

**Legislative Update**  
**For the**  
**National Cancer Advisory Board**  
**September 2009**

**Activities of the 111<sup>th</sup> Congress**

Office of Government and Congressional Relations  
National Cancer Institute  
Building 31-10A48  
[ncilegislative@mail.nih.gov](mailto:ncilegislative@mail.nih.gov)  
301-496-5217

Visit the Office of Government and Congressional Affairs website at  
<http://legislative.cancer.gov>

## ***Table of Contents***

I. Congressional Hearings .....	1
II. Public Laws .....	2
III. Pending Legislation	
A. Federal Funding Mechanisms.....	6
B. Federal Health Care Policy.....	8
C. Health Equity and Health Information .....	17
D. Health Promotion and Awareness .....	19
E. Science Research and Technology .....	23
F. Screening, Prevention and Treatment.....	32
G. Tobacco .....	45
IV. Glossary of Terms .....	48

## ***I. Congressional Hearings***

**Field Hearing on Cancer Research**- On 7/6/09, the Senate Appropriations, Subcommittee on Labor, HHS and Education held a field hearing in Philadelphia, PA. Dr. Lawrence Tabak, Acting Deputy Director of NIH, testified on NIH Support of Innovative Research Projects. Cancer research was highlighted in Dr. Tabak's testimony.

<http://olpa.od.nih.gov/hearings/111/session1/Testimonies/CancerResearch.asp>

## **II. Public Laws**

### **This section provides information for the following bills:**

- American Recovery and Reinvestment Act of 2009 (H.R.1)
- Children's Health Insurance Program Reauthorization Act of 2009 (H.R.2/S.275)
- Continuing Appropriations Resolution, FY 2009 (H.J.RES.38)
- Continuing Appropriations Resolution, FY 2009 (H.R.2638)
- Family Smoking Prevention and Tobacco Control Act (H.R.1256/S.982)
- Nevada Cancer Institute Expansion Act (H.R.234/S.22/H.R.146)
- Omnibus Appropriations Act, 2009 (H.R.1105)
- Temporarily extends certain authorities of the Small Business Administration (H.R.1541)

### **American Recovery and Reinvestment Act of 2009 (H.R.1):**

- This bill provides \$10 billion in additional funding for the NIH:
  - \$8.2 billion to NIH Office of the Director;
    - \$8 billion for grants for projects that can be completed within two years, of which \$7.4 billion is to be transferred to the ICs and the Common Fund in proportion to the FY 2009 Appropriations base (because of the CR, currently this refers to the FY 2008 base levels).
- Introduced in the House by Appropriations Chairman David R. Obey (D-WI) on 1/16/09. The bill passed the House and Senate on 2/13/09.
- Became Public Law No: 111-5 on 2/17/2009.

### **Children's Health Insurance Program Reauthorization Act of 2009 (H.R.2/S.275):**

- To offset the cost of the expansion, it would increase the tax on cigarettes by 62 cents to \$1.01 per pack and raise taxes on other tobacco products.
- Rep. Frank Pallone (D-NJ) introduced H.R.2 on 1/13/09 and has 43 cosponsors; Sen. Max Baucus (D-MT) introduced Senate companion bill S.275 on 1/16/09 and has no reported cosponsors.
- H.R. 2 passed the House on 1/14/09 and then passed the Senate on 1/29/09.
- Became Public Law No: 111-3 on 2/4/2009.

### **Continuing Appropriations Resolution, FY 2009 (H.J.RES.38):**

- Making further appropriations for fiscal year 2009 until March 11, 2009.
- This bill was introduced to give the Senate more time to gather the votes needed to pass the regular appropriations bill.
- Introduced by Rep. David Obey (D-WI) on 3/6/09.
- Became Public Law No. 111-6 on 3/6/09.

## **Continuing Appropriations Resolution, FY 2009 (H.R.2638):**

- This bill provided continuing appropriations for all agencies and activities for fiscal year 2009 appropriations bills until 3/6/09.
- Introduced by Representative David E. Price (D-NC) on 6/8/07.
- Became Public Law No. 110-329 on 9/30/08.

## **Family Smoking Prevention and Tobacco Control Act (H.R.1256/S.982):**

- Establishes FDA authority over tobacco manufacturers and their products and prohibit the FDA from regulating tobacco leaf. Clarifies that provisions do not apply to the producers of tobacco leaf, such as growers.
- Requires that proprietary and brand specific information be submitted to HHS regarding ingredients, nicotine delivery and all documents related to the toxicology, behavioral or physiological effects of their products and the smoke constituents the FDA identifies as harmful.
- Requires HHS to establish a Tobacco Products Scientific Advisory Committee.
- Provides for the testing of tobacco products, where appropriate for the protection of the public health.
- Requires HHS to establish tobacco product standards to protect the public health and set forth standards for the sale of modified risk tobacco products. Prohibits or limits the allowable levels of substances in a finished product.
- Prohibits cigarettes from containing any artificial or natural flavor (other than tobacco or menthol.)
- Bans the introduction of modified risk tobacco products labeled as light, low tar and mild, etc.
- Requires 90 day pre-market approval for any new tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007 to pre-market review.
- Establishes a user fee assessment and collection system to provide the FDA the necessary funding to implement the new tobacco regulations.
- Reinstates the FDA's 1996 Youth Access and Advertising Rules, which restricted tobacco marketing and sales to youth.

### *Additional Background*

- The House version of the bill requires smaller warnings on cigarette packs than the Senate version. The House version states that each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The Senate version calls for each label statement to comprise at least 50 percent.
- The Senate version directs the Secretary of HHS to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany label requirements. The House measure states that the Secretary may adjust the format, text type, and text of any of the labeling requirements, but does not call for the issuance of regulations.
- The House version includes a section at the end of the bill titled "Federal Retirement Reform Act of 2009," which includes several retirement-related provisions concerning Federal employees.

### *Status Update*

- H.R.1256 was introduced by Rep. Henry Waxman (D-CA) on 3/3/09 for himself and has 178 total cosponsors. The bill was referred to the committees on Energy & Commerce and Oversight & Government Reform. The bill passed the House on 4/2/09 by a recorded vote of (298-112) and was referred to the Senate.
- S.982 was introduced by Sen. Edward Kennedy (D-MA) on 5/5/09 and has 52 cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions and passed favorably out of committee with amendments on 5/20/09. The bill passed the Senate with an amendment on 6/11/09.
- Became Public Law No: 111-31 on 6/21/09.

### **Nevada Cancer Institute Expansion Act (H.R.234/S.22/H.R.146):**

- This bill provides for the conveyance of the Alta-Hualapai Site to the Nevada Cancer Institute, and for other purposes.
- Rep. Shelley Berkley (NV-1) introduced H.R.234 on 1/7/2009 and has no cosponsors. The bill was referred to the House Committee on Natural Resources.
- Identical provisions were included in the Omnibus Public Land Management Act of 2009 (S.22), which was introduced by Sen. Jeff Bingaman (D-NM) on 1/7/09.
- The Senate passed S.22 on 1/15/09. But the bill failed passage in the House on 3/11/09 by a (282-144) vote which needed a 2/3 majority to pass.
- The House Omnibus Public Land Management Act of 2009 (H.R.146) passed the House on 3/3/09 and passed the Senate on 3/19/09. The bill was agreed to and resolved in both chambers on 3/25/09.
- Became Public Law: 111-11 on 3/30/09.

### **Omnibus Appropriations Act, 2009 (H.R.1105):**

- This bill provides \$4.97 billion to NCI; of which up to \$8 million may be used for facilities repairs and improvements at the NCI-Frederick FFRDC in Frederick, Maryland.
- The NCI is directed to name a Fellowship in Surgical Pathology the "Alan S. Rabson Award" to provide lasting recognition to the work of Dr. Rabson, Deputy Director of NCI.
- The bill includes \$30.3 billion for the total NIH appropriation, which is \$937.5 million above the fiscal year 2008 level and \$1.1 billion above the budget request.
- The bill was introduced by Rep. David Obey (D-WI) on 2/23/09.
- The bill was passed in the House on 2/25/09 and in the Senate on 3/10/09.
- Became Public Law 111-8 on 3/11/09.

### **Temporarily extends certain authorities of the Small Business Administration (H.R.1541):**

- Extends through July 31, 2009, under the same terms and conditions, the authorization for any program, authority, or provision under the Small Business Act or the Small Business Investment Act of 1958.

- This extension provides for continuation of the SBIR/STTR programs.
- The previous Small Business Act authority extension (P.L. 110-234) expired on March 20, 2009.
- Introduced by Rep. Nydia Velazquez (D-NY) on 3/17/09. The bill passed both the House and Senate on 3/17/09.
- Became Public Law No: 111-10 on 3/20/09.

### **III. PENDING LEGISLATION**

#### **A. Federal Funding Mechanisms**

Before the August recess, both the House and the Senate introduced their fiscal year 2010 Labor, HHS, and Education appropriations bills. The House appropriations bill was approved by the Appropriations committee and passed the House on July 24. The House bill provides \$5.15 billion to NCI for fiscal year 2010, which is in line with the President's budget request. The Senate bill, which was passed by the Appropriations Committee on July 30, proposes to appropriate \$5.05 billion to the NCI for fiscal year 2010, which is \$100 million less than the President's request.

Congress returned from August recess on September 8 with much work still to be done on Appropriations before the fiscal year ends on Sept. 30. The Labor, HHS, Education is one of 8 Appropriations bills that has not been voted on by the full Senate. It is unclear when the Senate will schedule that vote. In the event that the Senate votes on and passes the Labor, HHS bill, a conference committee will need to be appointed to reconcile the differences in the House and Senate versions, and report that out. The Conference Report would then need to be passed by the House and Senate before going to the President for his signature. If all of this is not completed before September 30, it is likely that a Continuing Resolution will be passed to allow the Government to keep running.

#### Newly Introduced Bills:

#### **Fiscal Year 2010 Labor-HHS-Education Appropriations (H.R.3293):**

- This bill makes appropriations for the Departments of Labor, HHS, and Education, and related agencies for the fiscal year ending September 30, 2010, and for other purposes.
- Recommends \$31 billion for the National Institutes of Health.
- Provides NCI with \$5.15 billion for fiscal year 2010, of which up to \$8 million may be used for facilities repairs and improvements at the NCI Frederick Federally Funded Research and Development Center in Frederick, Maryland.

#### *Status Update*

- Introduced by Rep. David Obey (D-WI) on 7/22/09.
- Passed the House on 7/24/09.
- The bill was received in the Senate on 7/27/08 and approved by the Senate Appropriations Committee on 7/30/09 with an amendment in the form of a substitution.
- The appropriations bills are accompanied by House Report 111-220 and Senate Report 111-66.

Previously Introduced Bills:

**Taxpayers Cancer Research Funding Act of 2009 (H.R.2463):**

- This bill establishes in the Treasury the Breast and Prostate Cancer Research Fund to award grants for breast or prostate cancer research.
- Amends the Internal Revenue Code to allow taxpayers to designate on their tax returns a contribution to the Breast and Prostate Cancer Research Fund.
  - Every individual may designate that \$5 shall be paid to the Breast and Prostate Cancer Research Fund; (\$10 for joint returns)
- Amounts in the Breast and Prostate Cancer Research Fund shall be available, as provided in appropriation Acts, for purposes of making qualified research grants;
  - Such amounts shall be used to supplement, not supplant, existing funding for research with respect to breast and prostate cancer.
- The term `qualified research grant' means a grant, to a qualified person selected by the NCI by qualified peer review, for the purpose of conducting research with respect to breast or prostate cancer.
  - NCI shall administer and determine the amount of such grant.
- The provisions of this bill shall apply to taxable years beginning after the date of the enactment of this Act.

*Status Update*

- Introduced by Rep. King (D-NY) on 5/18/09 for himself and Rep. Tiahrt. The bill was referred to the committees on Ways & Means and Energy & Commerce, and has one cosponsor.
- Rep. King has introduced a similar bill in every Congress since the 104<sup>th</sup> (1996).

