NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

LEGISLATIVE UPDATE:

An overview of enacted legislation from the 110th Congress and pending legislation from the 111th Congress

February 2009

OFFICE OF SCIENCE POLICY & PLANNING

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PUBLIC LAWS

Public Law 110-85: Food and Drug Administration Amendments Act of 2007

Summary: This law is focused primarily on the reauthorization of certain FDA authorities, and contains provisions regarding user fees and drug safety monitoring procedures. S. 1082 was initially introduced in the Senate on April 10, 2007, by Senator Edward Kennedy (D-MA) and passed the Senate on May 9, 2007 by a vote of 93-1. H.R. 2900 was introduced in the House on June 28, 2007, by Representative John Dingell (D-MI) and passed the House on July 11, 2007 by a vote of 403-16. On September 19, 2007, Representative John Dingell (D-MI) introduced H.R. 3580, which represented the conference agreement for S. 1082/H.R. 2900. H.R. 3580 was then passed by the House on September 19, 2007, by a vote of 405-7, and by the Senate by unanimous consent on September 20, 2007. The President signed H.R. 3580 into law on September 27, 2007, as Public Law 110-85, the Food and Drug Administration Amendments Act of 2007. Listed are the major provisions that affect NIH included in PL 110-85.

- Title III: Pediatric Medical Devices
    - Requires that NIH identify a point of contact to help researchers and physicians identify funding sources
    - The Secretary of the Department of Health and Human Services is required to create a research plan to expand research on pediatric medical devices
- Title IV: Pediatric Research Equity Act
    - Requires manufacturers seeking new drug approvals or new indications for pediatric use to complete studies in children
- Title V: Best Pharmaceuticals for Children Act
    - Reauthorizes the original 2002 law
    - Provides economic incentives for manufacturers to conduct pediatric studies on drugs currently on the market as requested by the FDA
    - NIH is to identify the areas that require further study, and to conduct pediatric studies in cases where drugs are no longer on patent, or where a manufacturer has declined to conduct a requested study
    - NIH is required to develop a list of pediatric needs (rather than a list of drugs), allowing NIH to articulate an entire area of medicine that requires further study.
    - NIH is required to study the feasibility of compiling information on pediatric drug use
- Title VIII: Clinical Trials Databases
    - Expands the clinicaltrials.gov registry to include all stage II-IV clinical trials, and requires the registration of all applicable ongoing drug and device trials by December 26, 2007 (90 days after enactment)
    - Expands the registry to include results of clinical trials
        - Within 90 days, NIH is responsible for linking to the FDA information for late Phase II and III trials
        - Within 1 year, the database should include demographic information and primary and secondary outcomes

- Within 3 years, the database should include approved products. In most cases, results information must be submitted 1 year after trial completion
- Grants supporting trials funded in whole or in part by the Department shall include certification of compliance of the described provisions prior to the release of additional funds
- Failure to comply can result in civil monetary penalties

Public Law 110-161: Consolidated Appropriations Act, 2008

Summary: After a difficult path through Congress, a Consolidated Appropriations bill was signed by the President on December 26, 2007, becoming Public Law 110-161. This bill included eleven of the twelve appropriations bills, including Labor-Health and Human Services (L-HHS), and appropriates $473.5 billion for the operation of nearly every government agency, save for those funded by the previously approved Defense Appropriations Act.

On July 19, 2007, the House passed the Fiscal Year (FY) 2008 Labor, Health and Human Services, and Education (L-HHS) appropriations bill H.R. 3043. This measure included $29.650 billion for NIH, or $750 million above the FY07 level. The Senate bill, S. 1710, which was reported from the Senate Committee on Appropriations, included $29.9 billion for the NIH, $1 billion over the FY07 level. On October 17, 2007, the Senate began debate on H.R. 3043/S. 1710, which included language introduced by Senators Tom Harkin (D-IA) and Arlen Specter (R-PA), allowing researchers to use Federal money for research using human embryonic stem cell lines created before June 15, 2007, essentially overturning the President's Executive Order which limited Federal research funding to human embryonic stem cell lines created before August 9, 2001. Senator Harkin later introduced an amendment to strip the bill of this language, leading to its passage by the Senate on October 25, 2007 by a vote of 75-19, clearing it for conference with the House. On November 5, 2007, the House approved a conference measure by a vote of 269-142, which included $30 billion for NIH in FY08. The Senate approved the measure on November 7, by a vote of 56-37. The final conference measure for H.R. 3043 was approved by the House the following day by a vote of 274-141. H.R. 3043 was vetoed by the President on November 13, 2007. The House failed in its subsequent attempt to override the President's veto on November 14, 2007. The vote of 277-141 was two votes shy of the two-thirds majority required to override a Presidential veto.

