U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NCI Legislative Update **Clinical Trials and Translational Research Advisory** Committee (CTAC) M.K. Holohan, J.D. Deputy Director, Office of Government and **Congressional Relations** July 15, 2009

Legislative Activities

Appropriations Information Legislation of Interest Congressional Priorities 2009

FY 2010 Appropriations Activities

President's Budget released May 7
➢ NIH - \$30.8 Billion
➢ NCI - \$5.15 Billion
➢ NIH "Cancer" - \$6 Billion

- House hearing on NIH budget March 26
- Senate hearing on NIH budget May 21
- Subcommittee Work
 Allocations to Subcommittees
 Bills drafted by Subcommittees

Labor, HHS Education Bill - Timeline

• House

- July 10 Subcommittee consideration
 NIH \$31.3B, \$500M+ PB and \$941M + FY2009 enacted
- July 17– Full Committee consideration
 July 24 Vote on House floor

• Senate

➢ No dates set – Chairman stated intention to pass all 12 bills before end of Fiscal Year Legislative Activities

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Legislative Highlights

- Kennedy Cancer Bill
- Comparative Effectiveness Research Bills
 Comparative Effectiveness Research Act
 Healthy Americans Act
 Patient-Centered Outcomes Research Act

✓ Tobacco Bill

S 717

21st Century Cancer Access to Life-Saving Early Detection Research and Treatment (ALERT)

- Introduced by Sens. Kennedy and Hutchison on March 26, 2009.
 - Referred to Senate HELP Committee

Provisions of Introduced Version Related to NCI

- Purpose To enhance and improve the cancer research conducted and supported by NCI and NCP
- Focus on Biospecimens
- Enhance Reporting on Cancer Research

ALERT Bill

Recent Discussion Topics

- Options to best provide coordination of NCP
 - > May require strategic plan and annual report
- Biorepositories
 - Focus on issues of quality, access
- Rare and low survival cancers
 - Additional reporting

<u>Timeline</u>

• Will not meet goal of markup before August recess

Comparative Effectiveness Research Act

HR 2502

- Introduced May 19 by Rep. Schrader (D-OR)
 <u>Key Provisions</u>
- Establish nonprofit corporation Health Care Comparative Effectiveness Research Institute
- Create CER trust fund imposes fee on selfinsured health plans and policies
- Require that research be peer reviewed
- Require HHS to make CMS data available
- Require Institute to disseminate findings to clinicians, patients and general public

Healthy Americans Act

HR 1321 and S 391

- Introduced by Rep. Eshoo on March 5
- Introduced by Sen. Wyden on February 5
- To provide affordable, guaranteed private health coverage that will make Americans healthier <u>Key CER Provisions</u>
- Establish Comparative Effectiveness Advisory Board (AHRQ Director plus 14 members)
 - Board to establish peer review advisory panel
 - Board to recommend at least 1 FFRDC
- Establish Research Trust Fund

Patient-Centered Outcomes

S 1213

- Introduced by Sen. Baucus on June 9
- Baucus Chairs Senate Finance Committee (key player in health care reform)

Key Provisions

- Establish a private, nonprofit corporation
 - Identify national research priorities/agenda
 - Board of Governors (21 members)
- Establish Research Trust Fund

Cures Acceleration Network and NIH Reauthorization Act •\$ 914

- Introduced by Sen. Specter on April 28
 <u>Key Provisions</u>
- Establish a new \$2 billion independent agency outside of HHS that would provide funds to translate research discoveries from bench to bedside
- •Raises NIH authorization to \$40 billion
- •Requires enforcement of COI policies
- •Elevates the National Center for Minority Health and HD to Institute status

Tobacco Bill

Signed into law June 22!

Key Provisions

•gives FDA authority to regulate the manufacturing, marketing, and sale of tobacco products

•Restrict advertising and promotions

•Require large, graphic warnings on packs

•Ban misleading claims such as "light" "low-tar"

•Funded by user fees on tobacco companies

Legislative Activities

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Outlook – 111th Congress

- Appropriations Bills
- Health Care Reform a bill by August recess?
- •Supreme Court confirmation

Will there be time for anything else?

National Cancer Institute

NCI Legislative Update

visit our website: http://legislative.cancer.gov/

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