## ***B. Federal Health Care Policy***

### **This section provides information for the following bills:**

- Accelerates Cures for Patients Act of 2009 (H.R.3475)
- Comparative Effectiveness Research Act of 2009 (H.R.2502)
- Cures Acceleration Network and NIH Reauthorization Act of 2009 (S.914)
- Federal Advisory Committee Act (FACA) Amendments of 2009 (H.R.1320)
- Healthy Americans Act (H.R.1321/S.391)
- Improvement of the National Program of Cancer Registries Act (S.792)
- National Pain Care Policy Act of 2009 (H.R.756)
- Oncology Care Quality Improvement Act of 2009 (H.R.2939)
- Promoting Innovation and Access to Life-Saving Medicine Act (H.R.1427/S.726)
- Recognizing the United States Military Cancer Institute within the Uniformed Services University of the Health Sciences (S.51)

### Newly Introduced Bills:

#### **Accelerates Cures for Patients Act of 2009 (H.R.3475):**

- This bill amends the Public Health Service Act to double the amount of funds authorized to be appropriated to the NIH for medical research with the greatest potential for near-term clinical benefit.
- The potential benefit must be supported by substantial evidence from basic research or clinical trials. Such evidence may include, but is not limited to:
  - Improvement in one or more patients suffering from illness or injury (as documented by peer-reviewed literature, reports by professional medical or scientific associations, etc.)
  - Approval for use in human trials by the Food and Drug Administration

#### *Status Update*

- Introduced by Rep. Forbes (R- VA) on 7/31/09 and has no cosponsors. This bill was referred to the Committee on Energy and Commerce.

#### **Oncology Care Quality Improvement Act of 2009 (H.R.2939):**

- HHS shall establish an Oncology Care Quality Improvement (OCQI) pilot program to evaluate the impact of three provider-led approaches to the delivery of oncology care.
- The purpose of the OCQI pilot program is improve care quality and outcomes for Medicare beneficiaries with cancer, while addressing care cost drivers and creating greater efficiencies in the program.
- The OCQI pilot program shall provide performance payments to participating oncology groups that implement these three provider-led approaches:
  - Reduce variation in care by adhering to evidence-based guidelines that improve quality and reduce error.

- Provide patients with coordinated support throughout the course of their care and educational sessions about the likely effects of their cancers and treatments, preferably from an oncology nurse.
- Provide patients with poor prognoses with end-of-life planning and counseling services to empower patients and their families with the best information available about their options.
- Directs HHS to establish per capita expenditure targets for participating oncology groups. Those that meet the performance goals and achieve program savings against the expenditure targets will receive performance payments.
- The OCQI program shall be conducted over a 3-year period and no more than 75 groups may participate in the program at any time.
- The Secretary of HHS shall appoint an advisory committee composed of representatives of the oncology community to collaborate on the creation and implementation of the OCQI program, including the development of appropriate expenditure targets, and to help analyze the data generated by the program.
- The advisory committee shall advise HHS on the methods for selecting practices in different regions of the U.S to participate in the OCQI program.

#### *Evaluation*

- HHS shall evaluate the outcomes for patients participating in the OCQI program as compared to patients with the same health conditions not participating.
- HHS shall analyze the cost effectiveness of the services for which performance payments are made, including an evaluation of the cost savings to the Medicare program attributable to reductions in physicians' services, emergency room visits, hospital stays, drug costs, advanced imaging costs, and end-of-life care.
- HHS may impose penalties on groups participating in the OCQI program that have inappropriately reduced cancer therapies, including supportive care therapies.
- If the OCQI program is successful at improving care quality while lowering the rate of growth of Medicare program expenditures, HHS is authorized to make the performance payments permanent under the Medicare program.

#### *Status Update*

- Introduced by Rep. Joseph Crowley (D-NY) on 6/18/09 and has 23 cosponsors. The bill was referred to the committees on Ways & Means, and Energy & Commerce.
- This pilot program is similar to programs introduced in the Comprehensive Cancer Care Improvement Act of 2009 (H.R.1844).

#### Previously Introduced Bills:

### **Comparative Effectiveness Research Act of 2009 (H.R. 2502):**

#### *Health Care Comparative Effectiveness Research Institute*

- This bill establishes a nonprofit corporation, the Health Care Comparative Effectiveness Research Institute, which is neither an agency nor establishment of the U.S. Government.
- The Institute shall identify national priorities for comparative clinical effectiveness research, and establish a research project agenda.

- The Institute may enter into contracts with Federal agencies that have experience in conducting comparative clinical effectiveness research, with private sector researchers, or study-conducting entities for the conduct of research.
- Requires the Institute to take into consideration any conflicts of interest of potential appointees, participants, and staff in appointing members to advisory panels and the methodology committee; in selecting individuals to contribute to any peer-review process, and in employing executive staff.

#### *Comparative Effectiveness Research Trust Fund and Governance*

- This bill establishes a Comparative Effectiveness Research Trust Fund within the U.S. Treasury. The Secretary of HHS shall be a trustee of the Trust Fund.
- Imposes a fee on self-insured health plans and health insurance policies equal to 1 dollar multiplied by the number of lives covered under that policy each year.
- For fiscal year 2009 and each subsequent fiscal year, amounts in the Trust Fund shall be available, without further appropriation, to the Institute.
- Transfers to the Trust Fund the amounts appropriated to carry out comparative effectiveness research under the American Recovery and Reinvestment Act of 2009, Public Law 111-5.

#### *Committee Provisions*

- A Board of Governors shall carry out the duties of the Institute. The Board shall have 21 members, including the Secretary of HHS, the Director of AHRQ, and the Director of NIH. The other 18 members are to be appointed by the U.S. Comptroller General within 6 months of enactment.
- The Comptroller General shall designate a Chairperson and Vice-Chairperson from among the Board members to serve a 3-year term.
- Allows the Institute to appoint permanent or ad hoc advisory panels to assist in the establishment and carrying out of the research project agenda.

#### *Providing for the Peer Review Process*

- Requires the Institute to ensure that there is a process for peer-review of the research.
- Allows the Institute to utilize existing peer-review processes which are already utilized by entities with which the Institute contracts, if such processes meet the Institute's own requirements.
- Requires that any peer-review process be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and that such review be conducted by experts in the scientific field relevant to the research under review.

#### *Dissemination of Research Findings*

- Requires the Institute to disseminate the findings of research to clinicians, patients, and the general public so that they are comprehensible and useful to patients and providers in making health care decisions.
- The Institute shall make public and disclose through the official public Internet website of the Institute, and through other forums and media; the methods for the conduct of research and the identity of the entity conducting such research.
- The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public.

### *Status Update*

- Introduced by Rep. Schrader (D-OR) on 5/19/09 and has 19 cosponsors. The bill was referred to the committees on Ways & Means and Energy & Commerce.
- A similar bill was introduced by Sen. Baucus (D-MT) in the 110<sup>th</sup> Congress.

### **Cures Acceleration Network and NIH Reauthorization Act of 2009 (S. 914):**

- Establishes a new, \$2 billion, independent agency that would provide funds to translate research discoveries from the bench to the bedside.
- The independent agency, the Cures Acceleration Network (CAN), would not be part of HHS.
- Raises the authorization level of the NIH to \$40 billion in fiscal year 2010.
- Requires the Director of NIH to enforce conflict-of-interest policies, requiring primary investigators with financial interests to provide a detailed report of how the grant recipient will manage the investigator's conflict-of-interest.
- Elevates the National Center for Minority Health and Health Disparities to Institute status.

### *CAN Governing Board*

- The CAN would be run under the direction of a Board comprised of 24 members appointed by the President. From those 24 members, the Chairman and Vice Chairman shall also be appointed by the President with the advice and consent of the Senate.
  - The term of office of each member of the Board shall be 4 years; each shall not serve more than 3 terms and more than 2 terms consecutively.
- In addition to the 24 members, the President shall appoint as members to the board ex-officio members representing the NIH, FDA, DOD, VA and NSF; each shall serve a 3 year term.
- The Chairman of the CAN board shall have the authority to enter into an interagency agreement with the Center for Scientific Review at the NIH to utilize advisory panels to review applications and make recommendations to the CAN.

### *Grant Making Authorities*

- The CAN would fund two types of grant awards, each with an authorization of \$1 billion in the first year and additional funds in succeeding fiscal years.
  - The Cures Acceleration Grant Awards will provide grant awards of up to \$15 million per year per project with out-year funding available. These awards would be available to applicants who do not have access to private matching funds.
  - The Cures Acceleration Partnership Awards also would provide grants for up to \$15 million per year per project with additional funds available in the out-years. However, grant awards would require a match of three Federal dollars to one grantee dollar, as a way to partially offset development costs.
- Eligible grantees would include public or private entities such as institutions of higher education, medical centers, biotechnology companies, universities, patient advocacy organizations, pharmaceutical companies and academic research institutions.
- Grant proposals would be evaluated by a 24-member board comprised of experienced individuals, representative of a broad range of disciplinary interests.

### *Status Update*

- Introduced by Sen. Arlen Specter (D-PA) on 4/28/09 and has no cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions.

### **Federal Advisory Committee Act (FACA) Amendments of 2009 (H.R.1320):**

- Amends the Federal Advisory Committee Act (FACA) to increase the transparency and accountability of Federal advisory committees.
- Directs each agency head to ensure that no individual who has a conflict of interest is appointed unless the need for the individual's services outweighs the potential impacts of the conflict.
- For each advisory committee member, a record of Conflicts of Interest (COI) would need to be available for public inspection.
- Regards an individual who is not a full-time or permanent part-time officer or employee of the federal government as a member of a committee if the individual regularly attends and participates in committee meetings as if the individual were a member, even if the individual does not have the right to vote or veto the committee's advice or recommendations.
- The head of the agency is required to make public disclosure of information about the advisory committee, their charters, the appointment process, determinations, and the decision making process. Agency heads are required to make such information available electronically on the official public intranet site of the agency 15 days before each meeting (or 30 days after meetings for transcripts or recordings).

### *Additional Background*

- It appears that this bill does not apply to full or temporary members of peer review groups as we do not appoint them as Special Government Employees; this would not change. What would change is that National Advisory Councils, Program Advisory Councils, and Boards of Scientific Counselors who have people attending regularly (as members or not) would have to fill out additional paperwork.
- A requirement of posting COI disclosures on the web may deter potential members from serving in a time where we already face serious obstacles in recruiting qualified individuals to serve on advisory committees.

### *Status Update*

- Introduced by Rep. William Lacy Clay (D-MO) on 3/5/09 for himself and Rep. Edolphus Towns (D-NY). The bill has one cosponsor and was referred to the Committee on Oversight & Government Reform on 3/5/09. The committee held a mark up for the bill and reported it out favorably on 3/10/09.
- Rep. Clay introduced a similar bill for himself and Rep. Henry Waxman (D-CA), which passed the House during the 110<sup>th</sup> Congress. However, the Senate never acted on the bill, and when the 110<sup>th</sup> Congress ended the bill died.

## **Healthy Americans Act (H.R.1321/S.391):**

- This bill calls for the expansion of the scope of research in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to include clinical research and identify gaps in current research which may necessitate research beyond systematic reviews of existing evidence.
- This bill calls for the establishment of a Comparative Effectiveness Advisory Board (CEAB), which shall have the authority to identify, the highest priorities for research, demonstrations, and evaluations to support and improve Federal health care programs.

### *Comparative Effectiveness Advisory Board (CEAB)*

- The members of the CEAB shall consist of the Director of the AHRQ and up to 14 additional members who shall represent broad constituencies of stakeholders including: clinicians, patients, researchers, third-party payers, consumers of Federal and State beneficiary programs, and health care industry professionals.
- The Comptroller General of the U.S shall appoint the members of the Board and each member shall be appointed for a term of 2 years.
- The CEAB shall make recommendations to the Congress and the Secretary regarding the establishment of one or more Federally Funded Research and Development Centers.
- The CEAB shall establish a clinical peer review advisory panel for each such priority to advise the Secretary of HHS on validating the science and methods used to conduct comparative effectiveness studies.
- The Secretary of HHS, in consultation with the CEAB, shall submit an annual report to Congress on the activities conducted, including an evaluation of the return on investment and an assessment of how the program is working.

