



LEGISLATIVE UPDATE:

An overview of legislation from the 111th Congress and outlook for the 112th Congress

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OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

FY 2011

The FY 2011 Labor-HHS-Education appropriations bill passed the House L-HHS appropriations subcommittee on July 15, 2010, and then passed out of both the Senate L-HHS appropriations subcommittee as well as the full Senate appropriations committee on July 27, and July 29, 2010, respectively. However, since the spending bill made no further progress, it became one of the 12 spending bills which failed to pass in both the House and Senate. In order to keep the government running, Congress passed two Continuing Resolutions (the first through December 3, 2010 and the second through December 18, 2010) which kept the government funded at FY 2010 levels. In December, the 12 spending bills were grouped into H.R. 3082, the Full-Year Continuing Appropriations Act of 2011, a House bill to continue funding for all 12 appropriations bills through September 30, 2011. It was thought that the Senate would amend this bill, by deleting its contents and inserting the text of an Omnibus, the Consolidated Appropriations Act of 2011. The Omnibus included higher spending levels for a number of programs including L-HHS and also contained a large number of earmarks, a practice which many members of Congress had vowed to ban. However, the Senate Omnibus was pulled from the Senate floor by Senate Majority Leader Harry Reid due to GOP opposition to the bill. Instead, Congress quickly passed a third Continuing Resolution (CR) to extend government funding through December 21, 2010 while they debated a longer-term CR. On December 22, 2010, a fourth CR was signed by the President, providing for continued government operations through March 4, 2011.

Outlook: Republican Congressional leadership and appropriators have made reducing federal spending a priority for the start of the 112th Congress. A proposal to rollback funding to FY 2008 levels for non-security spending for the remainder of FY 2011 is moving forward in the House.

FY 2012

Given the delays in the FY 2011 budget process, the release of President Obama's FY 2012 budget has also been delayed and is now expected at the end of February.

Legislative highlights from the 111th Congress (calendar years 2009-2010) of interest to NINDS

Public Laws

Public Law 111-5: The American Recovery and Reinvestment Act of 2009

The American Recovery and Reinvestment Act of 2009 (Recovery Act) was signed into law by President Obama on February 17, 2009. The NIH was one beneficiary of funds from the Recovery Act, with \$10.4 billion allocated to the agency to stimulate biomedical research over the next two years. NIH worked quickly to develop funding opportunities and NINDS participated in a number of these programs. NIH staff worked tirelessly to get Recovery Act funds awarded by the deadlines required by the Recovery Act. Information on research funded by the Recovery Act can be found here: <http://recovery.nih.gov/>. The NIH RePORTER tool (<http://report.nih.gov/index.aspx>) also allows the public to search for Recovery Act and non-Recovery Act-funded projects within the NIH portfolio.

Public Law 111-11: The Omnibus Public Land Management Act of 2009 (includes text of the Christopher and Dana Reeve Paralysis Act)

In the 111th Congress, provisions of the Christopher and Dana Reeve Paralysis Act were included as part of the Omnibus Public Land Management Act of 2009, which became Public Law 111-11. The section of the law comprising the Christopher and Dana Reeve Paralysis Act authorizes the Director of the NIH to:

- Coordinate paralysis research and rehabilitation activities at the NIH.
- Establish consortia in paralysis research (to be named Christopher and Dana Reeve Paralysis Research Consortia) to conduct basic, translational, and clinical paralysis research, to facilitate and enhance the dissemination of clinical and scientific findings, and to replicate the findings of other researchers for scientific and translational purposes.
- Establish networks of clinical sites that will collaborate to design clinical rehabilitation intervention protocols and outcome measures on paralysis.

In addition, the Secretary of the Department of Health and Human Services, acting through CDC, is authorized to study the unique health challenges associated with paralysis and other physical disabilities and carry out projects and interventions to improve the quality of life and long-term health status of persons with paralysis and other physical disabilities.

Public Law 111-375: The National Alzheimer's Project Act

On January 4, 2011, the President signed into law P.L. 111-375, the National Alzheimer's Project Act, which was originally introduced into the Senate as S. 3036 by Senator Evan Bayh (D-IN) on February 24, 2010.

The legislation establishes a National Alzheimer's Project, located in the Office of the Secretary of Health and Human Services (HHS), which will be responsible for coordinating and overseeing Federal research on Alzheimer's disease. The bill also establishes an advisory council for the Project, which includes one representative designated by the NIH Director as well as representatives from other federal agencies, researchers, care providers, and advocates.

Two other Alzheimer's disease related bills were introduced in both the 110th and 111th Congresses. These bills focused on expanding Alzheimer's disease clinical research and research on Alzheimer's disease in Hispanic communities. No action occurred on either of these bills.

