# Legislative Update
# For the
# Director's Consumer Liaison Group
# October 2008

## Activities of the 110th Congress

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***TABLE OF CONTENTS***



## Legislative Topics

## *I. CONGRESSIONAL BRIEFINGS AND MEETINGS*

March 11 — NCI Director Met with Representative Walsh – Dr. John Niederhuber, Director, NCI, had a courtesy visit with Representative James Walsh (R-NY), the Ranking Member of the House Appropriations Labor, HHS, Education Subcommittee.

March 12 — NCI Director Met with Representative McCollum – Dr. John Niederhuber, Director, NCI, had a courtesy visit with Representative Betty McCollum (D-MN) a member of the House Appropriations Labor, HHS, Education Subcommittee.

March 12 — NCI Director Met with Representative Simpson – Dr. John Niederhuber, Director, NCI, had a courtesy visit with Representative Mike Simpson (R-ID), a member of the House Appropriations Labor, HHS, Education Subcommittee.

March 13 — NCI Director Met with Representative Tsongas – Dr. John Niederhuber, Director, NCI, had a courtesy visit with Representative Niki Tsongas (D-MA). Rep. Tsongas is a new member with an interest in cancer issues.

March 13 — NCI Director Met with Representative Boyda – Dr. John Niederhuber, Director, NCI, had a courtesy visit with Representative Nancy Boyda (D-KS). Rep. Boyda is a new member with an interest in biotechnology and cancer issues.

March 31 — NCI Staff Participates in Cancer Care IOM Report Briefing – At the request of Angela Sharpe, Deputy Director for Health Policy, Consortium of Social Science Associations, Dr. Robert Croyle, Director, Division of Cancer Control and Populations Sciences, NCI, served as a moderator of a panel presentation on the IOM Cancer Care report entitled, "Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs." The briefing was sponsored through the office of Representative Lois Capps (D-CA).

April 8 — NCI Staff Speaks at Leukemia and Lymphoma Society Event – At the request of George Dahlman, Senior VP, Public Policy, Leukemia and Lymphoma Society (LLS), Dr. Lee Helman, Scientific Director, Center for Cancer Research, NCI, spoke to members of the LLS at an event for congressional staff.

April 14 — NCI Staff Speaks at New Jersey Health Fair – At the request of Representative Rodney Frelinghuysen (R-NJ), Dr. Elise Kohn, Senior Investigator, Center for Cancer Research, NCI, gave a keynote address at an event sponsored by the HealthCare Institute of New Jersey, entitled, "A Women's Health Care Summit." Representative Frelinghuysen attended the event.

April 15 — NCI Participates in the Congressional Black Caucus Braintrust Event – At the request of Bill Griffith, National Minority Quality Forum, Dr. Pebbles Fagan, Health Scientist, Tobacco Control Research Branch, NCI, participated in the Congressional Black Caucus Braintrust, National Minority Quality Forum 2008 Leadership Summit. Dr. Fagan spoke to physicians about smoking cessation programs that are making a difference.

April 23 NCI Staff Participates in Brain Cancer Research Briefing – At the request of Chris Gaston, staff to Representative Rush Holt (D-NJ), and Lindsay McAllister, staff to Representative Jan Schakowsky (D-IL), Dr. Howard Fine, Chief, Neuro-Oncology Branch, Center for Cancer Research, NCI, provided a briefing on brain cancer research.

May 23 Staff to Representative Tsongas Visited NIH – At the request of Celine McNicholas, staff to Representative Niki Tsongas (D-MA), she and Mr. Thomas McNicholas visited the NIH to tour the Clinical Center and to be briefed on nanobiology research activities at NCI. Dr. Sriram Subramanian, Senior Investigator, Head Biophysics Section, Laboratory of Cell Biology, NCI, will conduct the briefing on nanobiology. NCI participants included Michelle Bennett, Deputy Director, CCR; Julie Gold, Clinical Center Guide. Jeanette Contreras, NCI, coordinated the event.

July 14 Representative Ron Klein Visits NIH – At the request of Jeff Champaign, scheduler for Representative Ron Klein (D-FL), the Congressman and his staff visited NIH to meet with Dr. Elias Zerhouni, Director, NIH, and NHLBI and NCI staff. The group also toured NHLBI and NCI research facilities in the Clinical Research Center. Representative Klein was accompanied by his Health Legislative Assistant, James Cho, and Legislative Aide, Virginia Neale. Presenters included Dr. Alan Koretsky, Chief, Laboratory of Functional and Molecular Imaging, and Director of the NIH MRI Research Facility, NHLBI; Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research, Dr. Stanley Lipkowitz, Senior Investigator, Laboratory of Cellular and Molecular Biology and Dr. Sheila Prindiville, Director, Coordinating Center for Clinical Trials, NCI; and Dr. David Henderson, Deputy Director for Clinical Care, Clinical Center. Betsy Dean and Rosalind Gray, OLPA, also attended.

July 17 NCI Staff Speaks at Luncheon Briefing on Vaccines – At the request of Biotechnology Industry Organization (BIO), Dr. Helen Sabzevari, Head of the Molecular Immunology Group, NCI, spoke at a briefing for congressional staff on the general concept of a cancer vaccine, the history of vaccines, and the new uses for vaccines.

July 21 NCI Director Toured Hollings Cancer Center with Senator Graham – At the request of Edward Mercer, staff to Senator Lindsay Graham (R-SC), Dr. John Niederhuber, Director, NCI, accompanied Senator Graham and former Senator Ernest Hollings (D-SC) on a tour of the Hollings Cancer Center, located in Charleston, South Carolina.

August 4 Senator Cardin Visits NIH – At the request of Ken Reichard, staff to Senator Ben Cardin (D-MD), the Senator and Mr. Reichard visited the NIH to meet with Drs. Anthony Fauci, Director, NIAID; John Gallin, Director, NIH Clinical Research Center; Griffin Rodgers, Director, NIDDK; and John Niederhuber, Director, NCI. The Senator also toured the NIDDK Metabolic Clinical Research Unit and an NCI research laboratory and patient ward. NIH participants also included Drs. Monica C. Skarulis, M.D., Acting Director Metabolic Clinical Research Unit; Kong Chen,

Director, Metabolic Research Core, NIDDK; and Steven Rosenberg, Chief, Surgery Branch, NCI.

## *II. CONGRESSIONAL HEARINGS*

May 21 House Energy and Commerce Subcommittee on Health Holds Hearing on Breast Cancer and Environment Legislation – The House Energy and Commerce Subcommittee on Health (Representative Frank Pallone [D-NJ], Chairman), held a hearing on H.R. 1157, the Breast Cancer Research and Environment Act. Dr. Deborah Winn, Associate Director, Epidemiology and Genetics Research Program, NCI, testified.

July 16 Senate Appropriations Subcommittee on Labor, HHS, Education conducted NIH Overview Hearing – The Senate Appropriations Subcommittee on Labor, HHS, Education held an overview hearing on NIH and heard testimony from Dr. Elias Zerhouni, Director, NIH, accompanied by Drs. John Niederhuber, Director, NCI; Anthony S. Fauci, Director, NIAID; Elizabeth Nabel, Director, NHLBI; and Francis Collins, Director, NHGRI.

September 9 House Science Subcommittee on Investigations and Oversight Holds Hearing on Biorepositories – The House Science Subcommittee on Investigations and Oversight (Representative Brad Miller [D-NC], Chairman) held a hearing titled "Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplaceable Collection of Legionella Samples." Dr. Jim Vaught, Deputy Director, Office of Biorepositories and Biospecimen Research, NCI, testified about NCIs work in developing best practices for the extramural community regarding the use of biospecimen resources.

September 9 House Energy and Commerce Subcommittee on Health Holds Hearing on Implementation of the NIH Reform Act – The House Energy and Commerce Subcommittee on Health (Representative Frank Pallone [D-NJ], Chairman) held a hearing titled, "NIH Reform Act of 2006: Progress, Challenges and Next Steps." Dr. Elias Zerhouni, Director, NIH, testified.

September 25 House Oversight and Government Reform Committee Subcommittee on Domestic Policy holds hearing on cell phone use - The House Government Reform Committee Subcommittee on Domestic Policy (Representative Dennis Kucinich [D-OH], Chairman) held a hearing on titled, "*Tumors and Cell Phone Use: What the Science Says*". Dr. Bob Hoover, DCEG, NCI, testified.

## *III. PUBLIC LAWS*

### Fiscal Year 2007 Continuing Resolution (HJ RES 20):

- Became Public Law 110-5 on February 15, 2007.
- Under this joint resolution, NCI is funded at FY 2006 levels.

### Continuing Resolution FY 2008 (HJ RES 52):

- Became Public Law 110-92 on Sept. 29, 2007.
- Under this joint resolution, NCI is funded at FY 2007 levels.
- Expires November 16, 2007.

### Div. B - Second Continuing Resolution FY 2008 (HR 3222):

- Became Public Law 110-116 on November 13, 2007.
- Attached to the Defense appropriations bill.
- Under HR 3222, Div. B, NCI is funded at FY 2007 levels.
- Expires December 14, 2007.

### Third Continuing Resolution FY 2008 (HJ RES 69):

- Became Public Law 110-137 on December 14, 2007.
- Under this joint resolution, NCI is funded at FY 2007 levels.
- Expires December 21, 2007.

### Fourth Continuing Resolution FY 2008 (HJ RES 729):

- Became Public Law 110-149 on December 14, 2007.
- Under this joint resolution, NCI is funded at FY 2007 levels.
- Expires December 31, 2007.

### Fiscal 2009 Continuing Resolution (HR 2638, PL 110-329)

- Became Public Law 110-329 on September 30, 2008.
- This spending bill keeps most agencies funded at FY 2008 levels through March 6, 2009.
- Bill contains full-year fiscal 2009 funding for military construction and the departments of Defense, Veterans Affairs and Homeland Security.

### The State, Foreign Operations, and Related Programs Appropriations Act FY 2008 (HR 2764)

- Became Public Law 110-161 on December 26, 2007.
- HR 2764 became the vehicle for the 11 consolidated domestic spending bills after the Labor-HHS-Education bill was vetoed and the veto override was unsuccessful.
- The bill was broken into two separate amendments and two votes were held.
    - One for the domestic spending included as part of the omnibus bill
    - A second vote for the amendment primarily related to the war in Afghanistan
- The amendment covering the omnibus included $484.7 billion for the 11 remaining domestic spending bills (including NIH) and was adopted in the House by a vote of 253-154.
- The Senate passed the omnibus amendment by a vote of 76-17 on December 18th, and made changes to the amendment on the war funding.

- The House agreed to the Senate language and cleared the omnibus spending bill by a vote of 272-142.
- The omnibus includes $4.8 billion for the NCI, an increase of $12.5 million above FY 2007 and an increase of $23 million above the FY 2008 President's Budget.
- However, the amount in the omnibus is $120 million below the vetoed FY2008 Conference Report.

## National Breast and Cervical Cancer Early Detection Program Reauthorization Act of 2007 (HR 1132/S 624):

- Became Public Law 110-18 on April 20, 2007.
- HR 1132 was introduced by Rep. Tammy Baldwin (D-WI).
- S 624 was introduced by Sen. Barbara Mikulski (D-MD).
- Amends the Public Health Service Act (PHSA) to allow States to apply for federal waivers to spend a greater share of funds on hard-to-reach women that advocates say have been underserved.
- Authorizes funding up to $275 million by 2012; $201 million is authorized for 2007.

## Food and Drug Administration Amendments Act of 2007 (HR 3580):

- Became Public Law 110-85 on September 27, 2007
- Introduced by Rep. John Dingell (D-MI) on Sept. 19, 2007
- Amends the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the post market authorities of the Food and Drug Administration (FDA) with respect to the safety of drugs, and for other purposes.
- Of particular relevance for NIH, Title VIII expands the clinical trial registry (clinicaltrials.gov) and creates a clinical trial results database.
    - Enhances the current clinicaltrials.gov registry to include all stage II-IV clinical trials
    - Requires the registration of all applicable drug and device clinical trials that are ongoing 90 days after enactment (date of enactment: Dec. 26, 2007)
    - Sets up a results database in 3 phases.

## Breast Cancer Research Stamp Reauthorization Act (S 597):

- Became Public Law 110-150 on December 21, 2007.
- A bill to amend Title 39, United States Code, to extend the authority of the United States Postal Service to issue a semipostal to raise funds for breast cancer research.