### *Comparative Effectiveness Research Trust Fund*

- This bill also establishes in the Treasury of the United States the 'Health Care Comparative Effectiveness Research Trust Fund'.
- The Secretary of HHS shall compute revenues to the Trust Fund for each fiscal year as follows:
  - \$100 million for fiscal year 2010,
  - \$200 million for fiscal year 2011,
  - \$900 million for each of fiscal years 2012-2014,
  - In no case shall the amount transferred for any fiscal year exceed \$200 million.

### *Status Update*

- H.R.1321 was introduced by Rep. Anna Eshoo (D-CA) on 3/5/09 and has 10 cosponsors. The bill was referred to the House committees on Energy & Commerce, Ways & Means, Education & Labor, and Oversight & Government Reform.
- S.391 was introduced by Sen. Ron Wyden (D-OR) on 2/5/09 for himself and 12 original cosponsors. The bill has 14 cosponsors and was referred to the Committee on Finance.

## **Improvement of the National Program of Cancer Registries Act (S.792):**

- Improves the National Program of Cancer Registries by expanding data collection, ensuring data is collected in a standardized manner and allowing data sharing for public health objectives, while preserving the confidentiality of patients.
- The CDC shall develop standards for the collection of each data element and provide a basic electronic collection tool to facilitate standardized data collection for the State cancer registries.
- The CDC shall also develop interoperability and security standards for data exchange and integration.
- The Secretary of HHS shall facilitate appropriate coordination of the National Program of Cancer Registries with other federally-supported registry programs, including infectious disease registries, environmental disease registries, and other non-cancer, chronic disease registries.
- \$100,000,000 is to be appropriated for each of the fiscal years 2010-2013.

### *Status Update*

- Introduced by Sen. Bernard Sanders (I-VT) on 4/2/09. The bill was referred to the Committee on Health, Education, Labor, & Pensions and has no cosponsors.
- While serving in the House, Mr. Sanders successfully introduced the Cancer Registries Amendment Act which became public law 102-515 on 10/24/92. That bill created the nationwide system of cancer registries designed to provide basic data on environmental causes of cancer across the country.

## **National Pain Care Policy Act of 2009 (H.R.756/S.660):**

- Provides that HHS shall work with the Institute of Medicine to convene a Conference on Pain. A report summarizing the Conference's findings and recommendations shall be submitted to Congress no later than June 30, 2011.
- The NIH Pain Consortium shall develop and submit to the Director of NIH recommendations for pain research initiatives.
- HHS shall establish the Interagency Pain Research Coordinating Committee to develop a summary of advances in pain care research supported or conducted by the Federal agencies;
- The Interagency Pain Research Coordinating Committee shall make recommendations to ensure that the activities of the NIH and other Federal agencies are not unnecessarily duplicated, including the DOD and the VA.
- HHS may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of pain care education and training programs
- HHS shall establish and implement a national public awareness campaign to educate consumers, patients, their families, and other caregivers about pain management.

### *Status Update*

- S. 660 was introduced by Sen. Orrin Hatch (R-UT) and Chris Dodd (D-CT) 3/19/09 and has 6 cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions.

- H.R. 756 was introduced by Rep. Lois Capps (D-CA) on 1/28/2009 for herself and Rep. Rogers (R-MI) and has 15 cosponsors. H.R.756 was reported favorably out of the Committee on Energy & Commerce on 3/23/09 and passed the House on 3/30/09.

## **Promoting Innovation and Access to Life-Saving Medicine Act (H.R.1427/S.726):**

- The purpose of this bill is to authorize the FDA to approve abbreviated applications for biosimilar and biogeneric (interchangeable) biological products.
- The FDA has full discretion to require post-market safety studies and to determine what studies are necessary to establish that a biosimilar is as safe and effective as the original product, and a biogeneric is interchangeable with the original product. FDA can require the applicant to conduct clinical studies in these instances.

### *Approval of Biosimilars and Biogeneric or Interchangeable Products*

- An application for a biosimilar version of a biological drug must demonstrate to FDA that there are no clinically meaningful differences between the two products. The two products must be highly similar in molecular structure and share the same mechanisms of action, if known.
- An applicant may also try to establish that the product is “biogeneric,” i.e., “interchangeable” with the original product and can be safely substituted for the original product, if state law permits.

### *Exclusivity Guidelines*

- The bill grants 6 months of exclusive marketing to the first applicant to demonstrate interchangeability to FDA.
- Consistent with Hatch-Waxman exclusivity periods, an original product with a novel molecular structure is entitled to 5 years of exclusive marketing. A modification of a previously approved product is entitled to 3 years of exclusive marketing in some instances.
- These periods can be extended by up to 1 year if the applicant establishes that the product can be used for a new disease indication or conducts pediatric studies.

### *Status Update*

- H.R.1427 was introduced by Rep. Henry Waxman (D-CA) on 3/11/09 for himself and Reps. Pallone (D-NJ), Deal (R-GA), and Emerson (R-MO). The bill was referred to the committees on Energy & Commerce and Judiciary and has 14 cosponsors.
- S.726 was introduced by Sen. Charles Schumer (D-NY) on 3/26/09 for himself and Sens. Collins (R-ME), Brown (D-OH), Vitter (R-LA), Stabenow (D-MI), Martinez (R-FL), Shaheen (D-NH). The bill has 9 cosponsors and was referred to the Committee on Health, Education, Labor, & Pensions.
- Both Rep. Waxman and Sen. Schumer introduced similar bills in the 109<sup>th</sup> and 110<sup>th</sup> Congresses.

## **Recognizing the United States Military Cancer Institute within the Uniformed Services University of the Health Sciences (S.51):**

- Establishes within the U.S. University of the Health Sciences, the U.S. Military Cancer Institute, headed by a Director, to carry out research studies on:
  - The epidemiological features of cancer among populations of various ethnic origins, as well as complementary research on oncologic nursing;
  - The prevention and early detection of cancer; and
  - Basic, translational, and clinical investigation matters relating to such studies, and for other purposes.
- Introduced by Sen. Daniel Inouye (D-HI) on 1/6/09 and has no cosponsors. The bill was read twice and referred to the Committee on Armed Services.
- Sen. Inouye has introduced this bill in every congress since May 2003.

## **C. Health Equity and Health Information**

### **This section provides information for the following bills:**

- Assisting Doctors to Obtain Proficient and Transmissible Health Information Technology (ADOPT HIT) Act of 2009 (H.R.1087)
- Health Information Technology Act of 2009 (S.179)
- Health Information Technology Promotion Act of 2009 (H.R.1031)
- National Health Information Technology and Privacy Advancement Act of 2009 (S.444)
- Promoting Health Information Technology Act of 2009 (H.R. 1039)

There have been several bills related to Health Information Technology (HIT) introduced in the 111<sup>th</sup> Congress. It is not yet clear which, if any, of these health technology bills will have the support to move through Congress. Two bills call for the establishment of an Office of the National Coordinator for Health Information Technology within HHS. While others call for HHS to develop standards for HIT interoperability, exchange and services.

#### Previously Introduced Bills:

### **ADOPT HIT Act of 2009 (H.R.1087) - Assisting Doctors to Obtain Proficient and Transmissible Health Information Technology Act of 2009:**

- Allows medical care providers to expense (i.e., deduct all costs in the current taxable year) up to \$250,000 of the cost of HIT creation, maintenance, and exchange.
- Directs the Secretary of HHS to develop standards for hardware, software, and support services for the electronic exchange of health information.

#### *Status Update*

- Introduced by Rep. Phil Gingrey (R-GA) on 2/13/09 and has 19 cosponsors. The bill was referred to the House Committees on Ways & Means and Energy & Commerce.
- Rep. Gingrey introduced identical bills in both the 109<sup>th</sup> (which had 15 cosponsors) and 110<sup>th</sup> (which had 1 cosponsor) Congresses.

### **Health Information Technology Act of 2009 (S.179):**

- The Secretary of HHS shall establish a program to award grants to eligible entities to offset the costs incurred after December 31, 2008, related to clinical health care informatics systems and services designed to improve quality in health care and patient safety.
- The Secretary shall provide for the development and adoption of interoperability standards that promote efficient exchange of data between varieties of HIT systems.

#### *Status Update*

- Introduced by Senator Debbie Stabenow (D-MI) for herself and Sen. Olympia J. Snowe (R-ME) on 1/8/09. The bill was referred to the Committee on Finance.

### **Health Information Technology Promotion Act of 2009 (H.R.1031):**

- Amends titles XI and XVIII of the Social Security Act to create safe harbors from civil and criminal penalties in current anti-kickback laws for providing certain HIT and training services.

#### *Status Update*

- Introduced by Rep. Michael Burgess (R-TX) on 2/12/09 and has no cosponsors. The bill was referred to the Committees on Energy & Commerce and Ways & Means.

### **National Health Information Technology and Privacy Advancement Act of 2009 (S.444):**

- Establishes the Office of the National Coordinator for Health Information Technology within HHS, which shall be headed by a 'National Coordinator'. The National Coordinator shall be appointed by the President and report directly to the Secretary of HHS.
- The Secretary of HHS shall provide Federal coordination in the development and operation of a national HIT and privacy system.

#### *Status Update*

- Introduced by Sen. Sheldon Whitehouse (D-RI) on 2/13/09 and has no cosponsors. The bill was referred to the Senate Committee on Health, Education, Labor, & Pensions.

### **Promoting Health Information Technology Act of 2009 (H.R.1039):**

- Establishes the Office of the National Coordinator for Health Information Technology within HHS, which shall be headed by a 'National Coordinator'. The National Coordinator shall be appointed by the President and report directly to the Secretary of HHS.

#### *Status Update*

- Introduced by Rep. Sam Johnson (R-TX) on 2/12/09 and has 26 cosponsors. The bill was referred to the Committees on Energy & Commerce and Ways & Means.

## ***D. Health Promotion and Awareness***

### **This section provides information for the following bills:**

- Breast Cancer Education and Awareness Requires Learning Young Act of 2009 or EARLY Act (H.R.1740)
- Colorectal Cancer Awareness Month (H.CON.RES.60)
- Honoring the 20th anniversary of the Susan G. Komen Race for the Cure in the Nation's Capital (H.CON.RES.109)
- National Childhood Cancer Awareness Day (S.RES.200/H.RES.576)
- Pancreatic Cancer Research and Education Act (H.R.745)
- Paget's Cancer Awareness Act (H.R.822)
- Recognizing that Prostate Cancer in African-American Men has Reached Epidemic Proportions (H.RES.346)
- Supporting efforts to raise awareness of inflammatory breast cancer (H.RES.395)
- Supporting the goals and ideals of National Ovarian Cancer Awareness Month (H.RES.727)

### Newly Introduced Bills:

#### **National Childhood Cancer Awareness Day (S.RES.200/H.RES.576):**

- This resolution designates September 12, 2009, as 'National Childhood Cancer Awareness Day'.
- Whereas childhood cancer is the leading cause of death by disease for children in the U.S.; and more than 40,000 children and adolescents in the U.S. currently are being treated for childhood cancers.
- Whereas the results of peer-reviewed clinical trials have raised the standard of care and improved the 5-year cancer survival rate in children to greater than 80 percent overall.
- Requests that the Federal Government, States, localities, and nonprofit organizations observe the day with appropriate programs and activities, with the goal of increasing public knowledge of the risks of cancer.
- Recognizes the profound toll a diagnosis of cancer has on children, families, and communities and pledges to make its prevention and cure a public health priority.
- Urges public and private sector efforts to promote awareness, invest in research, and improve treatments for childhood cancer.

### *Status Update*

- S.RES.200 was introduced by Sen. Udall (D-CO) on 6/23/09 and has 8 cosponsors. The bill passed the Senate by unanimous consent on 8/3/09.
- H.RES.576 was introduced by Rep. Sestak (D-PA) on 6/23/09 and has 3 cosponsors. The bill was referred to the Committee on Energy & Commerce.

## **Supporting the goals and ideals of National Ovarian Cancer Awareness Month (H.RES.727):**

- Be it resolved that the House of Representatives supports the goals and ideals of National Ovarian Cancer Awareness Month.
- Whereas ovarian cancer is the deadliest of all gynecological cancers, and the reported mortality of ovarian cancer is increasing over time.
- Whereas if ovarian cancer is diagnosed and treated at an early stage before the cancer spreads outside of the ovary the survival rate is as high as 90 percent.
- Whereas awareness and early recognition of ovarian cancer symptoms are currently the best way to save women's lives.

