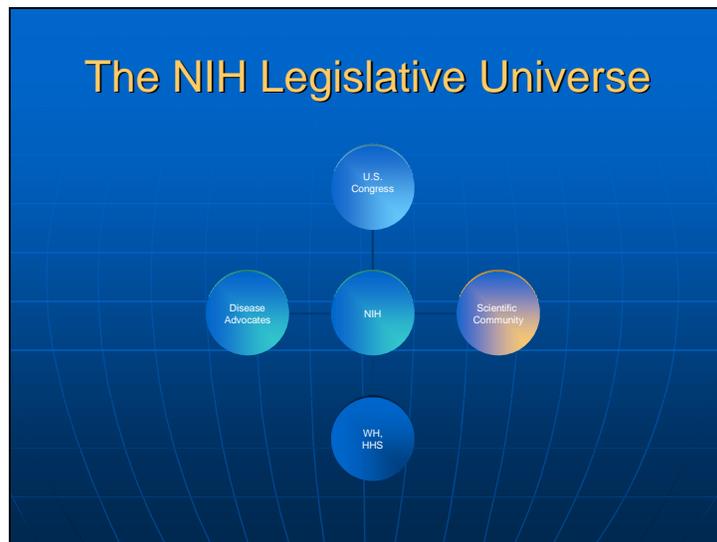


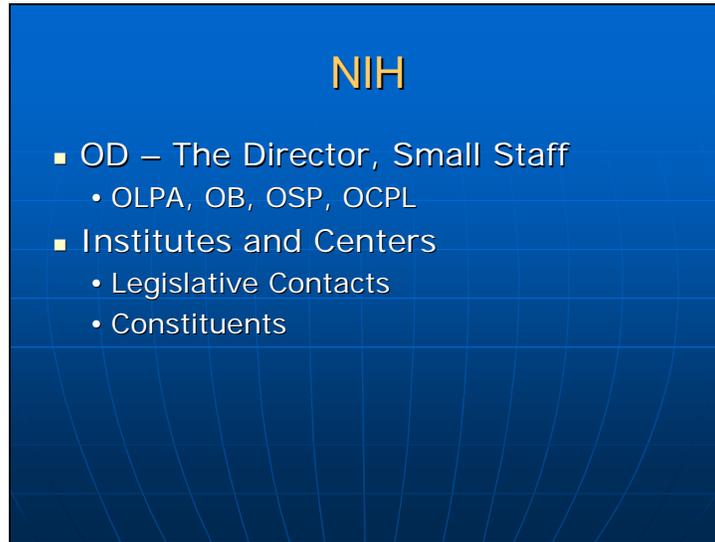
Slide 1



Slide 2



Slide 3

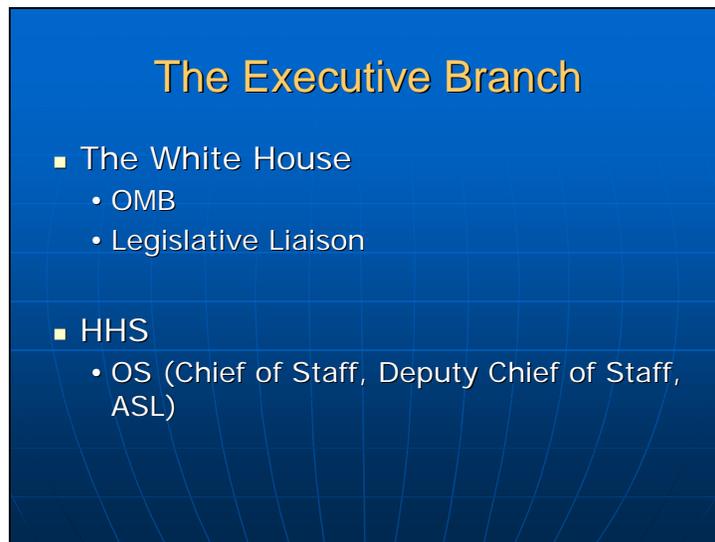


NIH

- OD – The Director, Small Staff
 - OLPA, OB, OSP, OCPL
- Institutes and Centers
 - Legislative Contacts
 - Constituents

The slide features a blue background with a subtle grid pattern. The title 'NIH' is centered at the top in a yellow font. Below it, two main bullet points are listed in white, each with a sub-bullet point indented to the right.

