

November 30, 2012

**Legislative Update
for the
Clinical Trials and Translational Research Advisory Committee**

**Activities of the 112th Congress-
Second Session**

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I. Appropriations

FY2013 Appropriations and Continuing Resolution

The FY2013 President's Budget was announced on February 13, 2012. The NIH budget request is \$30.86 billion, including approximately \$5.07 billion for the NCI (which is approximately \$2.7 million more than the FY2012 Enacted level for the NCI).

Senate Appropriators introduced their FY2013 Labor-HHS Appropriations bill (S.3295) on June 14, 2012, providing \$30.7 billion for NIH. Of that amount, NCI would receive \$5.08 billion. The bill was passed by the Subcommittee on June 12, and the full Committee on June 14. In both instances, all Democrats voted to pass, and all Republicans voted against.

In the House, the Labor, HHS, Education Subcommittee did not report or vote on a bill. We are currently operating under a Continuing Resolution (CR) which is in effect through March 27, 2013. Final consideration of the Labor, HHS, Education, and Related Agencies Appropriations bill (Labor-HHS), is expected to be part of an omnibus appropriations bill that would be considered either during the lame duck session or in the new Congress when it convenes in January. Another possibility is for the current CR to be extended for the full fiscal year. That would allow the new Congress to dispense with the FY 2013 budget begin acting on the FY 2014 budget quickly.

Continuing Appropriations Resolution 2013 (H.J.Res. 117, Public Law 112-175 / 112th Congress)

- The measure will provide funding through March 27, 2013, under the same terms and conditions as fiscal year 2012, for most federal agencies, including NIH.
- To meet the bipartisan agreement between the House, Senate, and White House that ensured a total rate of operations at \$1.047 trillion, a government-wide, across-the-board increase of 0.6 percent over the base rate was also included. A provision is included extending the current pay freeze for federal employees.

II. Congressional Hearings, Briefings, and Visits

Congressional Staff Visits to NCI with the American Society for Radiation Oncology (ASTRO): ASTRO has contacted the NCI to host three staff visits to NCI in recent months, with a visit on August 15, September 7, and October 19. At each visit Congressional staff toured the Radiation Oncology Branch, with Branch Chief Dr. Kevin Camphausen. The visits also incorporated tours of other NCI laboratories and clinics with Dr. Ola Landgren, Metabolism Branch, and Dr. Christina Annunziata, Medical Oncology Branch, as well as conversations with Drs. Norm Coleman, Vik Vikram, and James Deye of the NCI Radiation Research Program. The August and September visits also included a tour of The Children's Inn at NIH. Staff attending the various visits included: Adriane Casalotti (Rep. Lois Capps, D-CA), Nathan Greene (Rep. Mike Simpson, R-ID); Kristyn Vermeesch (Rep. Jack Kingston, R-GA); Aubrey Waldock (Rep. Martha Roby, R-AL); Helen Dwight (Rep. Charles Bass, R-NH); Jessica Robertson (Rep. Austin Scott, R-GA); Landon Stropko (Rep. Cynthia Lummis, R-WY); Jeremy Harrell (Rep. Paul Gosar, R-AZ); Melinda Cep (Rep. Rosa DeLauro, D-CT); Keith Studdard (Rep. Marsha Blackburn, R-TN); Courtney Austin (Rep. Bill Cassidy, M.D., R-LA); and Emily Herzog (Rep. Jo Ann Emerson, R-MO).

University of Kansas Cancer Center, Medical research Town Hall (10/5/12): Dr. Varmus participated in a town hall discussion examining how private and public medical research is leading to groundbreaking advancements in discovery and development of therapies for patients with rare and neglected diseases. Dr. Varmus also participated in a tour of the center, which recently received its NCI designation in July 2012. Senator Jerry Moran (R-KS) and Governor Sam Brownback also attended.

Senator Mikulski and Congressman Van Hollen visit the Frederick National Laboratory for Cancer Research (10/3/12): Senator Barbara Mikulski (D-MD) and Rep. Chris Van Hollen (D-MD) participated in a briefing and a tour

of the Frederick National Lab's Advanced Technology Research Facility. Participants included Dr. Harold Varmus, Director, NCI, John Czajkowski, Deputy Director for Management, NCI, and the following SAIC-Frederick staff: Dr. Atsuo Kuki, Chief Technology Officer; Dr. Barry Gause, Chief Medical Officer; David Butfer, Chief Administrative Officer; and Mitzi Guarino, Senior Project Officer.

Childhood Cancer Caucus Summit (9/20/12): Dr. Javed Khan, Senior Investigator in the NCI Pediatric Oncology Branch and Head of the Branch's Oncogenomics Section, participated in a panel presentation at the 3rd Annual Congressional Childhood Cancer Caucus Summit. The summit was hosted by Caucus Co-chairs Congressmen Michael McCaul (R-TX) and Chris Van Hollen (D-MD), and Rep. Michael Kelly (R-PA) also spoke. Dr. Khan was joined by Dr. Greg Reaman, Associate Director, Office of Hematology and Oncology Products, at the U.S. Food and Drug Administration.

Representative Yoder Visit to NIH (9/19/12): Representative Kevin Yoder (R-KS) met with Dr. Francis Collins, Director, NIH, and visited several laboratories at the NIH Clinical Center. Representative Yoder met with Dr. Harold Varmus, Director, NCI, and toured the Multiple Myeloma lab with Dr. Ola Landgren, Metabolism Branch, NCI. He also visited the MRI lab with Dr. Story Landis, Director, and Dr. Alan Koretsky, Scientific Director, NINDS.