## Openness Promotes Effectiveness in our National Government Act of 2007 or the OPEN Government Act of 2007 (S 2488):

- Became Public Law 110-175 on December 31, 2007.
- Amends the Freedom of Information Act (FOIA) to revise requirements for federal agency disclosures of information requested under that Act.
- The aim of this bill is to speed up the process for public access to government documents under the act PL 85-619, known as FOIA.

## Genetic Information Nondiscrimination Act of 2007 (HR 493):

- Became Public Law 110-233 on May 21, 2008.

- Forbids insurers and employers from requiring people to submit to genetic testing and from using genetic information to deny people insurance coverage, raise insurance premiums, or hire and fire workers.

## Fiscal Year 2008 War Supplemental Appropriations (HR 2642):

- Became Public Law 110-252 on June 30, 2008.
- This bill appropriates $186.5 billion in supplemental fiscal year 2008 and 2009 funds to cover costs relating to the wars in Iraq and Afghanistan, foreign aid and various domestic spending programs, including NIH.
- The NIH received an additional amount of $150 million, of which NCI received $25 million.

## Medicare Improvements for Patients and Providers Act (HR 6331):

- Enacted (over a president's veto) on July 15, 2008 and became PL 110-275.
- The law:
    - Prevents a 10.6 percent cut in payments to physicians treating Medicare patients that took effect on July 1, 2008.
    - Freezes current payment rates for 18 months and provides for a 1.1 percent increase in 2009.
    - Halts for one year a competitive bidding program under Medicare. The program, which requires durable medical equipment suppliers to compete for contracts, was designed to reduce Medicare spending.
    - Authorizes an additional $4 billion over five years and $16.6 billion over 10 years for changes to Medicare beneficiary programs. The law allows more beneficiaries to qualify for low-income assistance by adjusting asset requirements. For example, the law excludes life insurance from the asset test applied to beneficiaries.
    - Eliminates the higher co-payment rate for Medicare outpatient psychiatric services, which is currently 50 percent. The regular co-payment rate for medical services such as doctors' visits is 20 percent.

## Caroline Pryce Walker Conquer Childhood Cancer Act (HR 1553):

- Became Public Law 110-285 on July 29, 2008.
- This bill amends the Public Health Service Act to advance medical research and treatments into pediatric cancers, ensure patients and families have access to information regarding pediatric cancers and current treatments for such cancers, establish a national childhood cancer registry and promote public awareness of pediatric cancer.

## Medicare Improvements for Patients and Providers Act (HR 6331, PL 110-275):

- Became PL 110 – 275 on July 15, 2008.
- This bill was enacted over a Presidential veto.
- The law:
    - Prevents a 10.6 percent cut in payments to physicians treating Medicare patients that took effect on July 1, 2008.
    - Freezes current payment rates for 18 months and provides for a 1.1 percent increase in 2009.

- Halts for one year a competitive bidding program under Medicare. The program, which requires durable medical equipment suppliers to compete for contracts, was designed to reduce Medicare spending.
- Authorizes an additional $4 billion over five years and $16.6 billion over 10 years for changes to Medicare beneficiary programs. The law allows more beneficiaries to qualify for low-income assistance by adjusting asset requirements. For example, the law excludes life insurance from the asset test applied to beneficiaries.
- Eliminates the higher co-payment rate for Medicare outpatient psychiatric services, which is currently 50 percent. The regular co-payment rate for medical services such as doctors' visits is 20 percent.

## *IV. CONGRESSIONAL APPROPRIATIONS*

The House held fewer Appropriations hearing this year than in past years. In a single hearing, "Health Issues and Opportunities" on March 5, 2008, the Labor, HHS, Education Subcommittee heard testimony from the Directors of the National Institutes of Health, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, and the Agency for Health Research and Quality. Individual NIH Institutes did not have the opportunity to testify, but did submit written statements for the record.

In the House, the Labor, HHS, Education Appropriations Subcommittee marked up its draft bill on June 19, 2008. The bill would provide $30.238 billion for NIH, and $4.975 billion for NCI. The full Committee was scheduled to mark up the bill on June 26, 2008, but they adjourned before taking action. Representative Obey (D-WI) Chairman of both the Labor, HHS, Education Subcommittee and the full Appropriations Committee, halted the scheduled markup rather than allow Rep. Jerry Lewis to add an offshore drilling amendment to the bill. In the Senate, the draft bill was marked up by the Subcommittee on June 24, 2008, and the full Committee on June 26, 2008. The Senate bill, S 3230, would provide $30.113 billion for NIH, and $4.959 billion for NCI, and was reported by the Committee on July 8, 2008.

The Senate held an NIH overview hearing on July 16, 2008, with Dr. Zerhouni serving as the principal witness, accompanied by the Directors of NCI, NIAID, NHLBI, and NHGRI. Senator Harkin, Subcommittee Chairman, and Senator Specter, Ranking Member, bemoaning the fact that NIH funding amounts in the appropriation bill would not be sufficient to restore the purchasing power of NIH's budget after five consecutive years of inflationary cuts, stated their intention to introduce a supplemental spending bill to add $5.2 million to the NIH appropriation. They introduced S 3272 later that day. The NIH witnesses were encouraged to offer to the Subcommittee a vision of what the future should look like from both a science and a budgetary standpoint. Dr. Niederhuber noted that an increase of $2 billion a year for 5 years would greatly help NCI build capacity in terms of attracting young people and disciplines that haven't worked on cancer to begin working on cancer.

Congress was not able to pass stand alone appropriations bills for most of the federal agencies dependent on annual funding. Instead, a continuing resolution was passed (PL 110-329) that funds the government through March 6, 2009. It is likely that congress will not return after the November elections but choose to wait until the beginning of a new congress to take up federal funding issues.

### FY 08 – Supplemental Appropriations

Additional funds to be used in FY 2008 were provided to NIH and NCI through a supplemental spending bill that was signed into law on June 30, 2008. The purpose of the bill was to provide $186.5 billion to cover costs relating to the wars in Iraq and Afghanistan, for aid, and various domestic spending programs including NIH. As a result, NIH received an additional $150 million in FY 2008, of that amount, NCI receives $25 million.

## This section provides information for the following bills:

- Fiscal 2009 Continuing Resolution (HR 2638, PL 110-329)
- Fiscal 2009 Senate Budget Resolution (S CON RES 70)
- Fiscal 2009 Labor-HHS-Education Appropriations (S 3230)
- National Cancer Fund (HR 6791)
- NIH Emergency Supplemental (S 3272)
- Fiscal Year 2008 War Supplemental Appropriations (HR 2642, PL 110 - 252)
- Fiscal Year 2009 Financial Services Appropriations (S 3260)

## Fiscal 2009 Continuing Resolution (HR 2638, PL 110-329):

- HR 2638 was introduced by Rep. David Price (D-NC) on June 8, 2007, and has no reported co-sponsors.
- This spending bill keeps most agencies funded at FY 2008 levels through March 6, 2009.
- Bill contains full-year fiscal 2009 funding for military construction and the departments of Defense, Veterans Affairs and Homeland Security.
- The bill passed the House on September 24, 2008 (370 – 58) and passed the Senate on September 27, 2008 (78-12).
- The President signed the measure on September 30, 2008. (P.L. 110 – 329).

## Fiscal 2009 Senate Budget Resolution (S CON RES 70):

- S CON RES 70 was introduced by Sen. Kent Conrad (D-ND) on March 7, 2008, and has no cosponsors.
- The budget resolution conference agreement was passed by both the House and the Senate the first week of June, 2008.
- The conferees agreed that it would provide the House and Senate Appropriations committees with $1 trillion discretionary budget authority (appropriations) for fiscal 2009, $20.1 billion, or 2 percent, more than the president's proposed budget.

## Fiscal Year 2009 Labor-HHS-Education Appropriations (S 3230):

- S 3230 was introduced on July 8, 2008, by Sen. Tom Harkin (D-IA) and has no reported cosponsors.
- This bill makes appropriations for the Departments of Labor, Health and Human Services and Education, and related agencies for the fiscal year ending September 30, 2009.
- This bill is accompanied by S. Report 110-410.
- The Senate Appropriations Subcommittee on Labor, Health and Human Services held a hearing on July 16, 2008.
    - Drs. Zerhouni, Director, NIH, testified.
    - Dr. Niederhuber, Director, NCI, participated in the hearing but did not make an opening statement.
- S 3230 would provide $631 billion ($152.7 billion in discretionary spending) in fiscal year 2009 for the departments of Labor, Health and Human Services and Education and related agencies.
    - The measure would provide $30.2 billion for the National Institutes of Health, which would be $1 billion more than fiscal 2008 and $1 billion more than the president's request.

- The National Cancer Institute would receive $4.95 billion, which would be nearly $150 million more than the president's request and $153 million more than the FY 2008 appropriation.

## National Cancer Fund Act of 2008 (HR 6791):

- HR 6791 was introduced by Rep. Brian Higgins (D-NY) on August 1, 2008, and is cosponsored by Rep. Steve Israel (D-NY).
- This bill would establish a National Cancer Fund (The Fund) in the Treasury of the United States.
- The Fund would be used
  - to make expenditures for cancer research
  - develop and expand NIH cancer programs
  - study the long term effects of cancer treatment on cancer survivors
  - expand the breast, colorectal, and cervical cancer early detection program
  - implement a nationwide tobacco cessation program
  - expand and support regulatory sciences to speed the development of biomarkers, advanced disease modeling, co-development of diagnostics and therapeutics, enhance clinical trial design and expedite delivery of effective cancer treatments to patients
- The Fund would be funded through an increase in excise taxes on tobacco products.
- The bill would also make several changes to the President's Cancer Panel (Panel).
  - The Panel will have 5 members (currently the Panel has 3).
  - Members of the Panel will be appointed for 5 year terms (current term is 3 years).
  - The Panel shall submit a periodic progress report on the National Cancer Program that contains an evaluation of the efficacy of the National Cancer Program and suggestions for improvement.
  - The Panel shall submit an annual report of the short and long-term needs and opportunities of federally funded cancer programs and make recommendations on how funds from the National Cancer Fund could be used to better integrate and coordinate these activities.
  - The Panel will convene one or more meetings to examine the feasibility of additional sources (other than tobacco excise taxes) of funding that could be credited to the National Cancer Fund and will issue a one-time report on which supplemental funding sources for federally funded cancer programs would provide the greatest opportunities for strengthening these programs.

## NIH Emergency Supplemental Appropriations Act of 2008 (S 3272):

- S 3272 was introduced by Sen. Arlen Specter (R-PA) on July 16, 2008, and has 6 cosponsors (2 D, 4R).
- This bill would make emergency supplemental appropriations for the National Institutes of Health for the fiscal year ending Sept. 30, 2008.
- The NIH Office of the Director would receive $4 billion.
- The National Cancer Institute would receive $1.2 billion.

## Fiscal Year 2008 War Supplemental Appropriations (HR 2642, PL 110 - 252):

- HR 2642 was introduced by Rep. Chet Edwards (D-TX) on June 11, 2007, and was signed into law on June 30, 2008.

- This bill appropriates $186.5 billion in supplemental fiscal year 2008 and 2009 funds to cover costs relating to the wars in Iraq and Afghanistan, foreign aid and various domestic spending programs including NIH.
- The NIH received an additional amount of $150 million, of which NCI received $25 million.

## Fiscal Year 2009 Financial Services Appropriations (S 3260):

- S 3260 was introduced by Sen. Richard Durbin (D-IL) on July 14, 2008 and has no reported cosponsors.
- On July 14, the Senate Appropriations Committee (Senator Robert Byrd [D-WV], Chairman) reported (S. Rept. 110-417) S. 3260, the FY 2009 appropriations bill for financial services and general government.
- Provisions of interest include:
    - a 3.9 percent cost of living increase for Federal employees
    - a new provision that would place a year-long moratorium on the announcement of A-76 studies or competitions
    - a new provision requiring each agency to submit a report to OMB stating the total size of its workforce, differentiated by number of civilian, military, and contract workers as of December 31, 2008.
- OMB is required to submit a statement to the Appropriations Committee delineating the workforce data by individual department and agency, as well as aggregate totals of civilian, military, and contract workers.