On December 17, 2007, the House passed the Consolidated Appropriations Act of 2008 (H.R. 2764, the State, Foreign Operations, and Related Programs Appropriations Act of 2008) by a vote of 253-154. This $485 billion bill included the 11 remaining spending bills, and emergency funding for veterans programs and other priorities. In a separate vote, $31 billion in Afghanistan war funding was approved by the House. Further complicating the appropriations process, the Senate passed the bill the following day by a vote of 76-17, with an amendment to delete the $31 billion in Afghanistan funding and replace it with $70 billion in unrestricted funds for the wars in Iraq and Afghanistan. The House gave final approval of the measure including the additional war funds on December 19, 2007 by a vote of 272-142.

H.R. 2764 provides $29.3 billion for NIH, an increase of $328 million above the FY07 level and an increase of $606 million above the FY08 President's budget. However, this is $772 million below the vetoed FY08 conference measure. The bill includes a $295 million transfer within the NIH to the Global AIDS Fund, and $111 million for the National Children's Study. This bill also includes language requiring that researchers funded by NIH submit final peer-reviewed and accepted for publication manuscripts to NIH's digital archive PubMed Central within 12 months of the official publication date. H.R. 2764 provides $1.54 billion for NINDS in FY08, a $10 million increase over the funded FY07 level. H.R. 2764 was signed into law by the President on December 26, becoming Public Law 110-161, the Consolidated Appropriations Act of 2008.

Public Law 110-170: Chimp Haven is Home Act

Background: S. 1916, the Chimp Haven is Home Act was introduced by Representative Richard Burr (R-NC) on August 1, 2007. This bill passed by unanimous consent in the Senate December 13, 2007, and in the House on December 19, 2007. On December 26, 2007, the President signed the bill into law, as Public Law 110-170, Chimp Haven is Home Act.

Provisions of the Legislation/Impact on NIH: As required by the Public Health Service (PHS) Act, the Secretary of the Department of Health and Human Services operates a sanctuary system for the lifetime care of chimpanzees that have been used, bred, or needed for research. In the sanctuary system, chimpanzees can be used for research, but only in noninvasive behavioral and medical studies that are conducted during the normal course of veterinary care. Prior to enactment of the Chimp Haven is Home Act, chimpanzees could be removed from the sanctuary for studies if specific criteria were met, however the current law terminates this authority. This law does not have any direct provisions for NIH.

Public Law 110-206: The Traumatic Brain Injury (TBI) Act of 2008

On April 28, the President signed into law S. 793, the Traumatic Brain Injury Act of 2008, as Public Law 110-206. The legislation, introduced originally by Senator Orrin Hatch (R-UT), reauthorizes the Traumatic Brain Injury Act, authorizes funding for research, treatment, surveillance, and education activities related to trauma at HRSA and CDC, and NIH's trauma research program, and provides authorizations for FY09-FY12. For NIH, it requires the Secretary, HHS, acting through CDC and NIH, to report on activities and procedures that can be implemented by the CDC, Department of Defense, and Department of Veterans Affairs to improve the collection and dissemination of compatible epidemiological studies on the incidence and prevalence of traumatic brain injury in the military and veterans populations who return to civilian life.

In addition, the Act revises the national program for traumatic brain injury registries and authorizes CDC in consultation with NIH to conduct a study to:

- Determine the incidence of traumatic brain injury and prevalence of traumatic brain injury related disability
- Report national trends in traumatic brain injury
- Identify common therapeutic interventions which are used for the rehabilitation of individuals with such injuries
- Identify interventions and therapies that can prevent or remediate the development of secondary neurologic conditions related to traumatic brain injury
- Develop practice guidelines for such rehabilitation.