Public Law 111-148: The Patient Protection and Affordable Care Act

On March 22, 2010, President Obama signed H.R. 3590, the Patient Protection and Affordable Care Act into law. The legislation was previously passed by the House (by a vote of 219-212 on March 21, 2010) and by the Senate (by a vote of 60-39 on December 24, 2009). Provisions of particular interest to NINDS include:

- **Cures Acceleration Network:** The legislation establishes a Cures Acceleration Network (CAN) within the Office of the Director at NIH to provide funding to bridge the gap between laboratory discoveries and life-saving therapies in the form of medical products, drugs or devices, or biological products. The law also: establishes the Cures Acceleration Network Review Board to advise and provide recommendations to the Director of NIH on the activities of the CAN; establishes the Cures Acceleration Partnership Awards and the Cures Acceleration Grant Awards; and establishes the Cures Acceleration Flexible Research Awards to provide the Director of NIH flexible research authority to use other transactions to fund projects.
- **Pain Research:** The law includes provisions to encourage pain research at NIH and expand basic and clinical research on causes of and treatment for pain through the Pain Consortium. The Pain Consortium, in consultation with the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), is required to make recommendations on pain research initiatives that could be paid for by the Common Fund. The Secretary (through the IOM) is required to hold a conference to (1) increase the recognition of pain as a public health problem in the United States; (2) evaluate the adequacy of diagnosis, treatment, and management of pain in the general population and in specific groups that may be disproportionately affected by pain; (3) identify barriers to appropriate pain care; and (4) establish an agenda to reduce barriers and improve research, education, and clinical care of pain. The law also establishes an Interagency Pain Research Coordinating Committee to identify gaps in basic and clinical research, and make recommendations on ensuring that the activities of the NIH and other Federal agencies do not duplicate one another, disseminating information on pain care, and expanding public-private partnerships.
- **Comparative Effectiveness Research:** The law establishes a non-profit institute called the Patient-Centered Outcomes Research Institute (PCORI), a Board of Governors to oversee the institute, and a trust fund to pay for the research. PCORI is authorized to set research priorities and a research agenda. PCORI is authorized to conduct or support CER, develop

research methodologies, develop data resources, obtain and use data from the Federal government, and establish advisory panels to advise on research priorities, among other provisions. NIH is listed as a member of the Board of Governors and as a member of the Methodology Committee.

- Emergency Medicine Research: The law requires the Secretary to expand and accelerate research to improve emergency care systems and the treatment of acute conditions. It requires the participation of the NIH as well as AHRQ, the Health Resources and Services Administration (HRSA), CDC, and other agencies. The law also requires the Secretary to coordinate and expand research in pediatric emergency medicine and calls for an examination of the gaps and opportunities in pediatric emergency care research, such as the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings.
- National Center on Minority Health and Health Disparities (NCMHD) Designated as an Institute: The law designates NCMHD as an Institute; includes NCMHD Centers of Excellence as institutions eligible to receive endowments; and requires the NCMHD Director to plan, coordinate, review and evaluate research and other activities conducted or supported by the ICs.

Outlook: NIH has already made progress toward implementation of many of the provisions in P.L. 111-148. However, Republicans pledged during the 2010 campaign to repeal this measure at the start of the 112th Congress. On January 19, 2011, the House passed H.R. 2, the “Repealing the Job-Killing Health Care Law Act,” by a vote of 245-189. The bill was not expected to be taken up by the Senate but marks the first step in the Republican-led effort to dismantle the health care law.

Small Business Innovation Research (SBIR)

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant programs at the NIH and similar programs at other Federal agencies provide a funding source for U.S. small businesses. For over the past two years, Congress has been trying to reauthorize the SBIR/STTR program, which was set to expire on September 30, 2008. Since that date, Congress has not been able to agree on the provisions of legislation to reauthorize the programs, although different bills were passed independently in the House and the Senate during the 111th Congress. Some of the provisions in these bills include: increasing the size of small business awards; increasing the program set-asides for federal agencies, including NIH; and changes to the rules regarding the percentage of funds that may be awarded to companies that are majority owned and controlled by venture capital firms. The most recent legislative activity in this area occurred at the very end of the 111th Congress. A new version of the reauthorization bill was introduced in the Senate (S. 4053), brought to the Senate floor, and passed the Senate on December 22, 2010. This version of the bill would have reauthorized the SBIR/STTR programs, raised the set-aside from 2.5% to 3.5% over the next ten years, and increased the size of awards. The bill also included a provision that not more than 25% of funds allocated (by NIH, Department of Energy and NSF) for the SBIR program could go to small businesses that are owned in majority by venture capital firms. It was originally thought that the bill would be brought up on the House floor, but it was not.

Outlook: In the absence of a reauthorization, Congress has instead needed to pass a series of temporary extensions to keep the programs active since September 30, 2008. The current extension expires on January 31, 2011. It is expected that a new reauthorization bill will be introduced soon in the 112th Congress.

Disease-Focused Bills

A number of disease-focused bills were introduced in the 111th Congress, but failed to pass both the House and Senate. Of particular interest to NINDS were bills related to autism, brain tumor, Down syndrome, and spinal muscular atrophy. More broadly, bills on mitochondrial disease, neurological disease registries, and neurotechnology were all introduced and/or passed by one chamber during the 111th Congress, but did not progress further or become law.