## *V. FEDERAL HEALTH CARE POLICY*

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

- Assure Access to Mammography Act of 2008 (HR 5711)
- Compensation and Respect for Energy Workers Act of 2008 (HR 6766)
- Comprehensive Cancer Care Improvement Act of 2008 (S 2790)
- Family Smoking Prevention and Tobacco Control Act (HR 1108)
- Federal Advisory Committee Act Amendments of 2008 (HR 5687)
- Federal Financial Assistance Management Improvement Act of 2008 (S 3324)
- Genetic Information Nondiscrimination Act of 2007 (HR 493/S 358)
- Genomics and Personalized Medicine Act of 2008 (HR 6498)
- Medicare Improvements for Patients and providers Act (HR 6331, PL 110-275)
- Nevada Cancer Institute Expansion Act (HR 1311/S 758)
- Physicians Payments Sunshine Act of 2008 (HR 5605)

### Assure Access to Mammography Act of 2008 (HR 5711):

- HR 5711 was introduced by Rep. Anthony Weiner (D-NY) on April 23, 2008, and has 1 cosponsor (Peter King, D-NY).
- Referred to the House Energy and Commerce and House Ways and Means Committees.
- Amends part B (Supplementary Medical Insurance) of title XVIII (Medicare) of the Social Security Act to establish a floor for payment of screening and diagnostic mammography under the Medicare Program.
- Sets the payment floor for 2009 at 115% of the fee scheduled amount for mammography for 2008, increased by the percentage increase in the Medicare Economic Index (MEI).
- Requires the payment floor for subsequent years to be the previous year's amount, again increased by the percentage increase in the MEI.

### Compensation and Respect of Energy Workers Act of 2008 (HR 6766):

- HR 6766 was introduced by Rep. Mark Udall (D-CO) on July 31, 2008, and is cosponsored by Rep. Perlmutter (D-CO).
- This bill would amend the Energy Employees Occupational Illness Compensation Program Act of 2000 to expand the category of individuals eligible for compensation.
- Specifically this bill would expand the eligible cancer diagnoses for which individuals are eligible to receive compensation under the Energy Employees Compensation program Act of 2000 and the Radiation Exposure Compensation Act.
- Eligible cancer diagnoses are expanded to include chronic lymphocytic leukemia, parathyroid adenoma, malignant tumors of the brain and central nervous system, brochio-alveolar carcinoma, benign neoplasms of the brain and central nervous system, lung, skin, kidney, salivary gland, rectum, pharynx, and prostate.

### Comprehensive Cancer Care Improvement Act of 2008 (S 2790):

- S 2790 was introduced by Sen. Mary Landrieu (D-LA) on March 31, 2008, and has 4 cosponsors (3 D, 1 R).
- Referred to the Senate Finance Committee.
- Amends title XVIII (Medicare) of the Social Security Act to provide for coverage of comprehensive cancer care planning services to provide individuals diagnosed with cancer a plan that details all aspects of the care to be provided.

    - Requires the Secretary of Health and Human Services to establish standards for such services.
- Directs the Secretary 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 the Secretary 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 Director of the National Institutes of Health (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.

## Family Smoking Prevention and Tobacco Control Act (HR 1108):

- HR 1108 was introduced by Rep. Henry Waxman (D-CA) on Feb. 15, 2007, and has 233 cosponsors (192D, 41R).
- The bill had been marked-up in the House by the Energy and Commerce Subcommittee on Health (March 2008) and then by the full House Energy and Commerce Committee in April 2008.
    - During the full Committee mark-up, in an effort to win consensus among Republican members, Democrats agreed to incorporate, through a manager's amendment, several Republican suggestions offered at the subcommittee markup.
    - The manager's amendment further modified the user fees section, which Republicans had strenuously objected to at the subcommittee markup.
    - The substitute amendment at the subcommittee markup included a provision that would allow the Congressional Budget Office to determine a percentage increase that each year would be added on to the tobacco user fee.
        - The user fee would apply to tobacco manufacturers and importers and would help the FDA fund implementation of the new tobacco regulations. But the funds from the increase would go to the Treasury, according to the amendment.
    - At the March 6, 2008 markup, the panel's ranking Republican, Joe L. Barton of Texas, argued that the provision was not germane because the fees amounted to a tax and, therefore, fell outside the jurisdiction of the committee.
    - The manager's amendment at the full committee markup removed that language from the bill, instead specifically noting fee levels that increase each year.
    - The House Ways and Means Committee had stalled floor consideration of the bill, arguing that the original measure contained tax provisions.
    - Henry A. Waxman, D-Calif., and John D. Dingell, D-Mich., had agreed to drop the offending offset provision but were sent looking for a new one that would make the bill comply with pay-as-you-go budget rules.
    - In July 2008, committee members announced a new deal had been reached on the measure.

        - To solve the problem, members tacked on another Waxman bill regarding the Federal Thrift Savings Plan (HR 6500).
        - Provisions in the bill dealing with retirement accounts had a sufficient amount of savings left over to offset costs associated with the tobacco bill provisions, according to Waxman.
- Several Republicans, including House Minority Leader John A. Boehner, R-Ohio, continued to oppose the measure on the grounds that the measure created unnecessary government regulation.
- The White House issued its veto threat on July 30, 2008, before the House voted.
    - In a statement, the administration said the bill would "undermine one of the nation's premier public health and regulatory institutions and potentially lead the public to mistakenly conclude some tobacco products are safe."
    - The administration argues that the bill would divert the FDA from its primary responsibilities, such as reviewing new pharmaceutical drugs and overseeing food safety.
    - The White House also objects to the user fees on cigarettes that would be levied under the bill to pay for the FDA's new regulatory activities, calling them "a new tax that would be paid disproportionately by low-income individuals."
- Nevertheless, the House passed the bill, 326-102, on July 30, 2008.
- The Senate did not vote on HR 1108 before Congress adjourned before the November elections.
- **Provisions in HR 1108:**
- The FDA would have the authority to regulate the manufacture, transport, sale, labeling and advertising of tobacco products. The legislation would direct the FDA to create new regulations to prevent and control the trafficking of tobacco products.
- As amended by the House Energy and Commerce Committee, the bill would clarify that the FDA should be recognized as the primary federal authority with respect to tobacco products.
- As amended by the House, the bill would give the FDA authority to regulate tobacco, cigarette tobacco, smokeless tobacco and roll-your-own tobacco.
- It would require the secretary to publish a final rule regarding cigarettes and smokeless tobacco within six months of enactment. It would make the final rule effective one year after enactment.
- The FDA would not have any ability to regulate the agricultural side of tobacco. This includes the growing, cultivating or curing of tobacco.
- As amended by the Energy and Commerce Committee, the bill would prohibit foreign-grown tobacco from having a level of pesticide, insecticide, herbicide or fungicide in excess of any level that is applicable to domestically grown tobacco. It would require tobacco products containing foreign-grown tobacco to meet the same standards applicable to domestically grown tobacco.
- As amended by the Energy and Commerce Committee, the bill would define a "small tobacco product manufacturer" as a manufacturer with fewer than 350 employees. It would clarify that the secretary shall require tobacco manufacturers to comply with good manufacturing practices or hazard analysis and critical control point methodology.
- It would prohibit the secretary from requiring small tobacco manufacturers to comply with good manufacturing practices or hazard analysis and critical control point methodology for at least four years after the effective date of the regulations.

- It would provide small tobacco manufacturers additional time to comply with the testing and reporting requirements of the bill. It would allow them at least two years to comply with testing and reporting requirements. It also would allow small manufacturers four years after that to finish testing all products.
- As amended by the Energy and Commerce Committee, the bill would require the Federal Trade Commission (FTC) to conduct a study on the causes and effects of concentration in the tobacco industry. It would require the FTC to transmit a public report to Congress within five years of enactment and another report 10 years after enactment.
- It also would require the FTC to include in the report information on the trends in market share of any dominant tobacco manufacturer, the trends in competition in the industry and any recommendations to Congress on corrective action to address tobacco industry concentration.
- Rules for regulating tobacco first promulgated by the FDA in 1996 would be enacted through the bill. However, the FDA would have the latitude to amend those rules to conform to technological and legal developments that have arisen within the past 11 years; for example, the rise of the Internet as an advertising medium.
- As amended by the Energy and Commerce Committee, the bill would require the FDA to endeavor to consult with other federal agencies as appropriate prior to issuing rules.
- As amended by the Health Subcommittee, the bill would subject new tobacco products to pre-market review.
- The FDA would be prohibited from banning tobacco products. Congress would exclusively reserve this right. Requiring, through regulation, the amount of nicotine in a tobacco product to be zero would be prohibited. The FDA would not be allowed to require a prescription for the purchase of a tobacco product. Regulatory authority over tobacco labels would be transferred from the FTC to the FDA. Also, the FDA would have some authority to regulate the content of advertising for "modified-risk" tobacco products.
- Under current law, a product may be pulled from the market if it is "misbranded." Product manufacturers, importers and distributors also may be hit with fines and jail time for misbranding violations. This provision of current law would be the enforcement mechanism of the tobacco regulations, and the bill outlines all of the ways in which a tobacco product would be considered "misbranded." A product would be considered misbranded:
    - If its labeling is false or misleading.
    - If the container does not say the percentages of foreign-grown versus American-grown tobacco and "sale only allowed in the United States."
    - If the product does not contain all warnings required by FDA regulations, and if those warnings are not displayed "prominently" compared with other writing on the packaging.
    - If the product does not comply with any other required label statements.
    - If tobacco manufacturers or processors, either foreign or domestic, are not registered with the FDA or have not complied with all registration requirements.
    - If the tobacco product does not comply with a "tobacco product standard." Tobacco product standards include restrictions on flavorings allowable in cigarettes, allowable amounts of nicotine above zero and restrictions on harmful constituent parts in cigarettes or cigarette smoke.
    - If a tobacco manufacturer does not supply the FDA with information requested relating to the safety, ingredients, health effects, marketing efforts or marketing effects.

    - If an additive is put into, or eliminated from, a tobacco product and the manufacturer does not notify the FDA of that change within a required time period.
- Misbranding requirements would have extensive product label requirements. All new boxes of cigarettes would include a warning in addition to the surgeon general's warning. Those nine approved warnings would range from mild, "WARNING: Cigarettes are addictive," to intense, "WARNING: Smoking can kill you."
- As amended by the House, the bill would specify the font sizes in which the warning must appear depending on the type of advertising.
- As amended by the House, the bill would require the secretary to develop an action plan to enforce labeling and advertising requirements within six months of enactment.
- As amended by the Energy and Commerce Committee, the bill would further clarify the proposed tobacco standards. It would require that the proposed tobacco standard notice shall invite interested persons to submit comments.
- It would clarify that in adopting a tobacco product standard, the secretary shall consider scientific evidence concerning the risks and benefits to the population as a whole.
- It would clarify that a person objecting to a proposed tobacco product standard on the grounds that the standard will not reduce or eliminate the risk of illness or injury may provide scientific evidence to that fact.
- It also would require the secretary to consider the technical achievability of compliance with a proposed tobacco standard. It also would require the secretary to consider the technical achievability of compliance and any existing patents that could make compliance difficult when establishing an effective date of a proposed tobacco standard.
- HR 1108 would create regulations specifically related to light, low-tar, mild and other types of modified-risk tobacco products. This class of tobacco products would be more strictly regulated than regular tobacco products.
- As amended by the Health Subcommittee, it would allow the secretary of Health and Human Services to require prior approval of all label statements. It also would allow the secretary to restrict the sale or distribution of tobacco products, including advertising and promotion.
- As amended by the Health Subcommittee, it would allow the secretary to take specified actions, including public notification and recall, against unreasonably harmful products.
- The bill would prohibit the sale of all modified-risk tobacco products unless the FDA has approved the sale of the product. An application for a modified risk product would only be approved if it "significantly [reduced] harm and the risk of tobacco-related disease to individual tobacco users," and "[benefited] the health of the population as a whole taking into account both users of tobacco products and persons who currently use tobacco products."
- Modified-risk tobacco products would face further restrictions on the content of advertisements, to the extent allowable under the First Amendment. For example, marketing claims comparing one or more tobacco brands would have to use widely available products for their points of comparison. If a tobacco company wanted to claim their cigarette had "reduced tar," HR 1108 would require that brand to include on the label how much the tar levels had been reduced compared to other equivalent brands.
- Because modified-risk products would be regulated, the FDA would have the authority to withdraw a product's application, thereby removing the product from the market. This could be done if an applicant was found to have lied on their application, if the claims made by the applicant could no longer be proven or verified, if the tobacco product

standard for that product changed and the product failed to meet that standard or if an applicant failed to report any required information.