The 110th Congress has addressed treatment and support of veterans who have suffered TBI in a number of other bills:

- Public Law 110-23: Trauma Care Systems Planning and Development Act of 2007
- S. 1349: The Military and Veterans Traumatic Brain Injury Treatment Act
- H.R. 2199: The Traumatic Brain Injury Health Enhancement and Long-Term Support Act of 2007
- H.R. 2179: To amend title 38, US Code, to direct the Secretary of Veterans Affairs to establish traumatic brain injury centers.
- S. 1233: The Veterans Traumatic Brain Injury Act of 2007

Public Law 110-233: The Genetic Information Nondiscrimination Act of 2008

The Genetic Information Nondiscrimination Act (GINA; PL 110-233) was signed into law by the President on May 21, 2008, after being debated since the 103rd Congress. Although other measures have been enacted that protect patients from genetic discrimination (including the Health Insurance Portability and Accountability Act of 1996, which bars the use of genetic information in denying or limiting health insurance coverage for members of a group plan, and Executive Order 13145, issued by President Clinton, which prohibits discrimination based on predictive genetic information in Federal employment) GINA more comprehensively prohibits discrimination by health insurers and employers (or potential employers) on the basis of predictive genetic information.

This law prohibits health insurers in both the group and individual markets from:

- Using genetic information for decisions regarding coverage, rates, or preexisting conditions, including participation in research that includes genetic services
- Requesting genetic testing or test results, except as necessary for treatment, payment, or health care operations, and requesting or requiring the use of genetic information for the purposes of underwriting

This law also prohibit employers from requesting or requiring genetic information or using it for decisions regarding hiring, firing, or any terms of employment.

The law defines a genetic test as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The law specifically excludes any analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes or any analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

H.R. 493 was introduced by Representative Slaughter on January 16, 2007, and was referred to the House Committees on Energy and Commerce, on Education and Labor, and on Ways and Means. On January 30, the House Education and Labor Subcommittee on Health, Employment, Labor, and Pensions held a hearing on H.R. 493. The full Committee reported the bill out favorably on February 14. On March 8, the House Energy and Commerce Subcommittee on Health held a hearing on H.R. 493. The full Committee reported the bill out favorably, as amended by the Committee, on March 29. On March 14, the House Ways and Means Subcommittee on Health held a hearing on H.R. 493. The full Committee reported the bill out favorably on March 23. H.R. 493 was passed by the House under suspension of the rules by a vote of 420 to 3. On April 24, the Senate passed an amended version of H.R. 493 by a vote of 95 to 0. On May 1, H.R. 493, as amended by the Senate, was passed by the House by a vote of 414 to 1. This bill was signed by President Bush on May 21, 2008 as PL 110-233, becoming the Genetic Information Nondiscrimination Act of 2008.

Public Law 110-252: The Supplemental Appropriations Act of 2008

On June 30, 2008, the President signed into law H.R. 2642, the Supplemental Appropriations Act of 2008. H.R. 2642 was initially introduced on June 17, 2007 as the Military Construction and Veterans Affairs Appropriations Act of 2008, but on May 15, 2008, this bill served as the vehicle for FY08 supplemental appropriations for the wars in Iraq and Afghanistan, Veterans benefits and other domestic priorities. The House package divided the bill into three amendments, the first containing military funding (failed by a vote of 141-149 on May 15, 2008), the second containing policy provisions related to the wars (including a timeline for troop withdrawal), and the third containing foreign aid and domestic spending. The second and third amendments were adopted by the House by votes of 227-196 and 256-166 respectively on May 15, 2008. On May 22, 2008, the Senate passed its version of H.R. 2642 which contained both funding for the war (which the House had previously failed to pass), as well as more than $10 billion in domestic spending, including $400 million for NIH. On June 19, 2008, the House passed a revised version of H.R. 2642 which included war funding and domestic appropriations, with $150 million for NIH. The Senate cleared this version of the bill one week later, and on June 30, 2008, it was signed into law by the President and became Public Law 110-252. NINDS received $8.2 million dollars as a result of the enactment of this legislation.