### *Status Update*

- Introduced by Rep. Steve Israel (D- NY) on 9/9/09 and has 3 cosponsors. The bill was referred to the Committee on Oversight and Government Reform.

### Previously Introduced Bills:

## **Breast Cancer Education and Awareness Requires Learning Young Act of 2009 or EARLY Act (H.R.1740):**

- Increases awareness of the risks of breast cancer in young women and provides support for young women (ages 15 to 39) diagnosed with breast cancer.
- The CDC shall conduct a national evidence-based education campaign to increase public awareness regarding the threats posed by breast cancer to young women of all ethnic and cultural backgrounds, including the particular risks faced by certain ethnic and cultural groups.

### *Status Update*

- Introduced by Rep. Wasserman Schultz (D-OH), for herself and Rep. DeLauro, Rep. Myrick, Del. Christensen and Rep. Bean on 3/26/09.
- The bill has 366 cosponsors and was referred to the Committee on Energy & Commerce.

## **Colorectal Cancer Awareness Month (H.CON.RES.60):**

- A concurrent resolution supporting the observance of Colorectal Cancer Awareness Month
- Whereas observing a Colorectal Cancer Awareness Month during the month of March would provide a special opportunity to offer education on the importance of early detection and screening.

### *Status Update*

- Introduced by Rep. Kay Granger (R-TX) for herself and Rep. Kennedy on 2/25/09 and has 121 cosponsors. The bill was referred to the Committee on Energy & Commerce. The bill passed the House on 3/30/09.
- The bill was received in the Senate on 3/31/09 and referred to the Committee on Health, Education, Labor & Pensions

### **Honoring the 20th anniversary of the Susan G. Komen Race for the Cure in the Nation's Capital (H.CON.RES.109):**

- Whereas 2009 marks the 20th anniversary of the first Susan G. Komen National Race for the Cure in Washington, DC.
- Whereas this year the Susan G. Komen National Race for the Cure becomes the first-ever Susan G. Komen Global Race for the Cure.

#### *Status Update*

- Introduced by Rep. Gerald E. Connolly (D-VA) on 4/27/09 for himself and Rep. Wasserman Schultz (D-FL) and Rep. Gregorio Sablan (D-MP).
- The bill has 145 cosponsors and was referred to the Committee on Energy & Commerce.
- The bill passed the House on 6/03/09 and passed the Senate on 6/08/09.

### **Pancreatic Cancer Research and Education Act (H.R.745):**

- The Secretary of HHS shall establish and implement a Pancreatic Cancer Initiative to assist in coordinating activities to address the high mortality rate associated with pancreatic cancer.
- Allows the Secretary of HHS to designate two additional Specialized Programs of Research Excellence (SPoREs) focusing solely on pancreatic cancer research (\$20 million for FY 2010).
- Requires the Directors of the NIH and CDC to develop a communication tool kit for patients and their families that focuses on specific pancreatic cancer issues relating to patient choices and patient care.

#### *Status Update*

- Introduced by Rep. Anna Eshoo (D-CA) on 1/28/09 for herself and Representatives Brown-Waite (R-FL), Cummings (D-MD), Platts (R-PA), and Capps (D-CA). The bill was referred to the House Committee on Energy & Commerce and has 158 cosponsors.
- Rep. Eshoo introduced a similar bill in the 110th Congress that only had 1 cosponsor.

### **Paget's Cancer Awareness Act (H.R.822):**

- This bill provides for an awareness program, and a study of Paget's disease, a rare form of breast cancer.
- The Secretary of HHS shall implement a program which provides information and education to health professionals and the public on the symptoms of and treatment for Paget's disease.

#### *Status Update*

- Introduced by Rep. Peter King on 2/3/09 and has no cosponsors. The bill was referred to the Committee on Energy & Commerce.
- Rep. King introduced similar bills in the 107<sup>th</sup>, 109<sup>th</sup> and 110th Congresses.

## **Recognizing that Prostate Cancer in African-American Men has Reached Epidemic Proportions (H.RES.346):**

- Whereas African-Americans are more likely to be diagnosed earlier in age and at a later stage of cancer progression than all other ethnic and racial groups, thereby leading to lower cure rates and lower chances of survival.
- Urges Federal agencies to address that health crisis by designating additional funds for research, education, awareness, outreach, and early detection.

### *Status Update*

- Introduced by Rep. Gregory Meeks (D-NY) on 4/21/09 for himself, and 29 original cosponsors. The bill was referred to the Committee on Energy & Commerce.
- As of 8/31/09, the bill has 42 cosponsors.

## **Supporting efforts to raise awareness of inflammatory breast cancer (H.RES.395):**

- This resolution supports the efforts to raise awareness, improve education, and encourage research of inflammatory breast cancer.
- Therefore, it is the sense of the House of Representatives that the Federal Government has a responsibility to:
  - Raise awareness and improve education about inflammatory breast cancer; and
  - Encourage research that will improve treatments for inflammatory breast cancer

### *Status Update*

- Introduced by Rep. Carolyn McCarthy (D-NY) on 5/4/09 and has 5 cosponsors. The bill was referred to the Committee on Energy & Commerce.

## ***E. Science Research and Technology***

### **This section provides information on the following bills:**

- Enhancing SBIR Act of 2009 (H.R.2965)
- National Nanotechnology Initiative Amendments Act of 2009 (H.R.554/S.1482)
- National Neurotechnology Initiative Act (H.R.1483/S.586)
- SBIR and STTR Enhancement Act (H.R.2772)
- SBIR/STTR Reauthorization Act of 2009 (S.1233)
- Strengthening Our Economy through Small Business Innovation Act of 2009 (S.177)
- Temporarily extends certain authorities of the Small Business Administration (H.R.1541)

The SBIR and STTR program authorities are set to expire July 31, 2009. Several bills have been introduced to extend and reauthorize the the SBIR/STTR programs. Many of them call for increases in the agency allocations as well increases in the award levels for Phase I and II research projects. Most bills also require additional reporting requirements for agencies that participate in the programs. However, only two of the bills introduced are being considered and it is not yet clear which of these bills will have the support to become public law.

H.R. 2965 passed the House on July 8, 2009 and was sent to the Senate for approval. However, when H.R.2965 was considered by the Senate, the bill was passed with S.1233 inserted in the form of an amendment. Therefore, the version that passed the House is very different from the version that passed the Senate. The two chambers will have to come to some sort of compromise in a conference committee, where members of both the House and Senate will reconcile the bill differences.

#### Newly Introduced Bills:

### **Temporarily extends certain authorities of the Small Business Administration (H.R.1541):**

- Extends through July 31, 2009, under the same terms and conditions, the authorization for any program, authority, or provision under the Small Business Act or the Small Business Investment Act of 1958.
- This extension provides for continuation of the SBIR/STTR programs.
- The previous Small Business Act authority extension (P.L. 110-234) expired on March 20, 2009.
- Introduced by Rep. Nydia Velazquez (D-NY) on 3/17/09 and has 3 cosponsors.
- The bill passed both the House and Senate on 3/17/09.
- Became Public Law No: 111-010 on 3/20/09.

### **Enhancing SBIR Act of 2009 (H.R.2965):**

- Extends the SBIR and STTR programs authorization period through FY 2011.
- Provides increases to the SBIR and STTR award levels:
  - From \$100,000 to \$250,000 for Phase I
  - From \$750,000 to \$2 million for Phase II

- Provides an increase adjustment for inflation every 5 years.
- Provides funding to assist Federal Agencies with administrative, oversight, and contract processing costs related to SBIR; for up to the 3 percent of their respective agencies total SBIR set-aside.
- Provides preference to organizations located in underrepresented states and regions, rural companies and places hardest hit by economic downturn; and to those that are owned by women, minorities, or disabled veterans.
- Requires agencies to give special consideration to research related to rare diseases, nanotechnology, medical technology, renewable energy, water conservation technology and transportation and infrastructure.
- Requires each federal agency to issue research topic solicitations at least twice per year and to make final decisions on topic proposals within 90 days.

#### *Venture Capital Company Provisions*

- Allows small businesses (fewer than 500 employees) with substantial investment from venture capital companies to participate in the SBIR and STTR programs:
  - A venture capital company must own less than 50% of the small business and cannot constitute a majority of the board of directors of the small business.
- If a venture capital company under large business control has ownership in a small business that is majority owned by venture capital companies, the small business would be eligible to receive an award under the SBIR or STTR program only if:
  - Not more than two venture capital companies under large business control have an ownership interest in the small business; and do not collectively own more than 20 percent of the small business.
- Requires the GAO to examine and report to Congress on the effect that venture capital ownership restrictions have on eligibility and participation under this act.

#### *Commercialization- Phase III Provisions*

- Requires each agency to establish a commercialization program that supports the progress of SBIR awardees to Phase III.
- SBIR and STTR research and development projects shall be directed towards commercial applications or acquisition by federal agencies; and derives from research and development completed in earlier phases.
- Requires each Federal agency to obtain an SBIR applicants' consent to release contact information to the appropriate state and local economic development organizations, whose primary purpose is to further economic growth and job creation.
- Encourages partnerships between SBIR awardees and prime contractors, venture capital investment companies, business incubators, and larger businesses, for the purpose of facilitating the progress of the SBIR awardees to Phase III.
- Each agency shall report annually to Congress on the progress of the commercialization program and an analysis of its activities.
- Each Federal agency with an SBIR program that awards \$5 billion or more annually in procurement contracts shall establish annual goals for commercialization of projects funded by SBIR awards.

### *Outcomes and Evaluation*

- Directs each federal agency to establish and maintain program evaluation databases and a technology utilization database.
- The GAO shall conduct a study of how Federal agencies calculate their extramural research budgets for purposes of calculating the size of the agencies' SBIR and STTR Program budgets.
- Requires SBIR and STTR program participants to provide updated project information on the ownership structure of award recipients for the purposes of updating agency databases which evaluate the outcomes of Phase I and II awards.
- Requires the SBA to annually submit to the committees on small businesses a list identifying small businesses, which during the previous 5 fiscal years, received 15 or more Phase I awards and no Phase II awards.
- The Director of the Office of Science and Technology Policy (OSTP) shall establish an Interagency SBIR/STTR Policy Committee comprised of one representative from each Federal agency with an SBIR program. The director of the OSTP and NIST shall jointly chair the Committee. The Committee shall report to Congress on its review of issues and policy recommendations to improve program effectiveness and efficiency.

### *Phase One and Two Provisions*

- Requires each Federal agency to develop a 'fast-track' program to eliminate funding delays for Phase II awards, including simultaneously issuing Phase I awards.
- A Federal agency shall provide an award for Phase II of an SBIR project only if the small business has been awarded a Phase I grant or can demonstrate to agency SBIR proposal evaluators that the company has completed Phase I work.
- Requires each Federal agency to engage with SBIR awardees that have been awarded multiple Phase I awards but no Phase II awards, and to develop performance measures with respect to progression in the SBIR program.
- A small business that receives a second phase SBIR award for a project remains eligible to receive additional second phase SBIR awards for such project.
- Agencies are expressly authorized to provide additional second phase SBIR awards for testing and evaluation assistance for the insertion of SBIR technologies into technical or weapons systems.

### *Status Update*

- Introduced by Rep. Jason Altmire (D-PA) on 6/19/09 and has 9 cosponsors. The bill was referred to the committees on Small Business and Science & Technology. Reported favorably by the Committee on Small Business on 6/26/09 and the Committee on Science & Technology on 7/7/09.
- The bill passed the House on 7/8/09 by a vote of 386-41.
- The bill passed the Senate on 7/13/09 with bill language from S.1233 inserted in the form of an amendment.

### **SBIR and STTR Enhancement Act (H.R.2772):**

- Requires the SBA administrator to establish, by regulation, a process in which each agency conducts at least two rounds of SBIR research solicitations per year.