Slide 4



The Executive Branch

- The White House
 - OMB
 - Legislative Liaison
- HHS
 - OS (Chief of Staff, Deputy Chief of Staff, ASL)

The slide features a blue background with a subtle grid pattern. The title 'The Executive Branch' is centered at the top in a yellow font. Below it, two main bullet points are listed in white, each with a sub-bullet point indented to the right.

Slide 5

Scientific Community

- Academic Medical Centers
 - AAMC
 - AAU
- FASEB
- Ad Hoc Group for Medical Research
- Joint Steering Committee for Public Policy
- Research!America

Slide 6

Disease Advocates

- Cancer Coalition
- JDRF
- Cure Autism Now
- Parkinson's Action Network
- American Heart Association
- American Foundation for AIDS Research
- Parent Project for Muscular Dystrophy Research

Slide 7

Congress

Senate

Appropriations

- Labor, HHS, Education Appropriations Subcommittee
 - Tom Harkin, D-IA, Chair
 - Arlen Specter, R-PA, Ranking

Authorization

- Health, Education, Labor and Pensions Committee
 - Edward Kennedy, D-MA, Chair
 - Michael Enzi, R-WY, Ranking

Oversight

- Homeland Security and Governmental Affairs Cmte
 - Joseph Lieberman, D-CT, Chair
 - Susan Collins, R-ME, Ranking
- Finance Committee
 - Max Baucus, D-MT, Chair
 - Charles Grassley, R-IA, Ranking

Slide 8

Congress (cont'd)

House

Appropriations

- Labor, HHS, Education Appropriations Subcommittee
 - David Obey, D-OH, Chair
 - James Walsh, R-NY, Ranking

Authorization

- Energy and Commerce Committee
 - John Dingell, D-MI, Chair
 - Joe Barton, R-TX, Ranking

Oversight

- Oversight and Government Reform Committee
 - Henry Waxman, D-CA, Chair
 - Jim Davis, R-VA, Ranking
- Energy & Commerce Subcommittee on Oversight & Investigations
 - Bart Stupak, D-MI, Chair
 - John Shimkus, R-IL, Ranking

Slide 9

Major Congressional Issues

- Appropriations
- Authorization
- Oversight and Investigations

Slide 10

Appropriations

- 2006: \$28.541 billion
- 2007: \$29.228 billion
- 2008: \$29.230 billion (reflects the 1.747-percent across-the-board cut to NIH).
- 2008 Supplemental: \$150 million (to be distributed on a pro rata basis to ICs)

Slide 11

Authorization

Public Health Service Act
Key Authorities for NIH

- Prioritizes Research Through Organizational Structure
- Authorizes Biomedical Research
- Provides Grant-making Authority
- Authorizes Peer Review
- Authorizes Training
- Authorizes Dissemination of Information
- Requires Human Subjects Protections
- Authorizes the Solicitation of Public Advice

Slide 12

NIH Titles of PHS Act

Title III – General Powers and Duties of Public Health Service
Part A – Research and Investigation

Title IV – National Research Institutes
Part A – National Institutes of Health
Part B – General Provisions Respecting National Research Institutes
Part C – Specific Provisions Respecting National Research Institutes
Part D – National Library of Medicine
Part E – Other Agencies of NIH
Part F – Research on Women’s Health
Part G – Awards and Training
Part H – General provisions
Part I – Foundation for NIH

Slide 13

Authorization Process

- Authorization bills must be introduced by Member of Congress, but can emanate from various sources.
- Programs are authorized for a specific time period, usually 3 year cycles.
- Programs can continue without being reauthorized if funds are appropriated.
- At any time, Congress may make amendments to, and authorizations for, existing programs.
- Congress may also add prohibitions and requirements, at will.
- Authorization process has been subsumed by appropriations process.
- House and Senate rules allow circumvention of standard legislative process.

Slide 14

Evolution of NIH Reauthorization

- 1944 - 1985 – Individual bills amending missions of existing ICs or creating new ICs.
- 1985 – First omnibus reauthorization of NIH.
- 1993 – Second omnibus reauthorization of NIH.
- 1993 – 2004 – Authorization process subsumed by appropriations laws. Some individual bills created new ICs or amended authorities. Failed attempt for omnibus reauthorization in 1996.
- 2004 –2006– Post doubling era, focus on accountability and oversight, new successful attempt for omnibus reauthorization.
- 2006 NIH Reform Act enacted December 2006.