Public Law 110-361: The Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education (MD-CARE) Amendments of 2008

On October 8, 2008, the President signed into law H.R. 5265, The Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008, as P.L. 110-361. This legislation, introduced by Representative Eliot Engel (D-NY) on February 7, 2008 (the Senate companion bill, S. 2618, was introduced by Senator Amy Klobuchar (D-MN)), expands on the provisions of the MD-CARE Act first signed into law in 2001. P.L. 110-361 names in statute the Muscular Dystrophy Centers of Excellence as the Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers. Other provisions affecting NIH include:

- Naming the NHLBI as a member to the Muscular Dystrophy Coordinating Committee (MDCC)
- Authorizing the MDCC to give special consideration to enhancing the clinical research infrastructure for testing emerging therapies for the various forms of muscular dystrophy

P.L. 110-361 also expands the epidemiological research and educational activities on MD at the Centers for Disease Control and Prevention (CDC) by:

- Requiring the Secretary of HHS to ensure that any patient data that is collected as a part of Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet) be regularly updated to reflect changes in patient condition over time
- Requiring the Director of the CDC to submit an annual report concerning the activities of MD STARnet and containing the data collected and findings derived from the MD STARnet sites
- Requiring the Director of the CDC to provide outcomes data on the health and survival of people with MD
- Requiring the Director of the CDC to partner with leaders in the MD patient community and widely disseminate the Duchenne-Becker MD care considerations

Public Law 110-373: The ALS Registry Act

On October 8, 2008, the President signed into law P.L. 110-373, the ALS Registry Act. The ALS Registry Act was introduced in the House as H.R. 2295 by Representative Eliot Engel (D-NY) and in the Senate as S. 1382 by Senator Harry Reid (D-NV). By a vote of 411-3, H.R.2295 passed overwhelmingly in the House, but was one of more than 100 bills (many with overwhelming bipartisan support from the House) blocked from action in the Senate by Senator Tom Coburn (R-OK). On July 22, 2008, Senator Reid, in an attempt to circumvent the actions of Senator Coburn, introduced the Advancing America's Priorities Act (S.3297), which rolled up many of the bills blocked by Senator Coburn into one bill. Included among the many provisions of S.3297, were those found in the ALS Registry Act. Despite a level of bipartisan support for most of the provisions of S.3297, the Senate failed to invoke cloture to limit the bill's debate and ultimately S.3297 was stalled in the Senate. In a compromise move, Senator Reid introduced a substitute amendment to the original version of the ALS Registry Act (S.1382) which, to Senator Coburn's satisfaction, loosened the requirements of the bill. The newly amended version of S.1382 was passed on September 23, 2008 in the Senate, and on September 26, 2008 in the House.

This law amends the Public Health Service Act by authorizing the Director of the CDC to develop a system to collect data on ALS including data on the incidence and prevalence of the disease in the United States. In addition, this legislation authorizes the Director of the CDC to establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS. To make recommendations concerning the development and maintenance of the National ALS Registry, including the type of information to be collected and stored in the Registry, and the manner in which such data will be collected, the Director of the CDC is authorized to establish an Advisory Committee on the National ALS Registry. Members of the Advisory Committee will include representatives from the NIH, Department of Veterans Affairs, Agency for Toxic Substances and Disease Registry and the CDC. In addition, the Advisory Committee will include public members representing national and voluntary health associations, patients with ALS or their family members, clinicians with ALS-related expertise, epidemiologists with experience in data registries, and geneticists with experience in the genetics of ALS.

APPROPRIATIONS UPDATE

FY09:

On February 4, 2008, President Bush released his proposed budget for FY09. With a flat domestic budget, the FY09 budget proposal continued several years of flat funding for biomedical research at the NIH ($29.5 billion). After peaking in 2004, the NIH budget has declined every year in real terms, and the FY09 request positioned NIH funding 8 percent below FY04 after adjusting for economy-wide inflation and 13 percent below FY04 after adjusting for the Biomedical Research and Development Price Index (BRDPI).

On June 19, 2008, the House Appropriations Subcommittee on Labor, HHS, and Education marked up a draft bill for FY09, including funding for NIH. This bill included a $1.15 billion increase over the President's request for NIH programs ($1.598 billion for NINDS).