- As amended by the Energy and Commerce Committee, the bill would ensure the following phrases do not constitute modified-risk claims under the bill: smokefree; smoke-free; without smoke; no smoke; and not smoke.
- It also would direct the secretary to issue regulations or guidance within two years of enactment to establish a timeframe to review modified-risk product applications.
- As amended by the Health Subcommittee, it would prohibit cigarettes from containing any artificial or natural flavor other than tobacco or menthol.
- As amended by the Energy and Commerce Committee, it would define what a "characterizing flavor" is as it relates to tobacco product standards.
- As amended by the House, it would require the Secretary to conduct a study on the impact of menthol in cigarettes on the public health, particularly on African-American, Hispanic and minority health. The secretary would provide a report and recommendations to the appropriate congressional committees within one year of enactment.
- As amended by the Health Subcommittee, it would reinstate FDA's 1996 Rule, which restricted tobacco marketing and sales to youth. It also would require the secretary to establish a Tobacco Products Scientific Advisory Committee.
- As amended by the House, it would require the establishment of the advisory committee within six months of enactment.
- Retailers — whose primary business is tobacco and who allow access to their business by minors — would have to comply with new advertising requirements promulgated by the FDA. The legislation also would prevent the FDA from prohibiting face-to-face tobacco sales by specific classes of establishments. For example, prohibiting tobacco sales in drug stores would not be allowed.
- As amended by the Health Subcommittee, it also would establish a schedule of fines for violations by retailers that considers whether a retailer has training programs for employees.
- Retailers would be protected against accidental sales of tobacco to minors by a "good faith" clause in the bill. Good faith would be demonstrated if a retailer has: adopted and enforced a written policy about sales to minors, informed employees of relevant laws, established punishments for employees who violate that law and require employees to verify a purchaser's age using a government-issued photo-ID or an electronic scanning device.
- As amended by the Health Subcommittee, it also would clarify that a retailer cannot be held liable for a violation if a minor presents a false government-issued ID.
- As amended by the full committee, the bill would require the secretary of Health and Human Services to issue regulations within 18 months of enactment regarding the sale and distribution of tobacco products in other than direct sales, such as mail or Internet orders.
- It would direct the secretary to enforce provisions of the act with respect to American Indian tribes.
- It would require the secretary to send each notice of retailer violation to the location specified on the retailer's registration or the retailer's registered agent.
- It would require the secretary to consider whether a retailer has taken effective steps to prevent violations of the age requirements. It would clarify the time period within which a retailer shall be subject to civil penalties in the case of a sixth or subsequent violation.
- It also would direct the secretary to coordinate with states in enforcing the law and to consider any penalties paid by a retailer to a state when determining federal civil penalties.

- It would ensure that retailer liability for warning labels and advertising is consistent between cigarettes and smokeless tobacco products.
- HR 1108 would give fast-track approval of anti-nicotine products, such as the patch or nicotine gum. The bill also would direct the FDA to consider approving such products for long-term use.
- As amended by the Energy and Commerce Committee, the bill would clarify that no samples of smokeless tobacco products may be distributed to any person younger than the minimum age requirement.
- The bill would establish a user fee assessment and collection system to provide the FDA the necessary funding to implement the new tobacco regulations.
- The bill would charge each manufacturer and importer a "user fee." The fees would be allocated among the manufacturers and importers based on their respective shares of the U.S. tobacco market.
- As amended by the Energy and Commerce Committee, for fiscal years 2008 to 2018, the bill would specifically note the user fees for each year to ensure the bill has a deficit-neutral impact on the federal budget.
- As amended by the Health Subcommittee, it would prohibit the FDA from using any funds other than those raised through the user fees provision in the bill to execute the tobacco regulations.
- As amended by the House, it would allow the secretary to begin collections of unpaid fees if the fee is not received within 30 days.
- As amended by the Energy and Commerce Committee, it would require the Government Accountability Office to conduct a study on youth tobacco use and the feasibility of structuring the user fee based on a manufacturer's share of the youth market.
- As amended by the House, the bill would allow the secretary to contract with states to enforce the act. It would prohibit the secretary from entering into a contract with a state to enforce the act on American Indian tribal lands without the tribe's express permission.
- The bill would not affect any legal action pending at the time of enactment in any federal or state court. The bill would be inoculated against being overturned wholesale due to the severability provision, which says that if any portion of the bill is found to be unconstitutional the remainder of the bill is still sound law.
- As amended by the Health Subcommittee, the bill would specify that any rules made by the FDA under the law would have to comply with Title 5, Chapter 5 of the U.S. Code, which governs administrative rulemaking procedures.
- As amended by the Energy and Commerce Committee, it would require the secretary to convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products and submit a report to Congress on its findings no later than five years after enactment.
- It would provide a definition for a "tobacco warehouse" to include any person who removes foreign material from tobacco leaves through nothing other than a mechanical process, humidifies the leaf with nothing other than potable water in the form of steam or mist or de-stems, dries and packs leaf tobacco for storage and shipment.
- It would require a study on the illicit trafficking of tobacco products. It would require that the study also collect data on the health effects — particularly with regard to individuals under the age of 18 — resulting from cross-border trade in tobacco products. It would require the study to consider the health effects on minors of illicit trade of tobacco products, the trade of counterfeit tobacco products and the differing tax rates of tobacco products.

- **Thrift Savings Plan provisions in HR 1108:**
- As amended by the House, the bill would provide for the automatic enrollment of new federal employees into the Thrift Savings Program. The bill would allow participants to decline the automatic enrollment or modify the amount contributed to the plan.
- Employees could designate where their money is invested, with choices limited to funds that are low-cost, passively-managed and diverse. If employees do not designate specific investments for their funds, the money would be invested in the Government Securities Investment Fund or alternative funds.
- A fiduciary would not be liable for providing automatic enrollment or enrolling a participant in a default investment fund. The savings program also would be amended to allow contributions to a qualified Roth program.
- The bill would require the board that administers the program to file report to Congress on the Thrift Savings Plan, including information on how many people participate and information on their median balances. Participants would be given periodic statements outlining management fees and administrative expenses.
- The bill also would include an acknowledgment of risk by employees who opt out of the Government Securities Investment Fund.
- The bill would attempt to ensure the diversity of demographics be taken into consideration when a company or adviser is retained to manage assets in a thrift savings account.

## Federal Advisory Committee Act Amendments of 2008 (HR 5687):

- HR 5687 was introduced by Rep. William Clay (D-MO) on April 3, 2008, and is cosponsored by Rep. Henry Waxman (D-CA).
- The House passed HR 5687 on June 24, 2008.
- The bill would require that all appointments to advisory committees be made without regard to political affiliation or political activity.
- The bill also
    - Expands conflict of interest disclosure
    - extend advisory committee membership requirements to ad hoc members who attend meetings "regularly"
    - curtails the ability of contractors to create "FACA-type" committees
    - and expands transparency requirements (for example, who nominated each member and why the selectee was appointed).

## Federal Financial Assistance Management Improvement Act of 2008 (S 3324):

- S 3324 was introduced by Sens. Senators George Voinovich (R-OH) and Joseph Lieberman (I-CT) on July 26, 2008.
- The bill would reauthorize P.L. 106-107, which required consolidated grants management systems across the government (grants.gov).
    - It was due to sunset after 8 years, and this bill would codify the law permanently.
- This bill would add two new provisions, including establishing a public web site for Federal grant applicants and requiring the Director of the Office of Management and Budget to submit a strategic plan to establish a Web-based process for managing Federal financial assistance and to streamline the application process for and management of assistance.

- The bill was referred to the Committee on Homeland Security and Governmental Affairs, which reported the bill out of Committee on July 30, 2008 without amendment.

## Genetic Information Nondiscrimination Act of 2007 (HR 493/S 358):

- HR 493 was introduced by Rep. Louise Slaughter (D-NY) on Jan. 16, 2007, and became Public Law 110-233 on May 22, 2008.
- Senate Report 110-048 specifically addresses clinical trials:
    - "Genetic Services: The committee believes that, in addition to discrimination based on actual genetic information, there is potential for discrimination based on the mere action of requesting or receiving a genetic service. For example, a health plan could potentially wrongly assume that a participant has a genetic disorder, such as Huntington's disease, because the participant, or his or her family member, requested or received a genetic test for the disease. This assumption could also be made if an individual had participated in a clinical trial for a disease associated with a particular genotype. Thus, the term ''genetic services'' encompasses genetic services received as part of a clinical trial. This definition clarifies, within the existing prohibition banning discrimination in enrollment against an individual in the group, that the term genetic information includes ''information about a request for or receipt of genetic services by an individual or family member of such individual.'' Participation in a clinical trial in which genetic services are provided would also constitute ''information about a request for or receipt of genetic services.''"
- **Title I: Genetic Nondiscrimination in Health Insurance** - (Sec. 101) Amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code to prohibit a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information.
- Prohibits a group health plan from requesting or requiring an individual or family member of an individual from undergoing a genetic test.
- Allows a group health plan to request, but not require, a participant or beneficiary to undergo a genetic test for research purposes if certain requirements are met.
- Prohibits a group health plan from requesting, requiring, or purchasing genetic information:
    - for underwriting purposes; or
    - with respect to any individual prior to such individual's enrollment in connection with such enrollment (provides that incidentally obtains such information is not a violation)
- Applies such prohibitions to all group health plans, including small group health plans.
- Provides that any reference to genetic information concerning an individual or family member includes genetic information of:
    - a fetus carried by a pregnant woman; and
    - an embryo legally held by an individual or family member utilizing an assisted reproductive technology.
- Authorizes a penalty against any sponsor of a group health plan for any failure to meet requirements of this Act. Allows a waiver or limitation on such penalty if the failure was

not discovered after exercising reasonable diligence or was due to reasonable cause. (Sec. 102) Amends the PHSA to prohibit:

- a health insurance issuer offering health insurance coverage in the individual market from establishing eligibility rules for enrollment based on genetic information;
- discrimination on the basis of genetic information for health insurance offered in the individual market in the same manner as such discrimination is prohibited for group coverage; and
- the imposition by a health insurance issuer offering health insurance coverage in the individual market of a preexisting condition exclusion on the basis of genetic information.

- Applies such requirements to nonfederal governmental plans.
- (Sec. 104) Amends title XVIII (Medicare) of the Social Security Act (SSA) to prohibit an issuer of a Medicare supplemental policy, on the basis of genetic information, from:
  - denying or conditioning the issuance or effectiveness of the policy, including the imposition of any exclusion of benefits based on a preexisting condition; or
  - discriminating in the pricing of the policy, including the adjustment of premium rates.
- Prohibits an issuer of a Medicare supplemental policy from:
  - requesting or requiring an individual or a family member to undergo a genetic test; or
  - requesting, requiring, or purchasing genetic information for underwriting purposes or for any individual prior to enrollment.
- (Sec. 105) Amends title XI (General Provisions, Peer Review, and Administrative Simplification) of SSA to require the Secretary of HHS to revise Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy regulations to:
  - treat genetic information as health information; and
  - prohibit the use or disclosure by a group health plan, health insurance coverage, or Medicare supplemental policy of genetic information about an individual for underwriting purposes.
- (Sec. 106) Requires the Secretaries of HHS, Labor, and Treasury to ensure that their regulations, rulings, and interpretations under this title are administered so as to have the same effect at all times and that they adopt a coordinated enforcement strategy.
- **Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information** - (Sec. 202) Prohibits, as an unlawful employment practice, an employer, employment agency, labor organization, or joint labor-management committee from discriminating against an employee, individual, or member because of genetic information. Prohibits, as an unlawful employment practice, an employer, employment agency, labor organization, or joint labor-management committee from limiting, segregating, or classifying employees, individuals, or members because of genetic information in any way that would deprive or tend to deprive such individuals of employment opportunities or otherwise adversely affect their status as employees.
- Prohibits, as an unlawful employment practice, an employer, employment agency, labor organization, or joint labor-management committee from requesting, requiring, or purchasing an employee's genetic information, except for certain purposes.
- (Sec. 206) Requires an employer, employment agency, labor organization, or joint labor-management committee that possesses any genetic information about an employee or

member to maintain such information in separate files and treat such information as a confidential medical record.