Slide 15

NIH Revitalization Act of 1993
Key Provisions

- Reauthorized certain expiring authorities of the NIH
- Mandated establishment of the Office of Research Integrity in DHHS
- Lifted the moratorium on human fetal tissue transplantation research
- Mandated inclusion of women and minorities in clinical research protocols

Slide 16

1993 Reauthorization
Key Provisions (cont.)

Created New Research Structures:

- The Office of Alternative Medicine
- The Office of Research on Women's Health
- The Office of Research on Minority Health
- The Office of Behavioral and Social Sciences Research

Slide 17

Amendments to PHS Act since 1993 Reauthorization

Created in Statute:

- National Center for Complementary and Alternative Medicine (1998)
- National Center on Minority Health and Health Disparities (2000)
- National Institute of Biomedical Imaging and Bioengineering (2000)
- Office of Rare Diseases (2002)

Slide 18

Amendments to PHS Act since 1993 Reauthorization (cont.)

Research Priorities:

- Parkinson's program established (1998)
- Pediatric Research Initiative (2000)
- Clinical Research Enhancement Act (2000)
 - Loan Repayment Program
- Special funding Program for Type I Diabetes (2002)
- Muscular Dystrophy Research (2002)
- Best Pharmaceuticals for Children Act (2002)

Slide 19

Amendments to PHS Act since 1993 Reauthorization (cont.)

Coordinating Committees:

- Antimicrobial Resistance Task Force (2000)
- Asthma (2000)
- Autism (2000)
- Autoimmune Disease (2000)
- Validation of Alternative Methods (2000)
- Muscular Dystrophy (2002)

Slide 20

Amendments to PHS Act since 1993 Reauthorization (cont.)

Other:

- clinicaltrials.gov (1997)
- Expansion of clinicaltrials.gov (2007)

Slide 21

NIH Reform Act of 2006

- Passed Congress with virtually unanimous support (Dec 2006)
- Signed into law by the President (Jan 2007)
- Authorizes (but does not appropriate) an increase in NIH funding for each of the next 3 years
- New structure to facilitate trans-NIH research

One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Tuesday,
the third day of January, two thousand and six*

An Act

To amend title IV of the Public Health Service Act to revise and extend the
authorities of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health
Reform Act of 2006".

TITLE I—NIH REFORM

Slide 22

NIH Reform Act of 2006 Key Provisions

- Establishes Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within Office of the Director
 - Common Fund
 - Council of Councils to advise on research proposals that would be funded by the Common Fund
- Authorizes appropriations of:
 - \$30,331,309,000 for FY07
 - \$32,831,309,000 for FY08
 - such sums as may be necessary for FY 2009
- Deletes most IC and disease-specific authorization of appropriations sections

Slide 23

NIH Reform Act of 2006 Key Provisions (cont'd)

- Establishes Scientific Management Review Board (SMRB) to conduct periodic organizational reviews of NIH, and to make recommendations on the use of NIH organizational authorities
- Requires public process for reorganizing NIH programs
- Many reporting requirements are eliminated or subsumed in new biennial report

Slide 24

Implementation of the Legislation

- *Ad Hoc* Working Group chaired by Raynard S. Kington, M.D., Ph.D., NIH Deputy Director -- Group charged with completing a careful, detailed analysis of the legislation and propose plans for its implementation to aid NIH in serving the public and our scientific community more effectively
- Working Group membership included IC Directors and senior leaders in legislation, policy, management, communications, extramural and intramural activities, budget, general counsel
- Legislative Implementation Action Plans finalized June, 2007
- Many provisions in NIH Reform Act have been implemented

Slide 25

Oversight (2008 Investigations)

- Conflicts of Interest
 - Congress has identified extramural researchers who have failed to report, or underreported outside income
 - NIH is determining whether current policies and regulations need to be modified to increase oversight of extramural conflicts of interest
 - Congress expects that appropriate stewardship of grant funds includes effective oversight of extramural conflicts of interest.
- Biosafety
 - Congress is reviewing whether current policies and regulations regarding BSL3 and BSL4 laboratories are sufficient

Slide 26

Forecast

- FY 2009 Request: \$29.230
- Authorization:
 - Human Embryonic Stem Cell Research
 - SBIR
 - Health disparities
- Oversight: Extramural COI