On June 24, 2008, the Senate Appropriations Subcommittee on Labor, HHS, and Education marked up its FY09 draft spending bill. This bill included a $1.025 billion increase over the President's request for NIH, for a total of $30.254 billion for the Agency. For NINDS, the bill included $1.588 billion, an increase of $36.3 million (2.3%) over FY08 enacted (including the FY08 supplemental). The draft bill was reported out of the Senate Appropriations Committee the same day. On July 6, 2008, the bill was formally introduced by Senator Tom Harkin (D-IA) and given a number (S. 3230).

Because Congress was unable to pass all 12 of the required appropriations bills prior to start of the new fiscal year (October 1, 2008), on September 30, 2008, the President signed into law P.L. 110-329, The Consolidated Security, Disaster Assistance and Continuing Appropriations Act, which provided a fiscal stopgap to fund most of the government through March 6, 2009. Funding the government through a Continuing Resolution (CR) became necessary as President Bush threatened to veto any appropriations bills that exceeded his requested budget. This CR provides funding to NIH at the same rate and under the same terms and conditions as P.L. 110-161, the Consolidated Appropriations Act of 2008, which does not include the supplemental funding ($150 million) provided in P.L. 110-252.

On January 21, in an effort to draft legislation to stimulate the struggling economy, the House Appropriations Committee reported out the portion of the economic stimulus package under its jurisdiction by a 35-22 vote. This bill, known as the American Recovery and Reinvestment Bill, includes the following for NIH: $1.5 billion over two years for research; $500 million to fund high priority repair and improvement projects for NIH facilities on the Bethesda, Maryland campus and other agency locations; $1.5 billion (through NCRR) for extramural facility renovation and repair; and $400 million for comparative effectiveness research. The full $825 billion tax and spending package is currently (as of January 23, 2008) being debated in the House. The Senate is currently in the process of developing their draft bill.

As the 111th Congress convened in January 2009, only three FY09 appropriations bills had been completed (Defense, Homeland Security, and Military Construction/Veterans Affairs). As the Continuing Resolution currently funding the government expires on March 6, 2009, Congress

must take up FY09 appropriations once again, but it is currently unclear what strategy they will use to complete the funding for this fiscal year.

FY10:

The Congressional Budget Act of 1974 requires that the President submit to Congress, on or before the first Monday in February of each year, a budget request for the coming fiscal year beginning October 1st. This timeline is typically protracted in transition years, as new administrations take a few months to develop their first budget request. Peter Orszag, head of the White House Office of Management and Budget, has stated that President Obama will likely submit an overview of his budget plans in mid to late February, but that it is unlikely that a full budget request will be sent to Congress before April.

PENDING LEGISLATION

Small Business Innovation Research (SBIR)

Background: The Small Business Innovation Research (SBIR) grant program at the NIH and similar programs at other Federal agencies provide an important funding source for U.S. small businesses that help transform scientific knowledge into tangible benefits for public health. However, because of the time and expense involved in taking a new product from idea to the market, small businesses may also need additional funding sources, including venture capital. Small biotechnology companies can leverage their NIH SBIR awards with venture capital funding in order to support breakthrough technologies in fields such as gene therapy, proteomics, and pharmaceutical development.

In the 110th Congress, a number of bills were introduced to change the provisions of the SBIR program at NIH and throughout the Federal Government. In addition, both the House and the Senate introduced bills to reauthorize the SBIR program, which was set to expire on September 30, 2008. One issue that is particularly contentious in Congress, is the amount of money that is set aside from an agency's budget to support their SBIR efforts. On August 1, 2007, Senator Evan Bayh (D-IN) introduced S.1392 which would increase the SBIR funding set aside from the current levels of 2.5 percent to 5.0 percent by 2013 (STTR set aside levels would increase from 0.3 percent to 0.6 percent by 2013). On September 8, 2008, Senator Russ Feingold (D-WI) introduced S.3451 which would have gradually increased the SBIR set aside to 10.0 percent by 2011 and the STTR set aside to 1.0 percent by 2011. Although neither of the bills advanced, the issue of increasing agency set-asides was hotly debated in the Senate. Resulting from these debates was S. 3362, a bill to reauthorize the SBIR/STTR programs for 14 years, until 2022 and 2023 respectively. While this legislation required increased agency set-asides (3.5% for SBIR and 0.6% for STTR over a 10 year period), the Department of Health and Human Services (including NIH) was exempt from these provisions (SBIR only). The companion House bill only sought to reauthorize the SBIR program until 2010, and kept the set-aside at the current level of 2.5% (SBIR) and 0.3% (STTR). Ultimately, time to act on these reauthorization bills ran out, and rather than allowing this program to sunset, Congress quickly passed S.3029, which temporarily extended the SBIR program's authorization through March 20, 2009.