- Requires the agencies to render a final decision on each proposal within 90 days after the solicitation closes; a 180-day extension could be authorized on a case-by-case basis.
- The bill would authorize \$27.5 million for the SBA for administrative, oversight and contract processing costs related to SBIR in fiscal 2010 and 2011.
  - It would allow the SBIR program offices in each of the federal agencies to withdraw funds from the account that is equal to no greater than 3 percent of their respective agencies total SBIR set-aside.
- The measure would require the Government Accountability Office to conduct a study on the size of agencies extramural research budgets.
- Requires the Director of the Office of Science and Technology Policy (OSTP) to establish an Interagency SBIR/STTR Policy Committee to review program issues and make policy recommendations. The Interagency SBIR/STTR Policy Committee shall transmit to Congress several reports on its review of the programs and its recommendations.

#### *Phase 2 Award Provisions*

- Authorizes Federal Agencies to develop 'Fast-Track' programs to issue Phase Two grants as soon as practicable, including simultaneously with the issuance of phase one grants.
- Requires that a project that receives a phase two award remains eligible to receive additional phase two SBIR awards.
- Agencies are expressly authorized to provide additional second phase SBIR awards for testing and evaluation assistance for the insertion of SBIR technologies into technical or weapons systems.
- Federal agencies shall provide an award for the second phase of an SBIR project only if the small business concern has been provided an award for the first phase of an SBIR project or has completed the determinations of a project despite not having been provided an award for the first phase.
- Requires each agency to engage with SBIR recipients that have been awarded multiple "phase one" awards but no "phase two" awards, and to develop performance metrics to measure their progress in the SBIR program.

#### *Increased SBIR and STTR Award Levels*

- Not later than 180 days after the date of enactment of this Act, for both SBIR and STTR programs, the individual small business grant levels would increase from:
  - \$100,000 to \$250,000 for phase one grants
  - \$750,000 to \$2 million for phase two grants
  - Requiring mandatory annual adjustment to the levels to reflect economic conditions and program changes.
- No Federal agency shall issue an award under the SBIR or STTR program if the size of the award exceeds the amounts established.
- Allows participating federal agencies to exceed such award levels if the agencies provide annual reports to Congress and the small business community concerning the increase and the justification for each such instance.

#### *Agency Database to Support Program Evaluation*

- Each Federal agency with an SBIR or STTR program shall develop and maintain, for the purpose of evaluating such programs, a database containing required information.

- Each such database shall be designed to be accessible to other agencies that are required to maintain a database.
- Each such database shall be developed and operated in a manner to ensure that each such database is relevant to and contributes to the agency's oversight and evaluation of the SBIR and STTR programs.
- Each Federal agency shall create and maintain a Technology Utilization database, which shall be available to the public and shall contain data supplied by the award recipients specifically to help them attract customers for the products and services generated under the SBIR or STTR project, and to attract additional investors and business partners.
- A Federal agency shall not make a Phase I or Phase II payment to a small business unless the small business has provided all information required and available at the time of the award.
  - A small business receiving an award shall, in the case of a second phase award, update information in the databases concerning that award at the termination of the award period;
  - Additionally, upon termination of the award, a small business may be asked to update such information annually thereafter for a period of five years.

#### *Status Update*

- Introduced by Rep. Aaron Schock (R-IL) on 6/6/09 and has no cosponsors. The bill was referred to the committees on Small Business, and Science and Technology on 6/9/09.
- On 6/11/09 the House Small Business Committee, Subcommittee on Contracting & Technology held a markup session and voted the bill favorably to the full committee for consideration.

#### **SBIR/STTR Reauthorization Act of 2009 (S.1233):**

- Reauthorizes the SBIR and STTR programs through 2023.
- For fiscal year 2009, and each fiscal year thereafter, HHS shall increase its SBIR allocation to not less than 2.5 percent of the extramural research budget.
- Doubles the STTR allocation to .6 percent over five years.
- Provides increases to the SBIR and STTR award levels:
  - From \$100,000 to \$150,000 for Phase One awards.
  - From \$750,000 to \$1 million for Phase Two awards.
  - Provides an increase adjustment for inflation every three years.
- Eliminates Phase Two invitation requirements for eligibility from the selection process.
- Federal agencies and Federal prime contractors shall have special acquisition preferences when issuing Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology.
- Provides \$5000 for technical assistance to award recipients in addition to their SBIR awards.
- Each Federal agency participating in the SBIR or STTR program shall encourage the submission of applications for support of nanotechnology-related projects.
- Introduced by Sen. Landrieu on 6/10/09 and has 6 cosponsors. The bill was referred to the Committee on Small Business and Entrepreneurship. On 7/2/09 the committee recommended that the bill be passed and it was placed on the Senate legislative calendar.

### *NIH Provisions*

- Director of the NIH SBIR program may initiate a pilot program, under a formal mechanism for designing, implementing, and evaluating pilot programs, to spur innovation and to test new strategies that may enhance the development of cures and therapies.
  - Not more than a total of 1 percent of the NIH extramural research budget may be used for the pilot program.
- NIH shall reduce the time period between Phase I and Phase II funding of grants and contracts to 6 months.
- Allows limited involvement by small businesses, which are majority-owned by venture capital companies, in the SBIR program. The NIH may award not more than 18 percent of their SBIR funds to small businesses owned in majority part by venture capital companies. Any other Federal agency may award not more than 8 percent of their SBIR funds.
- Allows small businesses owned in majority part by venture capital companies to participate in the SBIR program, so long as no single venture capital company owns more than 49 percent of the small business.

### *SBIR National Academy of Sciences (NAS) Advisory Board*

- Establishes an independent advisory board at the NAS to assess the program management and effectiveness of the NIH SBIR programs.
- The NAS advisory board shall consist of the Director of the NIH; the Director of the SBIR program of the NIH; senior NIH agency managers selected by the Director of NIH; and other experts for a total not to exceed 10 members.
- NIH shall address the gaps and deficiencies in the data collection concerns identified in the 2007 report of the NAS entitled 'An Assessment of the SBIR programs at the NIH'.
- NIH shall submit an annual report to Congress and the advisory board on the activities of the SBIR program of the NIH.

### *Agency Program Collaboration*

- Each federal agency may make SBIR and STTR awards to any small businesses that collaborate with Federal laboratories and research and development centers.
- Encourages agency and program collaboration that allows awards to be granted for subsequent phases at another agency and under either program.
- A small business that received an award from one Federal agency shall be eligible to receive an award for a subsequent phase from another Federal agency, if the head of each relevant Federal agency makes a written determination that the topics of the relevant awards are the same.
  - A small business which received an award under the SBIR program or the STTR program may receive an award for a subsequent phase in either the SBIR program or the STTR program.
- Reauthorizes and increases funding from \$2 million to \$5 million for the Federal and State Partnership Program, which would allow each state to receive funding in the form of a grant to make available an array of services in support of the SBIR program.

### *Pilot Programs*

- Establishes a SBIR-STEM Workforce Development Grant Pilot Program to encourage the business community to provide workforce development opportunities for college students, in the fields of science, technology, engineering, and math, by providing a SBIR bonus grant.
  - The bonus grant shall be equal to 10 percent of either a Phase I or Phase II grant, as applicable, with a total award maximum of not more than \$10,000 per year.
- Improves and makes permanent the DOD Commercialization Pilot Program, which establishes goals for the transition of Phase III technologies into subcontracting plans.
- Allows civilian Federal agencies to establish a commercialization pilot program by applying to the SBA with compelling reasons for the additional investment in SBIR or STTR technologies.
  - Each Federal agency may set aside not more than 10 percent of the SBIR and STTR funds for this pilot program.
  - An award under a pilot program may not exceed 2 times the dollar amounts generally established for Phase II awards.
  - A Federal agency may make an award under a pilot program to any applicant that is eligible to receive a Phase III award related to technology developed in a Phase II project.
  - A Federal agency may not make an award under a pilot program unless new private or Federal (non-SBIR/STTR) funding, which at least matches the award from the Federal agency, is provided for any Phase II technology.

### *Evaluation and Data Requirements*

- Requires the GAO to conduct a fiscal and management audit of the SBIR and STTR programs every 3 years to assess the extent of compliance with the expenditure requirements of Federal agencies.
- Each agency shall cooperatively enter into an agreement with NAS for the National Research Council to conduct continued evaluation and make recommendations.
- The GAO shall conduct a study of the SBIR and STTR programs to assess whether Federal agencies comply with intellectual property protections of awardees.
- Requires agencies to collect annually, and maintain in a common format, information from awardees necessary to assess the SBIR and STTR programs and maintain the database.

### *Status Update*

- Introduced by Sen. Mary Landrieu (D-LA) on 6/10/09 and was referred to the Committee on Small Business and Entrepreneurship. The bill has 6 cosponsors and on 7/2/09 the Committee recommended the bill favorably to the Senate for a vote.
- On 7/13/09, the Senate substituted S.1233 into measure H.R.2965 in the form of an amendment and passed the bill.
- The respective House and Senate committees are currently in negotiations and will meet to reconcile the two bills in conference committee.

Previously Introduced Bills:

**National Nanotechnology Program Amendments Act of 2009  
(H.R.554/S1482):**

- This bill amends the 21st Century Nanotechnology Research and Development Act (PL 108-153) to authorize activities for support of nanotechnology research and development.
- The bill requires the development of a strategic plan (updated every three years) that specifies objectives for the National Nanotechnology Research Program along with anticipated timeframes for achieving the objectives and evaluation metrics for assessing progress.
- Requires the National Nanotechnology Coordination Office to be supported by funds from each agency participating in the Program.
- Requires the National Nanotechnology Coordination Office to develop a database of all projects funded under the Environmental, Health & Safety, the Education & Societal Dimensions, and the Nanomanufacturing programs.
- Each agency participating in the Program shall encourage the submission of applications for support of nanotechnology related projects to the Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer Program (STTR) administered by such agencies.
- Each agency shall submit a report to Congress detailing the number of proposals received by the SBIR Program and the STTR Program administered by the agency; the number of proposals funded; and descriptions of the projects identified.

*Status Update*

- H.R.554 was introduced by Rep. Bart Gordon (D-TN) on 1/15/09, and has 21 cosponsors. The bill was referred to the Senate Committee on Commerce, Science & Transportation and passed the House on 2/11/09.
- S.1482 was introduced on 7/21/09 by Sen. John Kerry (D-MA) and has 6 cosponsors. The bill was referred to the Committee on Commerce, Science & Transportation.

**National Neurotechnology Initiative Act (H.R.1483/S.586):**

- Requires HHS to establish the National Neurotechnology Coordination Office and the National Neurotechnology Advisory Council.
- Requires NIH to develop the Blueprint for Neuroscience Research to identify pervasive challenges in neuroscience and support the development of new tools, training opportunities, and other resources to assist neuroscientists in basic and clinical research.
- Requires that the directors of each Institute, where appropriate, give high priority to small business concerns that participate in or conduct neurotechnology research and development projects and annually report to the Director of the National Neurotechnology Coordination Office concerning the percentage of funds being used for such projects.

*Status Update*

- HR1483 was introduced by Rep. Patrick Kennedy (D-RI) on 3/12/09 and has 7 cosponsors. The bill was referred to the Committee on Energy & Commerce
- S.586 was introduced by Sen. Patty Murray (D-WA) on 3/12/09 and has no cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions.

**Strengthening Our Economy through Small Business Innovation Act of 2009 (S.177):**

- This bill amends the Small Business Act to extend the Small Business Innovation Research (SBIR) through FY2022 and the Small Business Technology Transfer (STTR) program through FY2023.
- The bill increases the allocation of federal agency grants for SBIR and STTR Programs.
- The bill increases the individual small business award levels for program participation from \$100k to \$300k for Phase I and from \$750k to \$2.2mil for Phase II levels for both SBIR and STTR programs.
- The bill also establishes the inclusion of water, energy, transportation, and domestic security related research to the list of topics deserving special consideration for the SBIR program.

*Status Update*

- Introduced by Sen. Russell Feingold (D-WI) on 1/8/09 and has no cosponsors. The bill was referred to Senate Committee on Small Business & Entrepreneurship.
- A similar bill was introduced and passed in the House in the 110th Congress.