- Prohibits an employer, employment agency, labor organization, or joint labor-management committee from disclosing such genetic information, except:
  - to the employee or member upon request;
  - to an occupational or other health researcher;
  - in response to a court order;
  - to a government official investigating compliance with this Act if the information is relevant to the investigation; or
  - in connection with the employee's compliance with the certification provisions of the Family and Medical Leave Act of 1993 or such requirements under State family and medical leave laws.
- Establishes the Genetic Nondiscrimination Study Commission six years after enactment of this Act to review the developing science of genetics and to make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.

## Genomics and Personalized Medicine Act of 2008 (HR 6498):

- HR 6498 was introduced by Rep. Patrick Kennedy (D-RI) on July 15, 2008, and has no reported co-sponsors.
- This bill would require the Department of Health and Human Services (DHHS) to establish a Genomics and Personalized Medicine Interagency Working Group (IWG).
- The IWG will be responsible for facilitating collaboration, coordination, and integration of the activities of DHHS and other Federal agencies.
- Duties of the IWG will include:
  - Reviewing current and proposed genomic initiatives
  - Prioritizing new genomic initiatives
  - Reaching consensus on standardized genomic terminology, definitions, and data code sets for adoption and use in federally conducted or supported programs
  - Establishing and disseminating quality standards and guidelines for the collection, processing, archiving, storage, and dissemination of genomic samples and data for research and clinical purposes
  - Developing and promulgating guidelines regarding procedures, protocols, and policies for the safeguarding of the privacy of biobank subjects
  - Reviewing and making recommendations to address ownership and patient access issues with respect to genomic samples and analyses
  - Developing guidelines regarding procedures, protocols, and policies for access to patient data, genomic samples, and associated health information by nongovernmental entities for research purposes
  - Developing guidelines for constructing informed consent forms that ensure patient privacy and confidentiality of associated clinical data and information
  - Providing recommendations for the establishment of a distributed database
- The IWG membership shall include members from NIH, CDC, FDA, HRSA, OMH, AHRQ, CMS, VA, DOE, Armed Forces Institute of Pathology, HIS, Office of the National Coordinator for Health Information Technology, and other Federal Departments.
- The IWG would be terminated after the submission of a report (not later than 18 months) on the deliberations, activities, and recommendations with respect to meeting the IWG duties.

- The bill requires the Secretary of DHHS to establish a national biobanking distributed database for the collection and integration of genomic data.
- The bill also requires that the Secretary of DHHS establish and maintain a registry on the analytical and clinical validity of laboratory-developed genetic tests submitted to the Secretary.

### Medicare Improvements for Patients and Providers Act (HR 6331, PL 110-275):

- HR 6331 was introduced on June 20, 2008, and was enacted (over a president's veto) on July 15, 2008.
- The law:
    - Prevents a 10.6 percent cut in payments to physicians treating Medicare patients that took effect on July 1, 2008.
    - Freezes current payment rates for 18 months and provides for a 1.1 percent increase in 2009.
    - Halts for one year a competitive bidding program under Medicare. The program, which requires durable medical equipment suppliers to compete for contracts, was designed to reduce Medicare spending.
    - Authorizes an additional $4 billion over five years and $16.6 billion over 10 years for changes to Medicare beneficiary programs. The law allows more beneficiaries to qualify for low-income assistance by adjusting asset requirements. For example, the law excludes life insurance from the asset test applied to beneficiaries.
    - Eliminates the higher co-payment rate for Medicare outpatient psychiatric services, which is currently 50 percent. The regular co-payment rate for medical services such as doctors' visits is 20 percent.

## Nevada Cancer Institute Expansion Act (HR 1311/S 758):

- HR 1311 was introduced by Rep. Shelley Berkley (D-NV) on March 5, 2007 and has 2 cosponsors (2 R).
    - HR 1311 passed the House on March 4, 2008, under suspension of the rules.
    - HR 1311 was received in the Senate on March 5, 2008, and referred to the Senate Energy and Natural Resources Committee.
        - Subcommittee hearing held on April 15, 2008.
        - Full committee consideration and markup on May 7, 2008; Committee voted to report the bill to the Senate.
- S 758 was introduced by Sen. John Ensign (R-NV) on March 5, 2007 and has 1 cosponsor (Harry Reid, D-NV).
- Referred to the Senate Energy and Natural Resources Committee
    - Subcommittee on Public Lands and Forests held a hearing on April 15, 2008.
- Directs the Secretary of the Interior, acting through the Director of the Bureau of Land Management (BLM), to convey to the City of Las Vegas, Nevada, all interest of the United States in and to the Alta-Hualapai Site for use by the City for the development of:
    - a nonprofit cancer treatment facility;
    - ancillary commercial projects;
    - an adjacent park;
    - a flood control project; and
    - a water pumping facility.

- Nevada Cancer Institute Expansion Act - Authorizes the Secretary of the Interior, acting through the Director of the BLM, to accept the relinquishment of all or part of the Alta-Hualapai Site by the city of Las Vegas, Nevada.
- Directs the Secretary, after relinquishment of all or part of the Alta-Hualapai Site, to convey to the Nevada Cancer Institute (the Institute) in Las Vegas, the part of the Site that is necessary for the development of a nonprofit cancer institute.
- Requires the Secretary, after a request from the city, to convey to the city any remaining part of the Alta-Hualapai Site necessary for ancillary medical or nonprofit use compatible with the Institute's mission.

## Physicians Payments Sunshine Act of 2008 (HR 5605):

- HR 5605 was introduced by Rep. Peter DeFazio (D-OR) on March 13, 2008, and has 13 cosponsors (13 D).
- Companion bill to S 2029, introduced Sept. 2007, by Sen. Charles Grassley (R-IA)
- Referred to the House Energy and Commerce and Ways and Means Committees.
- Amends part A of title XI of the Social Security Act to require quarterly transparency reports to the Secretary of Health and Human Services of payments to physicians or their employers, or to a covered organization in which a physician has a significant professional membership interest, by manufacturers of covered drugs, devices, or medical supplies under titles XVIII (Medicare), XIX (Medicaid), or XXI (State Children's Health Insurance Program (SCHIP)) of the Social Security Act.
- Amends the Internal Revenue Code to prohibit tax deductions for the advertising, promotion, or marketing by manufacturers of drugs, devices, and medical supplies on whom a penalty is imposed for failing to meet the requirements of this Act.

## *VI. HEALTH EQUITY AND HEALTH INFORMATION*

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

- Eliminating Disparities in Breast Cancer Treatment Act of 2008 (HR 5901)
- Health Equity and Accountability Act of 2007 (HR 3014)
- Promoting Health Information Technology Act of 2008 (HR 6179)

### Eliminating Disparities in Breast Cancer Treatment Act of 2008 (HR 5901):

- HR 5901 was introduced by Rep. Kathy Castor (D-FL) on April 24, 2008, and has 7 cosponsors (7 D).
- Referred to the House Energy and Commerce Committee and the House Ways and Means Committee.
- Amends title XVIII (Medicare) of the Social Security Act to direct the Secretary of HHS to establish a breast cancer treatment quality performance system to:
    - (1) assess and disclose publicly, through the use of quality measures, the quality of care provided for the treatment of breast cancer by specified health care providers; and
    - (2) base payment to such providers for such treatment on their performance with respect to such measures.
- Requires reduced payments to providers that either do not submit data in accordance with the reporting process in the system, or furnish low quality care for treatment of breast cancer.

### Health Equity and Accountability Act of 2007 (HR 3014):

- HR 3014 was introduced by Rep. Hilda Solis (D-CA) on July 12, 2007, and has 113 cosponsors (111 D, 2 R).
- The House Energy and Commerce Committee Subcommittee on Health held a hearing on this legislation on June 24, 2008.
    - An HHS official on the witness bench spoke in support of certain provisions of the bill that would increase funding for the education of individuals in the realm of minority health. “The infrastructure that we have established has to be strengthened ... and sustained,” said John Ruffin, director of the National Center on Minority Health and Health disparities at the National Institutes of Health (NIH).
- This bill amends the Public Health Service Act to require the Secretary of Health and Human Services to establish the Robert T. Matsui Center for Cultural and Linguistic Competence in Health Care.
- Provides for health care workforce diversity activities, including the establishment of: (1) a technical clearinghouse on health workforce diversity; and (2) Regional Minority Centers of Excellence Programs.
- Requires health-related programs of the Department of Health and Human Services (HHS) to collect data on race, ethnicity, and primary language.
- Directs each federal health agency to implement a strategic plan to eliminate disparities and improve the health and health care of minority populations.
- Requires the Secretary to establish: (1) an Office of Health Disparities within the Office of Civil Rights; and (2) civil rights compliance offices in each HHS agency that administers health programs.

- Reestablishes the Indian Health Service as an agency within the Public Health Service of HHS to be administered by an Assistant Secretary of Indian Health.
- Requires the establishment of an Office of Minority Health within specified agencies.
- Directs the President to execute, administer, and enforce provisions to address environmental justice in minority and low-income populations.
- Provides for the establishment of health empowerment zone programs in communities that disproportionately experience disparities in health status and health care.
- Requires the Secretary to designate centers of excellence at public hospitals and other health systems that demonstrate excellence in providing care to minority populations and reducing health disparities.
- Makes immigrants from certain U.S. territories and possessions eligible for specified federal programs.
- Requires the Secretary to expand the Minority HIV/AIDS Initiative.
- Provides for grants for strategies to eliminate racial and ethnic health and health care disparities.
- Requires the Secretary to establish the Rural Health Quality Advisory Commission.

## Promoting Health Information Technology Act of 2008 (HR 6179):

- HR 6179 was introduced by Rep. Dave Camp (R-MI) on June 4, 2008, and has 10 cosponsors (10 R).
- Referred to the House Energy and Commerce, and Ways and Means Committees.
- This bill would establish an Office of the National Coordinator for Health Information Technology within HHS.
    - Presidentially appointed Coordinator.
    - Office would maintain, direct, and oversee the continuous improvement of a strategic plan to guide the nationwide implementation of interoperable health information technology.
- Transfers of functions, personnel, assets, and liabilities under the National Resource Center for Health Information Technology under the Agency for Healthcare Research and Quality to the Health Information Technology Resource Center under the Office of the National Coordinator for Health Information Technology established under this bill.
- Directs the Secretary of HHS to conduct a study of current Federal security and confidentiality standards to determine the strengths and weaknesses of such standards for protection of individually identifiable health information.
- This bill incentivizes the adoption of health information technology by medical care providers by increasing the amount of money that can be deducted from Federal taxes.
- Directs the Secretary of HHS to encourage and facilitate the adoption of State reciprocity agreements for the practitioner licensure to expedite the provision across State lines of telehealth services.

## *VII. HEALTH PROMOTION AND AWARENESS*

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

- Colorectal Cancer Awareness Month (H CON RES 302)
- National Brain Tumor Awareness Month (H RES 1124)
- National Childhood Cancer Awareness Day (S RES 563)
- National Cushing's Syndrome Awareness Day (S RES 498)
- National Mammography Day (S RES 698)
- National Pancreatic Cancer Awareness Month (H RES 1328)
- National Plan to Advance Pancreatic Cancer Act of 2008 (HR 7045)
- National Prostate Cancer Awareness Month (S RES 667)
- Pink Prayer Day (H RES 1412)
- Resolution to Encourage Research on Inflammatory Breast Cancer (H RES 1300)

### Colorectal Cancer Awareness Month (H CON RES 302):

- H CON RES 302 was introduced by Rep. Kay Granger (R-TX) on Feb 25, 2008.
- Resolution agreed to in the House by roll call vote, 371-0, under suspension of the rules.
- Received in the Senate and referred to the Senate Health, Education, Labor and Pensions Committee on April 1, 2008.
- This concurrent resolution expresses support for the observance of Colorectal Cancer Awareness Month to provide a special opportunity to offer education on the importance of early detection and screening.

### National Brain Tumor Awareness Month (H RES 1124):

- H RES 1124 was introduced by Rep. Jan Schakowsky (D-IL) on April 22, 2008.
- This resolution supports the establishment of a National Brain Tumor Awareness Month
- The resolution was agreed passed under suspension of the rules on May 21, 2008.

### National Childhood Cancer Awareness Day (S RES 563):

- S RES 563 was introduced by Sen. Wayne Allard (D-CO) on May 13, 2008.
- This resolution designates September 13, 2008, as National Childhood Cancer Awareness Day
- The resolution was agreed to by unanimous consent on May 22, 2008.

### National Cushing's Syndrome Awareness Day (S RES 498):

- S RES 498 was introduced by Sen. Harry Reid (D-NV) on April 2, 2008.
- This resolution designates April 8, 2008, as "National Cushing's Syndrome Awareness Day."
- The resolution was agreed to on April 2, 2008.