S.177 – *Strengthening Our Economy Through Small Business Innovation Act of 2009*

Provisions of the Legislation/Impact on NIH: S. 177 extends the SBIR program to 2022 and the STTR program to 2023. In addition, this measure would increase the SBIR set aside allocations to 2.5% in FY09, 5.0% in FY10, 7.5% in 2011, and 10.0% in FY12. The STTR set aside allocations would be increased to 0.3% in FY09, 0.6% in FY10, 0.8% in FY11, and 1.0% in FY12. S.177 also proposes to increase the SBIR and STTR award levels for Phase 1 and Phase 2 grants to $300,000 and $2,200,000 respectively from their current levels of $100,000 and $750,000. Finally, special consideration will be given to energy, security, transportation and water as SBIR research topics.

Status: S.177 was introduced on January 8, 2009 by Senator Russ Feingold (D-WI) and was referred to the Senate Committee on Small Business and Entrepreneurship. No further action has occurred on this bill.

Spinal Cord Injury/Paralysis

Background: Spinal Cord Injury research has been an issue of Congressional interest since the introduction of the Christopher Reeve Paralysis Act in the 108th Congress. This legislation sought to expand and coordinate paralysis research at the NIH through the formation of research consortia, and to expand and coordinate research on rehabilitative care for patients with paralysis through clinical trials networks. Though this bill did not reach a vote in either body of Congress, the issue stayed alive with the passage of P.L. 108-427, the Research Review Act of 2004. This law required the NIH to report on how the Roadmap had advanced multidisciplinary teams and consortia with respect to spinal cord injury and paralysis research. In the 109th Congress, the Christopher Reeve Paralysis Act (H.R. 1554 / S. 828) passed the House on December 9, 2006, but did not reach the Senate floor prior to the end of the Congressional session.

In the 110th Congress, H.R.1727 was introduced by Representative Tammy Baldwin (D-WI) on March 28, 2007, passed the House by a voice vote on October 15, 2007, and was referred to the Senate Committee on Health, Education, Labor and Pensions. The companion to H.R. 1727 (S. 1183) was introduced by Senator Tom Harkin (D-IA) on April 23, 2007, and on July 25, 2007, the bill was favorably reported out of committee by the Senate Committee on Health, Education, Labor and Pensions. S.1183 was unable to move forward in the Senate, as it was one of over 100 bills subject to a procedural hold by Senator Tom Coburn (R-OK). In response to Coburn's actions, Senate Majority Leader Harry Reid (D-NV) assembled the Advancing America's Priorities Act (S.3297), which was an amalgamation of many of the bills previously blocked by Senator Coburn, including The Christopher and Dana Reeve Paralysis Act. Although scheduled for floor debate several times in December 2008, the Senate was unable to pass what became known as the "Coburn Omnibus" prior to the end of the Congressional session.

H.R. 307 – *The Christopher and Dana Reeve Paralysis Act*

S. 22 – The Omnibus Public Land Management Act of 2009

Provisions of the Legislation/Impact on NIH: H.R. 307 and the relevant provision of S.22 authorizes the Director of the NIH to:

- Coordinate paralysis research and rehabilitation activities at the NIH
- Establish consortia in paralysis research (Christopher and Dana Reeve Paralysis Research Consortium) 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, these bills authorize the Secretary of the Department of Health and Human Services to:

- Develop a national paralysis and physical disability quality of life action plan, to promote health and wellness to be carried out in coordination with the State-based Disability and Health Program of the CDC

- Support programs to disseminate information involving care and rehabilitation options and quality of life grant programs for persons with paralysis and other physical disabilities
- Establish a population-based database that may be used for longitudinal research on paralysis
- Replicate and translate best practices and share information across States on: caregiver education, proper nutrition, increasing physical activity, reducing tobacco use, education and awareness programs for health care providers, prevention of secondary complications, home and community based interventions, and recognizing the unique needs of underserved populations.