## ***F. Screening, Prevention and Treatment***

### **This section provides information for the following bills:**

- 21st Century Cancer Access to Life-Saving Early Detection, Research and Treatment (ALERT) Act (S.717)
- Access to Cancer Clinical Trials Act of 2009 (H.R.716/S.488)
- Assuring and Improving Cancer Treatment Education and Cancer Symptom Management Act of 2009 (H.R.1927)
- Better Screening Test for Women Act (H.R.2042)
- Bone Marrow Failure Disease Research and Treatment Act of 2009 (H.R.1230)
- Childhood Cancer Survivorship Research and Quality of Life Act of 2009 (H.R.2109)
- Colorectal Cancer Screening and Detection Coverage Act of 2009 (H.R.1330)
- Comprehensive Cancer Care Improvement Act of 2009 (HR 1844)
- Eliminating Disparities in Breast Cancer Treatment Act of 2009 (H.R.2279)
- Lung Cancer Mortality Reduction Act (H.R.2112/S.332)
- Mammogram and MRI Availability Act of 2009 (H.R.995)
- Mitochondrial Medicine Research and Treatment Enhancement Act (H.R.3502)
- National Childhood Brain Tumor Prevention Network Act of 2009 (H.R.653/S.305)
- Ovarian Cancer Biomarker Research Act of 2009 (H.R.1816/S.755)
- Pediatric Research Consortia Establishment (H.R.758/S.353)
- Prostate Research, Imaging, and Men's Education (PRIME) Act (S.756)

### Newly Introduced Bills:

#### **Mitochondrial Medicine Research and Treatment Enhancement Act (H.R.3502):**

- This bill establishes an Office of Mitochondrial Medicine (OMM) within the Office of the Director of NIH; Headed by a Director, appointed by the Director of NIH.
- Establishes a Mitochondrial Medicine Centers of Excellence to promote interdisciplinary research and training related to mitochondrial medicine.
- Establishes a national registry for the maintenance and sharing for research purposes of medical information collected from patients with mitochondrial disease or dysfunction.
- Establishes a national biorepository for the maintenance and sharing for research purposes of tissues and DNA collected from patients with mitochondrial disease or dysfunction.
- Establishes need for scientific review groups with expertise in mitochondrial medicine to oversee relevant research projects in the NIH.

#### *Mitochondrial Medicine Research Plan*

- OMM shall develop, make publicly available, and implement a written plan to facilitate research into mitochondrial medicine. The plan shall be updated on a biennial basis.
- In developing the plan, OMM shall consult with the directors of NCI, NICHD, NIEHS, NHLBI, NINDS, NIDDK, NEI, and the heads of such other institutes and offices as the Director considers appropriate.
- The Mitochondrial Medicine Research Plan shall include the following objectives:

- Improve coordination of research related to mitochondrial medicine among the national research institutes and between the NIH and outside researchers.
- Provide training to research scientists and health professionals engaged in research related to mitochondrial medicine.
- Provide training to health care providers regarding the diagnosis of mitochondrial disease and dysfunction.

#### *Research Grants*

- Requires the award of at least five grants for integrated, multi-project research programs related to mitochondrial medicine; and
- Requires the award of at least five grants for planning activities associated with integrated, multi-project research programs related to mitochondrial medicine.
- An awarded grant shall be used to do the following:
  - Conduct basic and clinical research related to mitochondrial medicine;
  - Facilitate training programs for research scientists and health professionals seeking to engage in research related to mitochondrial medicine;
  - Develop and disseminate programs and materials to provide continuing education to health care professionals regarding the recognition, diagnosis, and treatment of mitochondrial disease and dysfunction; and
  - Provide living stipends for research scientists and health professionals enrolled in mitochondrial research training programs.

#### *Status Update*

- Introduced by Rep. Jim McDermott (D-WA) on 7/31/09 and has 13 original cosponsors. The bill was referred to the Committee on Energy & Commerce.

#### Previously Introduced Bills:

### **21st Century Cancer Access to Life-Saving Early Detection, Research and Treatment (ALERT) Act (S.717):**

#### *Advancement of the National Cancer Program*

- This bill reauthorizes the NCI and the National Cancer Program (NCP) in order to improve and enhance cancer research, and support the NCI in establishing relationships and scientific consortia with an emphasis on public-private partnership development.
- Requires NCI to develop the budgetary needs for the NCP and to submit the estimate to the National Cancer Advisory Board (NCAB) for review prior to submitting to the President.
- Requires NCI to submit the NCP budget to the House and Senate committees on the budget and committees on appropriations at the same time the budget is submitted to the President.
- Requires the NCI to develop a standard process through which federal agencies, including the DOD, can engage in early cancer detection research.

#### *Biological Resource Coordination and Advancement of Technologies for Cancer Research*

- Establishes an interconnected network of biorepositories ('Network') with consistent, interoperable systems, and builds upon existing resources.
- Requires that a biorepository in the Network that receives federal funds adopts the NCI Best Practices for Biospecimen Resources for NCI-supported biospecimen resources.
- The NCI Director will determine the leadership of the Network of biorepositories,
- Directs the Secretary of HHS to designate a lead agency within 2 years to administer and coordinate the contract based biomarker program.

#### *Comprehensive and Responsible Access to Research, Data, and Outcomes*

- Requires OHRP to issue guidance to NIH grantees on the use of a facilitated review process in conjunction with the central institutional review board of the NCI as the preferred mechanism for review of all NCI-supported translational and clinical research.

#### *Enhanced Focus and Reporting on Cancer Research*

- Requires the NCI to report annually, at the same time as the bypass is submitted, on plans and progress regarding research on cancers with less than 50% survival at 5 years, and cancers with less than 15 cases per 100,000 people, or fewer than 40,000 new cases per year.

#### *Other Initiatives*

- Requires NCI to coordinate NIH activities with respect to cancer survivorship, particularly for childhood cancers, with priority given to a comprehensive assessment of the prevalence and etiology of the late effects of cancer treatment.
- Calls for HHS to include cancers with especially low survival rates (i.e., survival of less than 25% at 5 years) in the NCI Cancer Genome Atlas Consortium.
- Calls for HHS to establish formal working groups for cancers with especially low survival rates in the NCI's Early Detection Research Network.
- Requires the NCI to collaborate with NIH to carry out a public education program on the value of clinical trials for oncology patients' and one aimed at health care professionals to consider clinical trials as treatment for their patients.
- The FDA, CMS and NCI would be required to jointly develop guidelines for the conduct of clinical trials designed to generate clinical data relating to cancer care and treatment biomarkers that is adequate for review by each agency.

#### *Status Update*

- The bill was introduced by Senator Edward Kennedy (D-MA) for himself, Sen. Kay Bailey Hutchison (R-TX) and Sen. Diane Feinstein (D-CA) on 3/26/09 and has 21 cosponsors.
- The bill was referred to the Committee on Health, Education, Labor & Pensions.
- Committee markup of the bill was scheduled for 5/19/09, but was cancelled.

#### **Access to Cancer Clinical Trials Act of 2009 (H.R.716/S.488):**

- This bill provides more cancer patients access to the latest cancer treatments by requiring insurance plans to provide coverage for clinical trials.

- Prohibits a group health plan from discriminating against an individual or denying (or limiting or imposing additional conditions on) the coverage of routine patient costs for items and services furnished in connection with such participation.

*Status Update*

- H.R.716 was introduced by Rep. Steve Israel (D-NY) on 1/27/2009 for himself and the other co-chairs of the House Cancer Caucus: Reps. Sue Myrick (R-NC), Lois Capps (D-CA), and Mary Jo Kilroy (D-Ohio). The bill was referred to the committees on Energy & Commerce, Education & Labor, and Ways & Means and has 44 cosponsors.
- S.488 was introduced by Sen. Sherrod Brown (D-OH) on 2/26/09 and has 3 cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions.
- The Access to Clinical Cancer Trials Act is similar to legislation introduced in the 107th, 108th, 109th and 110th sessions of Congress.

**Assuring and Improving Cancer Treatment Education and Cancer Symptom Management Act of 2009 (H.R.1927):**

- Provides for Medicare coverage of comprehensive cancer patient treatment education services.
- Provides for a one-hour patient treatment education session to be delivered by a registered nurse in advance of the onset of treatment.
- Directs the NIH, acting through the NCI, in collaboration with NINR, NIMH, NCMHD, NCAM, and AHRQ, to expand, intensify, and coordinate programs for the conduct and support of research with respect to:
  - Improving the treatment and management of symptoms and side effects associated with cancer and cancer treatment; and
  - Evaluating the role of nursing interventions in the amelioration of such symptoms and side effects.
- Directs the NIH, in collaboration with NINR and other relevant ICs, to make research grants available to registered nurses for the purpose of studying cancer symptom management care and services delivered by registered nurses.
- Directs HHS to enter into an arrangement under which the Institute of Medicine shall evaluate and report to HHS and Congress on the current state of symptom management, patient treatment education, and supportive care given to people with cancer.

*Status Update*

- Introduced by Rep. Steve Israel on 4/2/09 for himself and Rep. Tiberi and has 21 cosponsors. The bill was referred to the committees on Energy & Commerce, and Ways & Means.
- Rep. Israel introduced an identical bill in the 110<sup>th</sup> Congress that garnered 21 cosponsors.

**Better Screening Test for Women Act (H.R.2042):**

- This bill authorizes additional appropriations to the NIH for research on the early detection of and the reduction of mortality rates attributed to breast cancer.
- Authorizes \$55 million, for each of the fiscal years 2010 through 2014, to support clinical research and related activities on early detection and screening methods for breast cancer.

- Authorizes \$5 million, for each of the fiscal years 2010 through 2014, to support research and data collection on the link between early detection of breast cancer and reduction of mortality rates attributed to breast cancer.

*Status Update*

- Introduced by Rep. Nita Lowey (D-NY) on 4/22/09 and has no cosponsors. The bill was referred to the Committee on Energy & Commerce.

**Bone Marrow Failure Disease Research and Treatment Act of 2009 (H.R.1230):**

- This bill directs the CDC to establish and maintain a national and publicly available registry, to be known as the National Acquired Bone Marrow Failure Disease Registry, which shall:
  - Identify the incidence and prevalence of acquired bone marrow failure diseases in the United States;
  - Collect and store data on acquired bone marrow failure diseases;
  - Be made available to the general public and researchers to facilitate further research into the causes of, and treatments for, acquired bone marrow failure diseases.
- The CDC may award grants and enter into contracts and cooperative agreements with public or private nonprofit entities for the management, collection, analysis, and reporting of data to be included in the registry.
- The HHS Deputy Assistant Secretary for Minority Health shall establish and coordinate outreach and informational programs targeted to minority populations affected by acquired bone marrow failure diseases.
- \$3,000,000 is authorized for each of fiscal years 2010 through 2014.

*Advisory Committee*

- The CDC shall establish the Advisory Committee on Acquired Bone Marrow Failure Diseases. The Advisory Committee shall provide recommendations to HHS on the establishment and maintenance of the National Acquired Bone Marrow Failure Disease Registry, including recommendations on the collection, maintenance, and dissemination of data. HHS shall make the recommendations of the Advisory Committee publicly available.
- Members of the Advisory Committee shall be appointed by the Secretary of HHS, acting through the Director of the CDC, and shall include at least one representative from each of the following:
  - A national patient advocacy organization with experience advocating on behalf of patients suffering from acquired bone marrow failure diseases.
  - The NIH, including at least one representative from the NCI and NHLBI.
  - The CDC.
  - Clinicians with experience in diagnosing or treating acquired bone marrow failure diseases; and medical data registries.
  - Epidemiologists who have experience with data registries.
  - Publicly or privately funded researchers who have experience researching acquired bone marrow failure diseases.

- The entity operating the C.W. Bill Young Cell Transplantation Program and the C.W. Bill Young Cell Transplantation Program Outcomes Database.

#### *Status Update*

- Introduced by Rep. Doris Matsui (D-CA) on 2/26/09, for herself and has 29 cosponsors. The bill was referred to the Committee on Energy & Commerce.
- Rep. Matsui introduced an identical bill in the 110<sup>th</sup> Congress, which had 36 cosponsors.

### **Childhood Cancer Survivorship Research and Quality of Life Act of 2009 (H.R.2109):**

#### *NCI Provisions*

- NCI shall coordinate the activities of the NIH with respect to cancer survivorship, including childhood cancer survivorship.
- NCI shall provide guidance to states on projects and interventions that may be incorporated into state comprehensive cancer control programs to improve the long-term health status of childhood cancer survivors, including those in minority and other medically underserved populations;
- NCI shall improve existing surveillance systems or develop appropriate new systems for tracking cancer survivors and assessing their health status and risk for other chronic and disabling conditions.
- NCI shall make grants to conduct research relating to childhood cancer survivors and health disparities in cancer survivorship outcomes within minority or other medically underserved populations.