### National Mammography Day (S Res 698):

- S RES 698 was introduced by Sen. Joe Biden (D-DE) on September 30, 2008, and agreed to by unanimous consent the same day.
- This resolution designates October 17, 2008, as "National Mammography Day".

## National Pancreatic Cancer Awareness Month (H RES 1328):

- H RES 1328 was introduced by Rep. Todd Platts (R-PA) on July 9, 2008, and has 36 cosponsors (21 D, 15 R).
- This resolution expresses support for the goals and ideals of National Pancreatic Cancer Awareness Month.
- The resolution requests that Congress designate the month of November as "National Pancreatic Cancer Awareness Month".

## National Plan to Advance Pancreatic Cancer Act of 2008 (HR 7045):

- HR 7045 was introduced by Rep. Anna Eshoo (D-CA) on September 24, 2008, and is cosponsored by Rep. Brown-Waite (R-FL).
- This bill would require the Secretary to establish and implement a Pancreatic Cancer Initiative to assist in coordinating activities to address the high mortality rate associated with pancreatic cancer.
- This bill also requires that the Secretary establish an Interdisciplinary Pancreatic Cancer Coordinating Committee.
- The Committee will be tasked with developing a strategic plan to support pancreatic cancer research, including recommending budget requirements for grants and SPOREs.
- This bill has a provision that would authorize the Secretary to designate 2 additional SPOREs focusing solely on pancreatic cancer research.
- This bill also establishes the Cancer Research Incubator Pilot Project. Under this project, the Secretary is authorized to award grants to research institutions for use in developing innovative compounds of technologies for the prevention, early detection, or treatment of those cancers with a 5-year survival rate of less than 50 percent.

## National Prostate Cancer Awareness Month (S RES 667):

- Introduced by Sen. Jeff Sessions (R-AL), on September 18, 2008, and agreed to by unanimous consent the same day.
- This resolution designats September 2008 as "National Prostate Cancer Awareness Month".

## Pink Prayer Day (H RES 1412):

- H RES 1412 was introduced by Rep. Peter Roskam (R-IL) on Aug. 1, 2008, and has no reported cosponsors.
- This resolution expresses support for the designation of October 15th as Pink Prayer Day and applauds the actions of those who strive to combat and raise public awareness of breast cancer.

## Resolution to Encourage Research on Inflammatory Breast Cancer (H RES 1300):

- H RES 1300 was introduced by Rep. Carolyn McCarthy (D-NY) on June 24, 2008, and has 7 cosponsors (6 D, 1 R).
- This resolution declares that the federal government has a responsibility to:
    - raise awareness and improve education about inflammatory breast cancer
    - encourage the American Medical Association to take steps to increase awareness of the disease among physicians
    - encourage treatment research

- continue to consider ways to improve access to information on the disease for doctors and patients

## *VIII. SCIENCE RESEARCH AND TECHNOLOGY*

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

- Accelerating Cures Act of 2008 (S 2988)
- Comparative Effectiveness Research Act (S 3408)
- National Nanotechnology Initiative Amendments Act of 2008 (HR 5940)
- SBIR/STTR Reauthorization Act (HR 5819)
- SBIR/STTR Reauthorization Act (S 3362)
- Science and Technology Innovation Act of 2008 (HR 5789)
- Strengthening Our Economy Through Small Business Innovation Act of 2008 (S 3451)

### Accelerating Cures Act of 2008 (S 2988):

- S 2988 was introduced by Sen. Joseph Lieberman (I-Conn.) on May 7, 2008, and has no cosponsors.
- Referred to the Senate Health, Education, Labor and Pensions Committee.
- Would amend Title IV of the Public Health Service Act and establish a Pathways to Cures Subcommittee within the Council of Councils of the Office of Portfolio Analysis and Strategic Initiatives (OPASI) of the NIH.
    - The Committee shall make recommendations to the Director of OPASI in setting translational research priorities.
- Directs the NIH Director, in conjunction with AHRQ to establish a Federally Funded Research and Development Center (FFRDC) on clinical effectiveness research.
    - The Director of the FFRDC shall establish a Clinical Effectiveness Advisory Board. The Board shall recommend priorities for clinical effectiveness research to be undertaken by the FFRDC.
- The Director of NIH shall establish a Health Advanced Research Projects Program within OPASI. The Program will provide support to outstanding research performers in all sectors and encourage cross-disciplinary research collaborations that will encourage "team science".
- Directs the Director of OPASI to award grants for clinical trial design and execution to academic centers and practice-based research networks to fund multidisciplinary clinical research teams.
- This bill directs the Director of OPASI to appoint a Director of Centralized Institutional Review Boards to oversee the functioning and progress of a series of Centralized Institutional Review Boards (CIRBs).
- Directs the NIH Director to commission the Institute of Medicine to study the rules that protect patient safety and anonymity in clinical trials and to examine informed consent processes.
- Directs the Director of OPASI to establish training programs to increase the number of translational and clinical researchers.
- Directs the Director of OPASI to expand the existing Rapid Access to Intervention Development Program.

### Comparative Effectiveness Research Act of 2008 (S 3408):

- S 3408 was introduced by Sen. Max Baucus (D-MT) on July 31, 2008, and is cosponsored by Sen. Conrad (D-ND).

- The bill would establish a nonprofit corporation called the Health Care Comparative Effectiveness Research Institute to contract with appropriate Federal agencies or the private sector to conduct comparative effectiveness research.
- The Institute would be responsible for:
    - establishing and carrying out a research project agenda [in carrying out a research agenda, Institute must give preference for contracts to Federal government agencies with experience in conducting CER]
    - establishing a methodology committee to develop scientifically-based methodological standards for comparative clinical effectiveness research [would be required to consult or contract with IOM, AHRQ, NIH (can contract with one or more) in developing and updating standards]
    - ensuring that there is a process for peer-review of the research [Institute would be authorized to use existing peer-review processes used by entities with which the Institute contracts].
- Provisions would also establish a Board of Governors comprised of 21 members, including the Secretary of HHS, the Director of AHRQ, and the Director of NIH, to oversee the Institute's activities.
- The legislation would create the Comparative Effectiveness Research Trust Fund in the U.S. Treasury.
    - Total funding for the first year (FY 2009) would be $5 million, and funding would increase to $300 million a year by the year 2013.
    - Funding for the Institute would sunset after 10 years.

## National Nanotechnology Initiative Amendments Act of 2008 (HR 5940):

- HR 5940 was introduced by Rep. Bart Gordon (D-TN) on May 1, 2008, and has 31 cosponsors (15 D, 16 R).
- Referred to the House Science and Technology Committee.
    - Full committee consideration and markup on May 7, 2008, and reported as amended.
- HR 5940 was passed by the House on June 5, 2008, and referred to the Senate Commerce, Science and Transportation Committee.
- As amended, HR 5940 would:
- Reauthorize the 2003 law (PL 108-153) creating a national nanotechnology program.
- Streamline the interagency coordination review process. Specifically, it would require the President's Director of Science and Technology Policy to designate an associate director as the coordinator for the societal dimensions component of the National Nanotechnology Initiative (NNI) to, among other things, be responsible for coordination, planning and budget prioritization of nanotechnology activities.
- The coordinator would convene a panel from agencies funding research activities under the Environmental, Health and Safety program to develop, annually update, and coordinate the implementation of a research plan for the program. The plan would have to contain a number of items, such as research goals and milestones, including multiyear funding requirements by agency and by goal.
- It would require the preparation, within 12 months of the bill's enactment and every three years thereafter, of a strategic plan to describe the program's activities that explains its near-term and long-term objectives, the time frame for achieving the near-term objectives, and the metrics to be used for assessing progress toward the objectives. The plan would also have to describe:

    - How the program will move results out of the laboratory and into applications for the benefit of society.
    - How the program will encourage and support interdisciplinary research and development in nanotechnology.
    - Proposed research in areas of national importance.
- It would add a number of specifications to a report that has to be submitted to Congress every year, including an explanation of the program budget of the previous fiscal year, for each participating agency, including a breakout of spending for the development and acquisition of research facilities and instrumentation, for each program component area as well as a description of the funding required by the National Nanotechnology Coordination Office (NNCO).
- The bill would specify that agencies participating in the program would be required to support the activities of committees involved in the development of nanotechnology standards and may reimburse the travel costs of scientists and engineers who participate in these activities.
- The bill would specify how the office would operate through a funding formula for each participating agency.
- The measure would require the office to develop and maintain a public database of projects funded under the Environmental, Health, and Safety, the Education and Societal Dimensions, and the Nanomanufacturing program component areas and would have to include a description of each project, its source of funding by agency, and its funding history.
- The office would be required to develop, maintain, and publicize information on nanotechnology facilities supported under the program, and may include information on nanotechnology facilities supported by various states, are accessible for use by individuals from academic institutions and from industry.
- It would specify that the NNI Advisory Panel would be a stand-alone advisory committee.
- As amended, the bill would require that at least one member of the panel would be employed by and representing a minority-serving institution.
- It would direct the NNCO director to enter into an arrangement with the National Research Council to conduct a triennial program review. It would evaluate the following:
    - Research priorities and technical content of the program.
    - Effectiveness of the program's management and coordination across agencies and disciplines.
    - Program scientific and technological accomplishments and its success in transferring technology to the private sector.
    - Adequacy of the program's activities addressing ethical, legal, environmental and other societal concerns.
- The National Research Council would be required to create a report and submit it to Congress of every review and include recommendations for ways to improve the program's management and coordination processes and for changes to its objectives, funding priorities and technical content. It would authorize $500,000 each fiscal year between 2009-11 for the reviews.
- It would establish nanotechnology education partnerships to recruit and prepare secondary school students to pursue postsecondary education in nanotechnology. The partnerships must include one or more businesses engaged in nanotechnology and focus

the educational activities on curriculum development, teacher professional development, and student enrichment in areas related to nanotechnology.

- It would require the NNI to include within the Education and Societal Dimensions program area activities to support nanotechnology undergraduate education, including support for course development, faculty professional development and acquisition of equipment and instrumentation. It would use $5 million in fiscal 2009 and 2010 authorized in a section of a 2007 law (PL 110-69) for a course, curriculum and laboratory improvement program and use $5 million in fiscal 2009 and 2010 authorized in a section of the same 2007 law for an advanced technology education program.
- As amended, it would denote that any activities supported under the Education and Societal Dimensions program component area that involves informal, precollege or undergraduate nanotechnology education would be required to include environmental, health and safety, and other societal aspects of nanotechnology.
- As amended, it would require agencies supporting nanotechnology research facilities as part of the National Nanotechnology Initiative to require the entities which operate the facilities to allow remote access via the Internet using instruments and equipment for secondary school students and teachers for educational purposes and support the costs associated with the access. Agencies may waive this requirement for particular facilities if there are not appropriate for educational purposes or the costs would be prohibitive.
- It would also encourage and expand the use of nanotechnology facilities by companies to develop prototype products, devices or processes for determining proof of a concept. The agencies would be required to publicize the availability of these facilities and provide descriptions of the facilities capabilities as well as the procedures and rules for their use. Agencies may give special special consideration in selecting projects to applications that would meet a national need or requirement.
- It would require agencies to encourage applications for support of nanotechnology projects under the Small Business Innovation Research program and Small Business Technology Transfer program.
- It would require the National Institute of Standards and Technology to encourage submission of proposals under the Technology Innovation Program for the support of nanotechnology projects.
- Under the bill, the program would include support for nanotechnology research and development activities in areas with potential for significant contributions to national economic competitiveness and other societal benefits. The activities would be designed to develop research discoveries in such areas as nanoelectronics, energy efficiency, health care and water remediation and purification. Any activities supported must include a plan to allow for the transfer of research discoveries and technology demonstration activities to industry for commercial development.
- It would specify the inclusion of research under the Nanomanufacturing program component area to include projects to develop instrumentation and tools for rapid characterization and monitoring for nanoscale manufacturing.
- As amended, it would require the review of National Nanotechnology Initiative-supported nanotechnology facilities to include consideration of whether researchers at remote locations have adequate access to equipment and instruments at the facilities by means of networking technology and what the cost estimate would be for supporting remote access.