Status: In the 111th Congress, the provisions of the Christopher and Dana Reeve Paralysis Act were added to S.22, the Omnibus Public Land Management Act of 2009. S. 22 was introduced by Senator Jeff Bingaman (D-NM) on January 7, 2009, and on January 15, 2009, by a vote of 73-21, was passed in the Senate. S.22 has been sent to the House for their consideration. On January 8, 2009, Representative Tammy Baldwin (D-WI) introduced H.R. 307, which was referred to the House Committee on Energy and Commerce. No further action has occurred on this bill.

Stem Cell Research

Background: On August 9, 2001, President Bush announced that Federal funds may be used for research on human embryonic stem cell lines only if--

(A) prior to the President's announcement—
(i) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated; and
(ii) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
(B) the stem cells involved were derived from an embryo that was created for reproductive purposes;
(C) the embryo was no longer needed for such purposes;
(D) informed consent was obtained for the donation of the embryo; and
(E) no financial inducements were provided for donation of the embryo.

This policy has caused many members of Congress and advocacy groups to express their concern that the progress of research leading towards treatments for many diseases is being hindered. In addition, many scientists are concerned that the number of cell lines covered under the Bush policy is far less than originally thought, further hampering their research. By current counts, 21 lines are available for federal research dollars. Several recent scientific advances (e.g., reprogramming of human skin cells to pluripotency, generation of human embryonic stem cell lines without embryo destruction) have reignited the stem cell debate, and caused many who are opposed to embryonic stem cell research to question whether it is necessary at all. President Obama has publically expressed his support for "increased stem cell research, and allowing greater government funding on a wider array of stem cell lines" (http://www.whitehouse.gov/agenda/technology/). This issue will likely come to light again, as the NY Times and the Washington Post reported on January 23, 2009, that the FDA has approved a clinical study testing human embryonic stem cells in patients with severe spinal cord injury.

In the 110th Congress, several bills were introduced in both the House and the Senate with action on a few. Most significantly, H.R. 3, which was introduced by Representative Diana DeGette (D-CO), would have required the Secretary of the Department of Health and Human Services to support research using human embryonic stem cells regardless of the date on which the cells were derived. This bill passed the House by a vote of 253-174. The Senate companion bill, S.5 (introduced by Senator Harry Reid (D-NV)), contained similar provisions, and easily passed the Senate by a vote of 63-37. Following the passage of S.5 by the House, it was sent to President Bush for his signature, where instead it was vetoed. Concurrent with his veto, President Bush issued an Executive Order on June 19, 2007, which required the Secretary of HHS to enhance funding for research on alternative methods to derive pluripotent stem cells that do not involve human embryos.

S. 99 – *The Ethical Stem Cell Research Tax Credit Act of 2009*

Provisions of the Legislation/Impact on NIH: This bill is identical to S. 2863 introduced in the 110th Congress, and would amend the Internal Revenue Code of 1986 to provide a tax credit in an amount equal to 30 percent of the qualified stem cell research expenses paid or incurred during a tax year. Qualified stem cell research expenses are incurred in carrying out basic and applied research to develop techniques for the isolation, derivation, production, testing, and human clinical use of stem cells. However, no part of this research may involve the creation of a

human embryo for research purposes, or the destruction of or risk of injury to a human embryo. This bill has no direct provisions for NIH.

Status: S. 99 was introduced by Senator David Vitter (R-LA) on January 6, 2009, and was referred to the Senate Committee on Finance. No further action has occurred on this bill.

H.R. 110 – *The Human Cloning Prohibition Act of 2009*

Provisions of the Legislation/Impact on NIH: This bill is identical to H.R. 2564 introduced in the 110th Congress, would amend Title 18 of the United States Code (related to Crimes and Criminal Procedure) to prohibit any person or entity from performing or attempting to perform human cloning, participating in an attempt to perform human cloning, or from shipping or receiving the product of human cloning. Any person or entity convicted of violating any of these prohibitions shall be fined (not less than $1,000,000), imprisoned not more than 10 years, or both.

Status: H.R. 110 was introduced by Rep. Jeff Fortenberry (R-NE) on January 6, 2009, and was referred to the House Committee on the Judiciary. No further action has occurred on this bill.