#### *NIH Provisions*

- NIH shall make grants to establish or improve training programs for health care professionals (including physicians, nurses, physician assistants, and mental health professionals) to improve the quality of immediate and long-term follow-up care for survivors of childhood cancers and their families; each grant shall be for a period of 2 years.
  - \$5 million is authorized, for this section, for each of fiscal years 2010 through 2014.
- NIH, in consultation with HRSA, shall make grants to establish a pilot program to develop, study, or evaluate one or more model systems for monitoring and caring for cancer survivors; and in developing, studying, and evaluating such systems.
  - \$10 million is authorized, for this section, for each of fiscal years 2010 through 2014.

#### *CDC Provisions*

- The CDC shall encourage states to incorporate strategies for improving systems of care for childhood cancer survivors and their families into state comprehensive cancer plans.
- The CDC shall enhance national, state, and local comprehensive cancer control programs to include a focus on childhood cancer survivorship and initiatives for improving the monitoring and follow-up treatment for childhood cancer survivors; especially those in minority and other medically underserved populations.

### *HHS Provisions*

- Requires HHS to make grants to pay all or a portion of the costs incurred during the first 4 years of establishing and operating a clinic for comprehensive long-term follow-up services for childhood cancer survivors. Priority will be given to any eligible entity that demonstrates an expertise in improving access to care for minority and other medically underserved populations.
- Requires HHS to make grants to recognized childhood cancer professional and advocacy organizations to improve physical and psychosocial care for childhood cancer survivors; especially those in minority or other medically underserved populations. \$10 million is authorized, for this section, for each of fiscal years 2010 through 2014.

### *Status Update*

- Introduced by Rep. Jackie Speier (D-CA) on 4/27/09 for herself and Reps. Bono Mack (R-CA), Capps (D-CA), Moran (D-VA), Kilroy (D-OH), Schakowsky (D-IL) and Sestak (D-PA) and has a total of 25 cosponsors.
- The bill was referred to the Committee on Energy & Commerce.
- A similar bill was introduced in the 110<sup>th</sup> Congress by former Rep. Hilda Solis (D-CA).

## **Colorectal Cancer Screening and Detection Coverage Act of 2009 (H.R.1330):**

- This bill requires that individual and group health plans, and Federal employees' health benefit plans provide coverage for colorectal cancer screening for any participant or beneficiary who is 50 years of age or older, or is an individual who is at high risk for colorectal cancer.
- Individual's first receiving benefits under such plan or coverage may require a waiting period of not more than 6 months beginning on the first date of coverage.
- A group health plan and health insurance issuer offering group coverage in connection with a group plan, may not deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan.
- The Secretaries of HHS, Labor, and Treasury shall coordinate to ensure, through the execution of an interagency memorandum of understanding, that regulations, rulings, and interpretations issued have the same effect at all times, and have a coordinated enforcement strategy that avoids duplication.

### *Status Update*

- Introduced by Rep. Dan Boren (D-OK) on 3/5/09. The bill has 23 cosponsors and was referred to committees on Energy & Commerce, Ways & Means, Education & Labor, and Oversight & Government Reform.
- The bill was referred to the House Subcommittee on Health, Employment, Labor and Pensions on 4/29/09.

## **Comprehensive Cancer Care Improvement Act of 2009 (H.R.1844):**

- Provides for coverage of comprehensive cancer care planning services to individuals diagnosed with cancer.

- Directs HHS to conduct a two-year demonstration project under which Medicare payments will be made for comprehensive cancer care symptom management services furnished by an eligible entity in accordance with a described plan.
- Directs HHS to make grants to eligible entities to:
  - Establish new, or expand existing, palliative care and symptom management programs for cancer patients;
  - Improve the quality of graduate and postgraduate training of physicians, nurses, and other health care providers in palliative care and symptom management for such patients; and
  - Improve the quality of continuing professional education provided to qualified individuals regarding palliative care and symptom management for cancer patients.
- Requires the NIH to establish a program of grants for research on palliative care, symptom management, communication skills, and other end-of-life topics for such patients.
  - In carrying out the program, NIH should provide for the participation of NCI, NINR, and any other national research institute that has been engaged in research on palliative care, symptom management, communication skills, and other end-of-life topics for cancer patients.

#### *Status Update*

- Introduced by Rep. Lois Capps (D-CA) on 4/1/09 for herself and Rep. Charles Boustany (R-LA). The bill has 42 cosponsors. The bill was referred to the Committees on Energy & Commerce and Ways & Means.
- In the 110<sup>th</sup> Congress, Rep. Lois Capps (D-CA) introduced an identical bill and Sen. Mary Landrieu (D-LA) introduced the Senate companion bill.

#### **Eliminating Disparities in Breast Cancer Treatment Act of 2009 (H.R.2279):**

- Promotes the implementation of standardized health care practices for breast cancer treatment under the Medicare program and eliminates disparities in the provision of care to such patients.
- HHS shall establish a 6-year breast cancer treatment quality performance system to assess and publicly disclose, through the use of quality measures, the quality of care provided for the treatment of breast cancer by health care providers.
- HHS shall establish and implement a value-based purchasing program, with respect to health care providers, which requires reduced payments to providers that either do not submit data in accordance with the reporting process or furnish low quality care for treatment of breast cancer.
- HHS shall enter into agreements with the National Quality Forum to identify a uniform set of consensus-based performance measures to evaluate the quality of care provided by health care providers for the treatment of breast cancer.

#### *HHS Reporting Requirements*

- HHS shall establish a reporting process that provides for the voluntary submission of data on the quality of breast cancer treatment by providers.

- Requires that information with respect to the quality demonstrated by a health care provider of breast cancer treatment is made available on the official public Internet site of the HHS.
- Ensures that a health care provider has the opportunity to review the information that is to be made public at least 30 days prior to the data being made public.
- Not later than October 1, 2011, and for each 6-month period thereafter (before fiscal year 2017), HHS shall submit to Congress a report that evaluates the number of specified health care providers that submit data and the effect of the performance system on reducing disparities in the provision of breast cancer treatment.

#### *Status Update*

- Introduced by Rep. Kathy Castor (D-FL) on 5/6/09 and has 13 cosponsors. The bill was referred to the committees on Ways & Means, and Energy & Commerce.
- Rep. Castor introduced a similar bill in the 110<sup>th</sup> Congress which had 33 cosponsors.

#### **Lung Cancer Mortality Reduction Act (H.R.2112/S.332):**

- Requires the Secretaries of DOD, HHS and the VA to coordinate in the development of the lung cancer mortality reduction program.

#### *Lung Cancer Advisory Board*

- The Secretary of HHS, in consultation with the DOD, VA, NIH, CDC, FDA, CMS, NCMHD, shall establish a Lung Cancer Advisory Board
- The Lung Cancer Advisory Board shall monitor the programs established under this Act and provide annual reports to the Congress concerning benchmarks, expenditures, lung cancer statistics, and the public health impact of such programs.
- The Board shall be comprised of the following:
  - The Secretaries of HHS, DOD, and VA;
  - Two representatives each from the fields of clinical medicine focused on lung cancer, lung cancer research, imaging, drug development, and lung cancer advocacy, to be appointed by the Secretary of HHS.

#### *HHS Provisions*

- Requires HHS to conduct a strategic review, prioritization and expansion of research grants, and expedite the development of computer assisted diagnostic, surgical, treatment and drug testing innovations.
- Requires HHS to establish an early disease research and management program targeted at the high incidence and mortality rates of lung cancer among minority and low-income populations.
- Requires AHRQ to conduct a biannual review of lung cancer screening, diagnostic, and treatment protocols, and the issuance of updated guidelines.
- Amends the Food, Drug and Cosmetic Act to expand access to investigational drugs and devices for the diagnosis, monitoring, or treatment of lung cancer; and to provide incentives for the development of:
  - Chemoprevention drugs for precancerous conditions of the lung;
  - Drugs for targeted therapeutic treatments and vaccines for lung cancer;
  - New agents to curtail or prevent nicotine addiction.

- Calls for the cooperation and coordination of all tobacco control and cessation programs within HHS to coordinate drug and other cessation treatments with early detection protocols.
- Calls for the cooperation and coordination of all minority and health disparity programs within HHS to adequately address the burden of lung cancer on minority and rural populations.

#### *NIH Provisions*

- Provides funds to enable the Airway Biology and Disease Branch of the NHLBI to expand its research programs to include predispositions to lung cancer, the interrelationship between lung cancer and other pulmonary and cardiac disease, and the diagnosis and treatment of these interrelationships.
- Provides funds to enable the NIBIB to expedite the development of computer assisted diagnostic, surgical, treatment, and drug testing innovations to reduce lung cancer mortality, such as through expansion of the Institute's Quantum Grant Program and Image-Guided Interventions programs.
- Provides funds to enable the NIEHS to implement research programs relative to the lung cancer incidence.

#### *Status Update*

- H.R. 2112 was introduced by Rep. Christensen on 4/27/09 and has 19 cosponsors. The bill was referred to the committees on Energy & Commerce, Armed Services and Veterans' Affairs.
- H.R. 2112 was referred to the Subcommittee on Health on 5/1/09 and to the Subcommittee on Military Personnel on 6/8/09.
- S.332 was introduced by Sen. Dianne Feinstein (D-CA) on 1/27/2009 for herself and Sen. Brownback (R-KS). The bill has 8 cosponsors and was referred to the Committee on Health, Education, Labor & Pensions.
- Former Sen. Chuck Hagel (R-NE) introduced a similar bill in the 110th Congress.

### **Mammogram and MRI Availability Act of 2009 (H.R.995):**

- This bill requires that group health plans provide coverage for diagnostic mammography for any woman 40 years old or older and for annual magnetic resonance imaging for women at high risk for breast cancer.
- Prohibits a group health plan from denying enrollment or renewal solely to avoid the requirements of this Act, providing monetary incentives to encourage women to accept less than such minimum protections, penalizing providers for providing care in accordance with this Act, or providing incentives to induce providers to provide care in a manner inconsistent with this Act.
- Applies such requirements and prohibitions to coverage offered in the individual market.

#### *Status Update*

- Introduced by Rep. Jerrold Nadler (D-NY) on 2/11/09 and has 40 cosponsors. The bill was referred to the committees on Energy & Commerce, and Education & Labor. On 3/23/09 it was referred to the Education & Labor, Subcommittee on Health, Employment, Labor & Pensions.

- Rep. Nadler introduced a similar bill in the 108<sup>th</sup> and 110<sup>th</sup> Congresses and had gathered 63 cosponsors in both previous congresses.

### **National Childhood Brain Tumor Prevention Network Act of 2009 (H.R.653/S.305):**

- This bill requires the NIH, acting through the NCI, to establish, administer, and coordinate a National Childhood Brain Tumor Prevention Network to:
  - Provide grants for research on the causes of and risk factors associated with childhood brain tumors;
  - Assemble a panel of experts to provide ongoing guidance and recommendations on research funded by the Network, including on a common study design and standard protocols; and
  - Designate a central laboratory to collect, analyze, and aggregate data with respect to research funded by the Network and to make such data and analysis available to researchers.
  - Submit to Congress an annual report with regards to the Network.
- The bill would authorize \$25 million for Fiscal Years 2010 through 2014.

#### *Status Update*

- H.R. 653 was introduced by Rep. Barbara Lee (D-CA) on 1/22/2009 has 14 cosponsors.
- S.305 was introduced by Sen. Charles E. Schumer (D-NY) on 1/22/2009 and has 1 cosponsor.
- The bills were referred to the House Committee on Energy & Commerce and the Senate Committee on Health, Education, Labor, & Pensions respectively.

### **Ovarian Cancer Biomarker Research Act of 2009 (H.R.1816/S.755):**

- Authorizes funding for a national clinical trial that will enroll at-risk women in a study to determine the clinical utility of using these validated ovarian cancer biomarkers.
- Authorizes the NCI to make grants for the discovery and validation of biomarkers for use in risk stratification for, and the early detection and screening of, ovarian cancer; including fallopian tube cancer or primary peritoneal cancer.
- Not later than the end of fiscal year 2010, and annually thereafter, the NCI shall submit a report to Congress on the cooperative agreements entered into and the grants made under this bill.
- Not later than the end of fiscal year 2010, and annually thereafter, the NCI shall submit a report to the Congress on the activities proposed by this bill.

