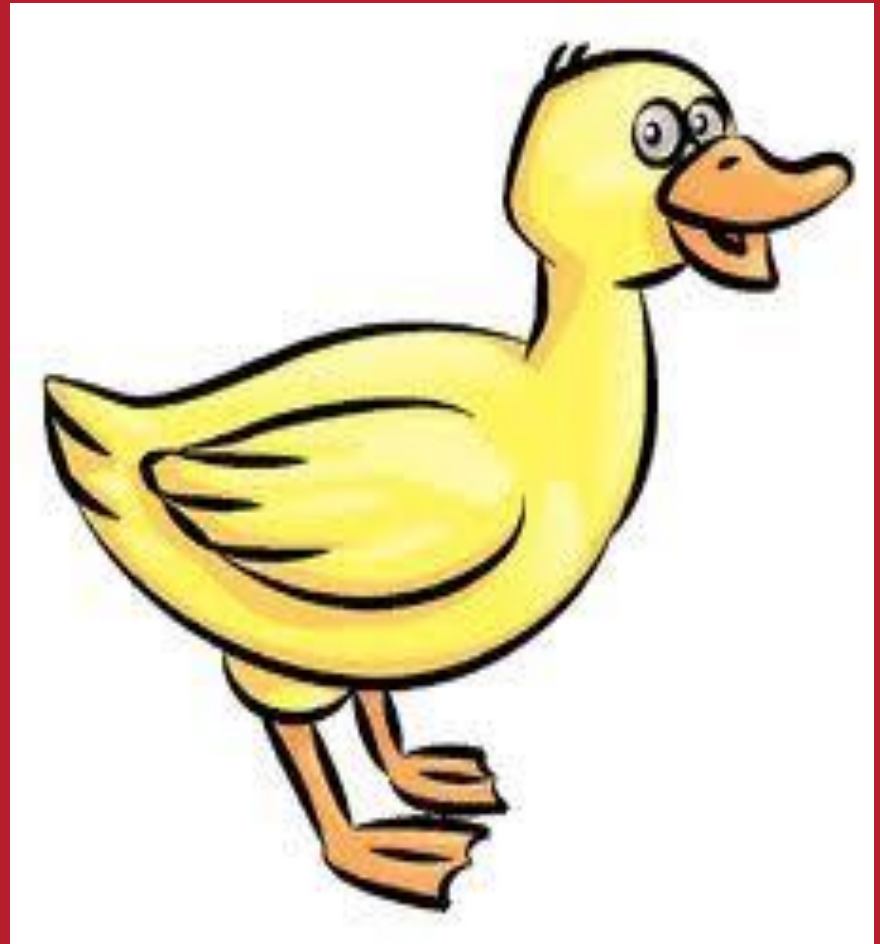
“Mother of all Lame Ducks”

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

➤ House – March 20th (9:30 am)

Subject: NCATS

(Collins & Insel, Industry)

➤ Senate – March 28th (9:30 am)

Subject: NIH

(Collins, Varmus, Fauci, Rodgers)



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

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
 - ✓ 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 – Legislation

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
 - Yesterday - questions from House Appropriations Labor-H Subcommittee (to Secy. Sebelius) from Rep. Kay Granger (R-TX)

-

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



NATIONAL[®]
CANCER
INSTITUTE