## SBIR/STTR Reauthorization Act (HR 5819):

- HR 5819 was introduced by Rep. Nydia Velazquez (D-NY) on April 16, 2008, and has 2 cosponsors (1 D, 1 R).
- Referred to the House Science and Technology and House Small Business Committees.
  - Small Business Committee held a markup on April 17, 2008.
- Bill considered by full House on April 23, 2008.
- As amended on the floor of the House, HR 5819 would:
- **Title I: Modernizing the SBIR and STTR Programs**
  - Amends the Small Business Act to extend through FY2010 (currently scheduled to expire at the end of FY2008) the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs of the Small Business Administration (SBA).
- (Sec. 102) Increases, for both the SBIR and STTR programs, the individual small business award levels from:
  - $100,000 to $300,000, for participation at a Phase One level; and
  - $750,000 to $2.2 million, for participation at a Phase Two level.
  - Allows participating federal agencies (agencies) to exceed such award levels if such agencies notify, and provide annual reports concerning such increase to, the congressional small business committees.
- (Sec. 103) Directs each federal agency that is required to conduct an SBIR program and that annually administers $50 million or more in SBIR grants to have an SBIR advisory board. Outlines advisory board duties and requirements, including an annual program report to the small business committees.
- (Sec. 104) Increases technical assistance funding for Phase One awardees and Phase Two grantees.
  - Includes under authorized technical assistance assistance in implementing manufacturing processes and production strategies.
  - Allows Phase One grantees to opt-out of the agency's technical assistance in favor of a payment of up to $2,500, to be used to purchase such assistance.
  - Requires agencies to select technical assistance vendors for a term not to exceed three years.
- (Sec. 105) Requires each agency to conduct at least two rounds of SBIR research solicitations per year, and to render a final decision on each proposal within 90 days after the solicitation closes (with an authorized extension to 180 days on a case-by-case basis).
- (Sec. 106) Includes energy-related and rare disease-related research topics as "special consideration" SBIR research topics.
- (Sec. 107) Requires the SBA Administrator to submit annually to the small business committees a list of small businesses that, during the previous five-year period, received 15 or more Phase One awards and no Phase Two awards.
- (Sec. 108) Requires each agency to engage with SBIR awardees that have been awarded multiple Phase One awards but no Phase Two awards, and to develop performance metrics to measure awardee progress in the SBIR program.
- (Sec. 109) Allows a small business that receives an:
  - SBIR award from one agency to receive an award for a subsequent phase from another agency, as long as the head of each agency certifies that the topics of the relevant awards are the same; and
  - award under either the SBIR or STTR program to receive an award for a subsequent phase under either program.

- (Sec. 110) Requires the Comptroller General to carry out, and report to the small business committees on, an audit of agency calculations of SBIR and STTR extramural research budgets.
- (Sec. 111) Requires that, whenever an entity applies for but does not receive a research and development (R&D) award under an SBIR or STTR program, the federal agency conducting the program shall:
    - notify the entity that it can request an explanation of why it did not receive the award; and
    - if requested, provide such explanation.
- **Title II: Venture Capital Investment Standards**
- (Sec. 201) Provides that, effective only for the SBIR and STTR programs:
    - a business concern that has more than 500 employees shall not qualify as a small business concern;
    - in determining whether a small business concern is independently owned and operated, the SBA Administrator shall not consider a business concern to be affiliated with a venture capital operating company if the venture capital operating company (VCOC) does not own 50% or more of the business concern and employees of the VCOC do not constitute a majority of the board of directors of the business concern; and
    - a business concern shall be deemed to be independently owned and operated if it is owned in majority part by one or more natural persons or VCOCs, there is no single VCOC that owns 50% or more of the business concern, and there is no single VCOC the employees of which constitute a majority of the board of directors of the business concern. States that, if a VCOC controlled by a business with more than 500 employees has an ownership interest in a small business owned in majority by VCOCs, that small business is eligible to receive an SBIR or STTR award only if:
        - not more than two of such VCOCs have an ownership interest in the small business;
        - such VCOCs do not collectively own more than 20% of the small business; and
        - such VCOCs do not collaborate to exercise more control over the small business than they could exercise individually.
- **Title III: SBIR and Economic Development**
- (Sec. 301) Directs the Administrator to make two-year grants to organizations to:
    - conduct SBIR outreach efforts to increase small business participation; and
    - provide application support and entrepreneurial and business skills support to prospective participants.
        - Provides assistance limits.
        - Requires organizations receiving grants to direct activities towards small business concerns located in underrepresented geographic areas and/or small business concerns owned and controlled by women, small business concerns owned and controlled by service-disabled veterans, and small business concerns owned and controlled by minorities.
- Requires the Administrator to establish an advisory board to:
    - assist with such activities; and
    - report annually to the small business committees.

        - Provides per-state limits on grant awards, with specific requirements for awards under the SBA's FAST (Federal and State Technology Partnership) program.
- (Sec. 302) Requires each agency to receive an SBIR applicant's consent to the release of contact information to economic development organizations.
- **Title IV: Advancing Commercialization of SBIR-Funded Research**
- (Sec. 401) Revises the definition of "Phase Three" of the SBIR program. Defines "commercialization" as the process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to government or commercial markets.
- (Sec. 402) Requires agencies to establish annual goals for:
    - the percentage of SBIR projects that receive Phase Three funds;
    - the percentage of SBIR projects that are integrated into a program of record; and
    - the amount of non-SBIR federal funds received by SBIR projects through federal contracts. Directs each agency to submit annually to its advisory board information on the extent to which such goals were met.
- (Sec. 403) Requires the Administrator to issue directives to ensure that:
    - a small business that receives a Phase Two award for an SBIR project remains eligible to receive additional Phase Two awards; and
    - agencies are expressly authorized to provide additional Phase Two awards for testing and evaluation assistance for the insertion of SBIR technologies into technical or weapons systems.
- (Sec. 404) Directs each agency to establish initiatives to encourage partnerships between SBIR awardees and prime contractors, venture capital investment companies, business incubators, and larger businesses in order to facilitate the progression of SBIR awardees to Phase Three.
- (Sec. 405) Authorizes agencies to develop fast-track programs to eliminate funding delays by issuing Phase Two SBIR awards as soon as practicable, including simultaneously with the issuance of the Phase One award.
- (Sec. 406) Requires each agency to establish a commercialization program that supports the progression of SBIR awardees to Phase Three. Requires commercialization program information to be included in each agency and advisory board's annual report.
- Directs the Administrator, from amounts authorized under this section, to establish and carry out a pilot program of grants to minority institutions that partner with nonprofit organizations in order to increase the number of SBIR and STTR program applications by minority-owned small businesses. Requires matching non-federal funds for pilot program participation.
- (Sec. 407) Requires each agency's advisory board to include in annual report requirements information on efforts to enhance manufacturing activities.
- **Title V: Supporting Program Utilization**
- (Sec. 501) Requires:
    - SBIR and STTR small business participants to provide updated project information for purposes of updating agency databases which evaluate the outcome of Phase One and Two awards; and
    - participating agencies to develop and maintain such databases.
- (Sec. 502) Requires each agency to create and maintain a technology utilization database, available to the public, containing data supplied by award recipients.
- (Sec. 503) Requires:

    - the Director of the Office of Science and Technology Policy to establish an Interagency SBIR/STTR Policy Committee; and
    - specified Committee reports to the small business committees.
- (Sec. 504) Adds nanotechnology-related research to the SBIR list of research topics deserving special consideration.
- (Sec. 505) Requires agencies to give a priority to SBIR and STTR award applications submitted by rural companies.
- (Sec. 506) Requires federal agencies, in making R&D awards to small businesses under the SBIR and STTR programs, to give a priority to:
    - businesses located in areas that have lost a major source of employment;
    - veterans; and
    - organizations that are making significant contributions toward energy efficiency.
- **Title VI: Implementation**
- (Sec. 601) Directs the Administrator to promulgate amendments to SBIR and STTR policy directives to conform such directives to this Act and its amendments.
- (Sec. 602) Amends the Small Business Reauthorization Act of 2000 to remove the requirement that the National Research Council provide an updated report on the SBIR program.
- (Sec. 603) Requires SBIR awardees to have their primary business operations in the United States.
- (Sec. 604) Prohibits SBIR or STTR R&D awards to small businesses with ownership interests by unlawful aliens.
- (Sec. 605) Prohibits any future SBIR or STTR R&D awards to applicants found to have engaged in a pattern or practice of hiring, recruiting, or referring for employment in the United States an unauthorized alien.
- HR 5819 passed the House on April 23, 2008, as amended and referred to the Senate Small Business and Entrepreneurship Committee.

## SBIR/STTR Reauthorization Act (S 3362):

- S 3362 was introduced by Sen. John Kerry (D-MA) on July 29, 2008, and has 14 cosponsors (9 D, 4R, 1 I).
- The Senate Committee on Small Business and Entrepreneurship approved the bill by a vote of 19-0.
- The measure would reauthorize the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (SBTT) programs for 14 years.
- The measure would:
    - Allow the National Institutes of Health to award up to 18 percent of its SBIR funds to companies majority owned and controlled by multiple venture capital firms. The 10 other SBIR agencies would be able to apply to award up to 8 percent of their SBIR funds to the venture capital firms.
    - Increase the SBIR award allocation from 2.5 percent of SBIR agencies' extramural research and development budgets to 3.5 percent, over the course of 10 years at a rate of increase 0.1 percent a year. That change would apply to all SBIR agencies, except for the Department of Health and Human Services.
    - Double the STTR allocation from 0.3 percent for STTR agencies' extramural research and development budgets to 0.6 percent over the course of six years for all STTR agencies.

- Increase the award guidelines for the SBIR and STTR programs from $100,000 to $150,000 for phase I of the programs and from $750,000 to $1 million for phase II of the programs.
- Include protections to address jumbo program awards. The measure would cap the amount agencies can exceed the Phase I and II award levels of one and a half times the award guidelines.
- Reauthorize through fiscal year 2014 the federal and state technology partnership program and the rural outreach program.
- Extend the Commercialization Pilot Program at the Department of Defense and create pilot programs at other SBIR agencies that would allow the agencies to issue awards up to two times the award guidelines.
- Require agencies that have the SBIR program to collect data on:
    - Whether an applicant for an award has venture capital
    - If it is majority owned and controlled by multiple venture capital firms
    - The amount of venture capital it has received at the time of the award
    - If it has foreign investors and who they are
    - If it is owned by a woman or a minority
    - If it received assistance from the federal and state technology program or the rural outreach program
    - If it has a university affiliation

## Science and Technology Innovation Act of 2008 (HR 5789):

- HR 5789 was introduced by Rep. David Wu (D-OR) on April 15, 2008, and has 3 cosponsors (3 D).
- Referred to the House Science and Technology and House Small Business Committees.
    - House Science and Technology Subcommittee on Technology and Innovation held a markup on April 15, 2008.
        - Amended to add nanotechnology-related research to the list of topics that receive special consideration in determining program awards.
        - Subcommittee voted to approve as amended for full committee consideration.
- Bill would increase from 2.5 percent to 3 percent the amount required by federal agencies -- which spend more than $100 million per year on intra-or extra-mural research -- to dedicate to SBIR.
- The measure would also increase from 0.3 percent to 0.6 percent the amount such agencies dedicate to STTR.
- It would increase the maximum award levels for both programs from $100,000 to $300,000 for Phase I and from $750,000 to $2.2 million for Phase II award levels.
- The bill would allow a small business that has received an award in either program to receive a subsequent phase award in either program.
- It would allow a small business to submit a SBIR Phase II application without completing a Phase I award and would allow a business to submit an STTR Phase II application without first completing a Phase I award.
- The legislation would allow small businesses backed by venture capital companies to get awards.
- It would allow federal agencies to use up to 3 percent of its innovation budget for administrative expenses.

- The bill would permit federal agencies to choose a vendor to assist award recipients to develop and commercialize new products for up to three years and would increase the amount an agency can provide for technical assistance to $5,000 for Phase I and $8,000 for Phase II awards.
- The bill would require every federal agency with an SBIR or STTR program to create and maintain a publicly available technology utilization database.
- As amended, it would add nanotechnology-related research to the list of topics that receive special consideration in determining Small Business Innovation Research and Small Business Technology Transfer program awards.
- It also would would require priority to be given to Small Business Innovation Research and Small Business Technology Transfer program applicants from rural areas.