#### *Ovarian Cancer Biomarkers Centers of Excellence*

- Requires NCI, in consultation NIH and the DOD Ovarian Cancer Research Program, to establish Ovarian Cancer Biomarker Centers of Excellence.
- NCI would be required to make available to the Centers banked serum and tissue specimens from clinical research funded by HHS.
- The bill authorizes the following types of research at the centers:
  - The development of new biomarkers, the refinement of existing biomarkers.
  - The clinical and laboratory validation of such biomarkers.

- The development and implementation of clinical and epidemiological research on the utilization of biomarkers for early detection and screening.
- The development of repositories for new tissue, urine, serum, and other biological specimens.
- Genetics, proteomics, and pathways of ovarian cancer.

#### *Biomarker Clinical Trial Committee*

- NCI shall establish an Ovarian Cancer Biomarker Clinical Trial Committee to assist with the design and implementation of one or more national clinical trials to determine the utility of using biomarkers for risk stratification, early detection and screening of ovarian cancer.
- The Committee shall consist of 11 voting members and such number of nonvoting members as the NCI Director determines appropriate.
- The members of the Committee shall be appointed by the NCI Director, in consultation with appropriate national medical societies, research societies, and patient advocate organizations.
- The voting members of the Committee shall select a chairperson from among such members.
- The Committee shall meet at the call of the chairperson or upon the request of the NCI Director, but at least four times each year.
- In designing and implementing the clinical trials, NCI shall provide for participation in the trial, the costs of enrollment to the centers, establishing a national data center and clinical guidelines for the medical community.

#### *Status Update*

- H.R.1816 was introduced by Rep. Berman on 3/31/09 and has 29 cosponsors. The bill was referred to the Committee on Energy & Commerce.
- S.755 was introduced by Sen. Barbara Boxer (D-CA) on 3/31/09 and has 1 cosponsor. The bill was referred to the Committee on Health, Education, Labor & Pensions.

#### **Pediatric Research Consortia Establishment (H.R.758/S.353):**

- The NIH, acting through NICHD, and in collaboration with all other Institutes of the NIH that support pediatric research, shall award grants, contracts, or cooperative agreements to public or nonprofit private entities to pay all or part of the cost of planning, establishing, and providing basic operating support for up to 20 national pediatric research consortia.
- Each consortium shall conduct basic, clinical, behavioral, social, and translational research, as well as training and demonstrations of advanced diagnostic and treatment methods relating to pediatrics.
- NIH shall provide for the coordination of information for the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.
- Each consortium shall be formed from a collaboration of cooperating institutions with a lead institution, meeting such requirements as may be prescribed by the NIH, including participation in a network of such consortium.

- Payments shall not exceed \$2,500,000 per year for each consortium in the first 5 year cycle. Support for a consortium established may be provided under this section for a period of 5 years and may be extended for additional periods of 5 years each.

*Status Update*

- H.R.758 was introduced by Rep. Diana DeGette (D-CO) on 1/28/2009 and has 31 cosponsors. The bill was referred to the House Committee on Energy & Commerce.
- S.353 was introduced by Sen. Sherrod Brown (D-OH) 1/29/09 and has 4 cosponsors. The bill was referred to the Senate Committee on Health, Education, Labor & Pensions.

**Prostate Research, Imaging, and Men's Education (PRIME) Act (S.756):**

- NIH, in consultation with the DOD, shall carry out a program to expand research on prostate cancer and provide the resources to develop innovative advanced imaging technologies for prostate cancer detection, diagnosis, and treatment comparable to state-of-the-art mammography technologies; \$100,000,000 is authorized, for this, for each of fiscal years 2010 through 2014.
- The national campaign shall include roles for HRSA, the HHS Office on Minority Health, CDC, and the CDC Office of Minority Health.
- NIH, in coordination with HHS and DOD, shall carry out research to develop an improved prostate cancer screening blood test using in-vitro detection. \$20,000,000 is authorized, for this, for each of fiscal years 2010 through 2014.
- HHS shall carry out a national public awareness and education campaign to increase the awareness of the need for prostate cancer screening and for improved detection technologies; \$10,000,000 is authorized, for this, for each of fiscal years 2010 through 2014.
- HHS shall establish a program to award grants to nonprofit private entities to test alternative outreach and education strategies to increase the awareness.
- Not later than 6 months after the enactment of this Act, HHS shall submit to Congress a report that details the strategy for implementing the requirements of this Act and the status of such efforts.
- Not later than 1 year after the enactment of this Act, and annually thereafter, HHS shall submit a report to Congress containing assurances that the provisions of this Act are fully implemented and certifies such compliance.

*Status Update*

- Introduced by Sen. Barbara Boxer (D-CA) on 3/31/09 and was referred to the Committee on Health, Education, Labor & Pensions. The bill has 1 cosponsor.
- In the 110<sup>th</sup> Congress, Sen. Boxer introduced an identical bill and Rep. Cummings introduced a companion bill in the House.

## **G. Tobacco**

### **This section provides information for the following bills:**

- Family Smoking Prevention and Tobacco Control Act (H.R.1256)
- Federal Tobacco Act of 2009 (S.579)
- Prevent All Cigarette Trafficking Act of 2009 or PACT Act (H.R.1676)
- Youth Prevention and Tobacco Harm Reduction Act (H.R.1261)

### Previously Introduced Bills:

#### **Family Smoking Prevention and Tobacco Control Act (H.R.1256/S.982):**

- Establishes FDA authority over tobacco manufacturers and their products and prohibit the FDA from regulating tobacco leaf. Clarifies that provisions do not apply to the producers of tobacco leaf, such as growers.
- Requires that proprietary and brand specific information be submitted to HHS regarding ingredients, nicotine delivery and all documents related to the toxicology, behavioral or physiological effects of their products and the smoke constituents the FDA identifies as harmful.
- Requires HHS to establish a Tobacco Products Scientific Advisory Committee.
- Provides for the testing of tobacco products, where appropriate for the protection of the public health.
- Requires HHS to establish tobacco product standards to protect the public health and set forth standards for the sale of modified risk tobacco products. Prohibits or limits the allowable levels of substances in a finished product.

#### *Status Update*

- H.R.1256 was introduced by Rep. Henry Waxman (D-CA) on 3/3/09 for himself and has 178 total cosponsors. The bill was referred to the committees on Energy & Commerce and Oversight & Government Reform. The bill passed the House on 4/2/09 by a recorded vote of (298-112) and was referred to the Senate.
- S.982 was introduced by Sen. Edward Kennedy (D-MA) on 5/5/09 and has 52 cosponsors. The bill was referred to the Committee on Health, Education, Labor & Pensions and passed favorably out of committee on 5/20/09. The bill passed the Senate with an amendment on 6/11/09.
- The bill became Public Law No: 111-31 on 6/21/09.

#### **Federal Tobacco Act of 2009 (S.579):**

- The bill prohibits tobacco products or nicotine-containing products from being regulated as a food, drugs, or devices under the Federal Food, Drug, and Cosmetic Act.
- Establishes a comprehensive Federal tobacco product regulatory program and to prevent use of tobacco products by youth.
- Establishes within HHS a “Tobacco Regulatory Agency,” which is not to be part of the Food and Drug Administration, or in any way be under the authority of the Commissioner of Food and Drugs.

- The Tobacco Regulatory Agency is to be headed by an administrator appointed by the President with the advice and consent of the Senate, who shall have the authority to perform the functions that relate to the subject matter of this Act, and have the authority to promulgate regulations for the efficient enforcement of this Act.

#### *Additional Background*

- This bill would place control of the tobacco industry under a newly created agency at HHS instead of the FDA, as HR 1256 (the Waxman bill) mandates.
- Both the Waxman and Burr bills would pay for the new federal regulation by imposing “user fees” on tobacco companies, but the Burr-Hagan bill would collect around \$1 billion for the government over the next decade while the Waxman measure would impose larger fees and collect more than \$5 billion.

#### *Status Update*

- Introduced by Sen. Richard Burr (R-NC) on 3/12/09 for himself and Sen. Kay Hagan (D-NC), both from a state with a multibillion-dollar tobacco industry.
- The bill was referred to the Senate Committee on Health, Education, Labor & Pensions and has 1 cosponsor.

### **Prevent All Cigarette Trafficking Act of 2009 or PACT Act (H.R.1676):**

- Prevents tobacco smuggling, to ensure the collection of all tobacco taxes; and include smokeless tobacco as a regulated substance.
- Amends the federal criminal code to treat cigarettes and smokeless tobacco as nonmailable and prohibit such items from being deposited in or carried through the U.S. mail.
- Prohibits a tobacco product manufacturer or importer from selling or delivering in states cigarettes not in compliance with model or qualifying state statutes.
- Limits the applicability of this Act with respect to Indian tribes and certain tribal matters.

#### *Status Update*

- Introduced by Rep. Weiner (D-NY) on 3/23/09 and has 3 cosponsors. The bill was referred to the Committee on the Judiciary. The committee held a hearing on 4/20/09 and approved the bill on 4/28/09. The bill was reported out of committee on 5/18/09.
- The bill passed the House on 5/21/09 and was sent to the Senate on 6/1/09. The bill was referred to the Committee on the Judiciary.
- The PACT Act was first introduced by Sen. Hatch in the 108<sup>th</sup> Congress. The bill passed the Senate that year (2004). Rep. Weiner introduced similar legislation in the 110<sup>th</sup> Congress that passed the House, but the Senate never took up the bill.

### **Youth Prevention and Tobacco Harm Reduction Act (H.R.1261):**

- Establishes, within HHS, the Tobacco Harm Reduction Center with certain authority to regulate tobacco products, headed by an Administrator, who shall have the authority to promulgate regulations to enforce this Act.

- The Administrator shall determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation.
- The Administrator shall determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users and the impact on the availability and use of tobacco products by minors.
- The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives.

*Status Update*

- Introduced by Rep. Steve Buyer (R-IN) on 3/3/09 and has 29 cosponsors. The bill was referred to the House Committee on Energy & Commerce.

## **IV. GLOSSARY OF TERMS**

### **Concurrent Resolutions (H Con Res or S Con Res):**

- Measures concerning the affairs of both houses, such as an expression of mutual sentiment of budget limits, the creation of a joint committee, agreement on a joint session or joint meeting, or agreement on the time of final adjournment of the whole Congress.
- A concurrent resolution must be adopted by both houses, but is not sent to the President for his signature and therefore does not have the force of law.

### **Simple Resolutions (H Res or S Res):**

- Measures that are formal expressions of opinion or proposals for action.
- A simple resolution deals with matters entirely within the prerogative of one chamber or the other. It requires neither passage by the other chamber, nor approval of the President and it does not have the force of law.

### **Joint Resolutions (HJ Res or SJ Res):**

- Joint resolutions require the approval of both houses and the signature of the President, just as a bill does, and has the force of law, if approved.
- Proposed amendments to the Constitution and continuing and supplemental appropriations are usually drafted as joint resolutions.

### **Continuing Resolutions:**

- Stopgap measures that keep all un-funded government operations running beyond the end of a fiscal year when any of the 13 annual spending bills have not been enacted.
- Continuing resolutions are also joint resolutions.

### **Suspension of the Rules:**

- A procedure used to pass bills in the House. On Monday and Tuesday of each week and during the last six days of a session, the Speaker may entertain a motion to suspend the rules of the House and pass a public bill or resolution.
- The motion to suspend the rules and pass a bill is debatable for 40 minutes, one half of the time in favor of the proposition and one half in opposition.
- The motion may not be separately amended but may be amended in the form of a manager's amendment included in the motion when it is offered.
- Because the rules may be suspended and the bill passed only by affirmative vote of the two thirds of the Members voting, a quorum being present, this procedure is usually used only for expedited consideration of relatively non-controversial public measures.

### **Companion bill:**

- A bill introduced in one chamber that is similar or identical to a bill introduced in the other chamber.