## Strengthening Our Economy through Small Business Innovation Act of 2008 (S 3451):

- S 3451 was introduced by Senator Russ Feingold (D-WI) on September 8, 2008, and introduced to the Senate Committee on Small Business and Entrepreneurship.
- This bill would amend the Small Business Act to:
    - extend the SBIR/ STTR Programs for fourteen years
    - increase the allocation for SBIR from the current 2.5 percent to 10 percent and for STTR from the current 0.3 percent to 1.0 percent over a three year period
    - increase Phase I award levels from $100,000 to $300,000 and for Phase II from $750,000 to $2.2 million
    - add water, energy, transportation, and domestic security-related research to the list of funding priorities.

## *IX. SCREENING, PREVENTION AND TREATMENT*

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

- Assuring and Improving Cancer Treatment Education and Cancer Symptom Management Act of 2008 (HR 5585)
- Breast Cancer and Environmental Research Act (HR 1157/S 579)
- Caroline Pryce Walker Conquer Childhood Cancer Act (HR 1553, PL 110-285)
- Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2007 (S 1042)
- Cytology Proficiency Improvement Act (HR 1237)
- Healthy Air for Federal Workers (HR 6571)
- House Resolution on Importance of Medical Imaging (H RES 1216)
- Lung Cancer Mortality Reduction Rate of 2008 (S 3187)
- Oncology Quality Care Improvement Act of 2008 (HR 6725)
- Pediatric, Adolescent, and Young Adult Cancer Survivorship and Quality of Life Act (HR 4450/S 2877)
- Quit Smoking for Life Act of 2008 (HR 6393)
- Sunscreen Labeling Protection Act of 2008 (S 3425)

### Assuring and Improving Cancer Treatment Education and Cancer Symptom Management Act of 2008 (HR 5585):

- HR 5585 was introduced by Rep. Steve Israel (D-NY) on March 11, 2008 and has 3 cosponsors (3 D).
- Referred to the House Energy and Commerce Committee.
- Amends title XVIII (Medicare) of the Social Security Act, as amended by the Medicare, Medicaid, and SCHIP Extension Act of 2007, to provide for Medicare coverage of comprehensive cancer patient treatment education services.
- Amends the Public Health Service Act to direct the Director of the NIH 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.
- Requires the NIH Director to make nursing intervention research grants for studying cancer symptom management care and services delivered by registered nurses.
- Directs the Secretary of HHS to enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall evaluate and report to the Secretary and Congress on the current state of symptom management, patient treatment education, and supportive care given to people with cancer.

### Breast Cancer and Environmental Research Act of 2007 (HR 1157):

- HR 1157 was introduced by Rep. Nita Lowey (D-NY) on Feb. 16, 2007, and has 271 cosponsors (201 D, 70 R).
- Referred to the House Energy and Commerce Committee.
    - Subcommittee hearing held on May 21, 2008.
    - Dr. Deborah Winn, NCI, testified.

    - Bill was amended in the nature of a substitute and reported to the House by the full committee on September 25, 2008.
- As amended, HR 1157 would no longer mandate specific research on breast cancer and environment but establishes an Interagency Breast Cancer and Environmental Research Coordinating Committee within HHS.
- The measure authorizes appropriations of up to $40 million for each of fiscal years 2009 through 2012.
- This bill was passed in the House on September 25, 2008, under suspension of the rules and passed by the Senate on September 27, 2008.
- The measure has been cleared for the president's signature but it has not been signed yet.

## Caroline Pryce Walker Conquer Childhood Cancer Act (HR 1553, PL 110-285):

- HR 1553 was introduced by Rep. Deborah Pryce (R-OH) on March 15, 2007, and became Public Law 110-285 on July 29, 2008.
- This bill amends the Public Health Service Act to advance medical research and treatments into pediatric cancers, ensure patients and families have access to information regarding pediatric cancers and current treatments for such cancers, establish a national childhood cancer registry and promote public awareness of pediatric cancer.

## Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2007 (S 1042):

- S 1042 was introduced by Sen. Mike Enzi (R-WY) on March 29, 2007 and has 26 cosponsors (9 D, 15 R, 2 I).
- Referred to the Senate Health, Education, Labor and Pensions Committee.
    - Committee markup held on March 13, 2008.
    - Committee voted to report the bill to the Senate.
- Amends the Public Health Service Act to require the Secretary of HHS to establish standards to ensure the safety and accuracy of medical imaging studies and radiation therapy treatments.
    - Imposes such standards on personnel who perform, plan, or evaluate, or verify patient doses for, medical imaging studies and radiation therapy procedures and not on the equipment used.
    - Exempts physicians, nurse practitioners, and physician assistants.
- Directs the Secretary to ensure that individuals demonstrate compliance with such standards.
- Requires the Secretary to provide a method for the recognition of individuals whose training and experience are determined to equal or exceed that of:
    - a graduate of an accredited educational program in that specialty; or
    - an individual who is regularly eligible to take the licensure or certification examination for that discipline.
- Directs the Secretary to certify qualified nonprofit organizations as approved bodies to provide accreditation to individuals that demonstrate compliance with such standards.
- Requires individuals who provide medical imaging services relating to mammograms to continue to meet standards under the Mammography Quality Standards Act of 1992.
- Deems state standards for licensure or certification of personnel, accreditation of educational programs, or administration of examinations to be in compliance with the standards under this Act unless the Secretary determines otherwise.

- Requires the Secretary to establish a process by which a state may appeal such a determination.
- Requires the Secretary to ensure that all programs under the authority of the Secretary meet such standards.
- Authorizes the Secretary to develop alternative standards for rural areas or health professional shortage areas as appropriate to assure access to quality medical imaging.

## Cytology Proficiency Improvement Act (HR 1237):

- HR 1237 was introduced by Rep. Bart Gordon (D-TN) on Feb. 28, 2007 and has 175 cosponsors (101 D, 74 R).
- Referred to the House Energy and Commerce Committee.
    - Subcommittee markup held on March 11, 2008.
    - Full Committee voted to report the bill House on March 13, 2008.
    - House passed the measure on April 8, 2008, and referred to the Senate Health, Education, Labor and Pensions Committee.
- Amends the Public Health Service Act to require the Secretary of HHS to revise national quality assurance standards to assure consistent performance by laboratories of valid and reliable cytology services in order to include requirements that each clinical laboratory:
    - ensure that all individuals involved in screening and interpreting cytological preparations participate annually in an approved continuing medical education program in gynecologic cytology that provides each participant with gynecologic cytological preparations designed to improve locator, recognition, and interpretive skills;
    - maintain a record of program results;
    - require the laboratory director to consider such results and other performance metrics in reviewing the performance of individuals involved in screening and interpreting cytological preparations; and
    - submit the continuing education program results for each individual and plans for corrective action or remedial training in a timely manner to the laboratory's accrediting organization for purposes of review and ongoing monitoring.
- Requires the Secretary to terminate individual proficiency testing that was in effect before enactment of this Act.

## Healthy Air for Federal Workers (HR 6571):

- HR 6571 was introduced by Rep. Eliot Engel (D-NY) on July 22, 2008, and is cosponsored by Republican Representative Todd Platts (PA).
- This bill would prohibit the smoking of tobacco products in any area outside of a Federal building which is within 25 feet of any of the building's entrances, exits, windows that open, or ventilation intakes that serve an enclosed area of the building where smoking is prohibited.

## House Resolution Regarding Medical Imaging (H RES 1216):

- HRES 1216 was introduced by Rep. Sue Myrick (R-NC) on May. 20, 2008, and has 3 cosponsors (2 D, 1 R).
- This resolution encourages radiologists, radiologic technologists, medical physicists, pediatricians, other pediatric health care providers, and parents to consider the different needs of children when it comes to radiation dosing.

- The resolution also encourages the appropriate use of computed tomography scans in children, and encourages radiation protection efforts in pediatric imaging.

## Lung Cancer Mortality Reduction Rate of 2008 (S 3187):

- S 3187 was introduced by Sen. Chuck Hagel (R-NE) on June 25, 2008, and is cosponsored by Sens. Diane Feinstein (D-CA) and Debbie Stabenow (D-MI).
- The bill would amend Title IV of the PHS Act to require the Secretary of HHS, in consultation with the heads of NIH, Defense, Veterans Affairs, CDC, FDA, CMS, NCMHD and other members of the Lung Cancer Advisory Board, to implement a program to reduce lung cancer by 50 percent by 2015.
- In addition, the bill would require the Secretary to implement a program to provide incentives for the development of chemoprevention drugs and new agents to curtail or prevent nicotine addiction.
- The bill would also require the Secretary to establish an early disease research and management program targeted at the high incidence and mortality rates among minority and low-income populations.
- Also included are provisions aimed at DOD and VA.

## Oncology Quality Care Improvement Act of 2008 (HR 6725):

- HR 6725 was introduced by Rep. Joseph Crowley (D-NY) on July 31, 2008, and has 7 cosponsors (5 D, 2 R).
- This bill directs the Secretary of Health and Human Services to establish demonstration projects to test and evaluate methods that improve the quality of care provided to eligible beneficiaries with certain cancer diagnoses and that reduce expenditures that would otherwise be made under the Medicare program on behalf of such individuals for such cancer diagnoses.

## Pediatric, Adolescent, and Young Adult Cancer Survivorship and Quality of Life Act (HR 4450 /S 2877):

- HR 4450 was introduced by Rep. Hilda Solis (D-CA) on Dec. 11, 2007 and has 20 cosponsors (18 D, 2 R).
- Referred to the House Energy and Commerce Committee.
    - Alliance for Childhood Cancer and City of Hope sponsored a news conference/briefing on June 9, 2008, to address ways to improve long-term care and quality of life for childhood cancer survivors and discuss HR 4450.
    - Susan Weiner, founder, Children's Cause for Cancer Advocacy, and Smita Bhatia, professor, City of Hope, were participants.
- S 2877 was introduced by Sen. Hillary Rodham Clinton (D-NY) on April 17, 2008, and has no cosponsors.
- Referred to the Senate Health, Education, Labor and Pensions Committee.
- Amends the Public Health Service Act to direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention (CDC), to expand and intensify CDC's cancer control programs.
- Requires the Secretary to:
    - provide guidance to states, in collaboration with the Director of the NCI, on interventions that may be incorporated into state cancer control programs to improve the long-term health status of childhood cancer survivors;

    - encourage states to incorporate strategies for improving their care into their comprehensive cancer plans;
    - collaborate with the NCI Director to improve or develop systems for tracking cancer survivors; and
    - enhance control programs to include a focus on childhood cancer survivorship.
- Directs the NCI Director to:
    - coordinate NIH activities regarding cancer survivorship;
    - make grants for research regarding pediatric cancer survivors and health disparities in cancer survivorship within minority populations;
    - conduct or support research to evaluate follow-up care for childhood cancer survivors; and
    - make grants to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for cancer survivors.
- Directs the Secretary to make grants to:
    - establish or improve training programs for health care professionals to improve follow-up care for young cancer survivors and to ensure that such care is linguistically and culturally competent;
    - pay costs incurred during the first four years of operating a clinic for comprehensive long-term follow-up services for childhood cancer survivors; and
    - improve physical and psychosocial care for such survivors.

## Quit Smoking for Life Act of 2008 (HR 6393):

- HR 6393 was introduced on June 26, 2008, and is cosponsored by Rep. Diana DeGette (D-CO) and Rep. Todd Platts (R-PA).
- This bill amends title XVIII (Medicare) of the Social Security Act (SSA) to cover diagnostic, therapy, and counseling services, furnished by or under a physician's supervision, for cessation of tobacco use.
- Provides for payment of 80 percent of the lesser of the actual charge or the fee schedule amount. Eliminates the deductible.
- Includes tobacco cessation agents as covered drugs under Medicare part D (Voluntary Prescription Drug Benefit Program).
- Amends SSA titles V (Maternal and Child Health Services) and XIX (Medicaid) also to cover counseling and medication for cessation of tobacco use. Requires inclusion of anti-tobacco messages in health promotion counseling as part of quality maternal and child health services.

## Sunscreen Labeling Protection Act of 2008 (S 3425):

- S 3425 was introduced by Sen. Chris Dodd (D-CT) on August 1, 2008, and has 5 cosponsors (5 D).
- This bill would make effective the proposed rule issued by the Commissioner of Food and Drugs entitled “Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph”, 72 Fed. Reg. 49070 (August 27, 2007).
- The bill states that the rule should take effect 180 days after the enactment of S 3425 unless the Commissioner issues the final rule, which includes formulation, labeling and testing requirements for both ultraviolet B and ultraviolet A radiation protection, before such effective date.

## *X. 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.