Childhood Cancer Caucus Staff Visit (9/6/12): NCI organized a visit for staff of members of the Congressional Childhood Cancer Caucus, which Representatives Michael McCaul (R-TX) and Chris Van Hollen (D-MD) co-chair. Congressional staff participants were Andrew Taylor (Representative Michael McCaul, R-TX), Erika Appel (Representative Chris Van Hollen, D-MD), Kathryn Mevis (Senator Jack Reed, D-RI), and Jennifer Boyer (Senator Pat Roberts, R-KS). Dr. Crystal Mackall, Chief of the Pediatric Oncology Branch, and Dr. Allan Wayne, Head of the Hematologic Diseases Section of the Branch, led the group on a tour of the Pediatric Oncology Branch. Dr. Malcolm Smith, Associate Branch Chief for Pediatric Oncology in NCI's Cancer Therapy Evaluation Program, joined the group for a discussion of NCI's extramural pediatric oncology efforts. Drs. Mary Purucker, Medical Officer, Division of Clinical Innovation; Steve Groft, Director, Office of Rare Diseases Research; and John McKew, Chief, Therapeutic Development Branch, NCATS, discussed the Center's activities. The group also visited The Children's Inn at NIH.

Congressman Hoyer Visit to NCI (8/28/12): Representative Steny Hoyer (D-MD) met with Dr. Harold Varmus, Director, NCI, and Dr. Francis Collins, Director, NIH. Dr. Hoyer also visited the laboratory and clinic of Dr. William Dahut, Head of the Prostate Cancer Clinic, NCI, Dr. Pete Choyke, Head of the Molecular Imaging Program, NCI, and Dr. Dougg Figg, Head of the Molecular Pharmacology Section NCI. Mr. Hoyer also met with a prostate cancer survivor from Maryland who has participated in a clinical trial at the NIH Clinical Center.

NIH Hearing, House Energy and Commerce Committee, Subcommittee on Health (6/21/12): The House Energy and Commerce Committee, subcommittee on health held a hearing entitled "The National Institutes of Health – A Review of Its Reforms, Priorities, and Progress." Dr. Francis Collins was the only witness called. The hearing reviewed the implementation of the 2006 NIH Reform Act, the progress of the National Center for Advancing Translational Sciences (NCATS), and the determination of NIH funding and research priorities. Specific NCI-related inquiries included questions about NCI's pancreatic cancer funding portfolio from Mr. Pallone, Mr. Lance, and Mr. Burgess. Rep. Waxman's opening remarks also noted NCI's contributions to understanding the complexity of cancer, and learning from commonalities across cancer types. Other topics discussed included sequestration and the impact of budget cuts across the NIH research portfolio, as well as on global competitiveness, the NIH's ability to support the next generation of the biomedical research workforce, and other economic consequences beyond NIH and the public sector. Additionally, questions and comments addressed indirect costs, Title 42, disease spending relative to burden of disease, budget implications of consolidation of NIDA/NIAAA, peer review and the role of advisory boards in funding decisions, NCATS, collaborations with FDA, Alzheimer's disease funding, intellectual property, diabetes, asthma, and health disparities.

Senate Cancer Caucus (06/19/12): Sen. Dianne Feinstein (D-CA), Sen. Kay Bailey Hutchison (R-TX), and the Senate Cancer Coalition convened a congressional forum, "Preventing and Treating Breast Cancer in the 21st Century: Seeking the Right Treatment at the Right Time." The forum focused on the role of precision medicine in cancer research and explored advances in the treatment, prevention and detection of breast cancer. Dr. Barbara Wold, Director of NCI's Center for Cancer Genomics, testified on behalf of NCI and emphasized NCI's work in applying modern genomics to breast cancer. Specifically, she discussed the Cancer Genome Atlas (TCGA), and the TARGET (Therapeutically Applicable Research to Generate Effective Treatment) programs and their significant contributions in understanding gene mutations. She stressed that learning the DNA signature for each patient will ultimately be an important and routine part of diagnosis and determining which drugs may or may not be effective for patient treatment. Other panelists included: Dr. Frank McCormick (President, AACR and Director, UCSF Helen Diller Family Comprehensive Cancer Center), Dr. Ana Maria Gonzalez-Angulo (Associate Professor, MD Anderson Cancer Center), Dr. Leslie Bernstein (Professor, City of Hope Comprehensive Cancer Center), and Zora Brown (Advocate and Senior Advisor, INTEGRIS Health).

Senator Harkin Visit to NIH (05/21/12): Senator Tom Harkin (D-IA), Chair of both the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies (Labor-HHS), and the Senate Health, Education, Labor, and Pensions Committee (HELP), and Erik Fatemi, Majority Clerk of the Senate Appropriations Labor-HHS Subcommittee on Labor, visited the NIH. Also attending were Dr. Francis Collins, and from NCI, Drs. Harold Varmus, Director; James Doroshow, Director, Division of Cancer Treatment and Diagnosis; Dinah Singer, Director, Division of Cancer Biology; Barbara Wold, Acting Director, Center for Cancer Genomics; and Louis Staudt, Center for Cancer Research. Discussion with NCI staff focused broadly on genomics and cancer, specifically, The Cancer Genome Atlas (TCGA), as well as NCI's Therapeutically Applicable Research to Generate Effective Treatments (TARGET) Initiative. Also attending the visit were Kathy Hudson, Deputy Director for Science, Outreach, and Policy, NIH, and Acting Deputy Director, NCATS; along with leadership and senior researchers from NINDS, NIMH, and NIA.

IV. Legislation of Interest

The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the CTAC membership, and in most cases, based on their support in Congress, reflected by high levels of cosponsorship. More detailed information about these bills and others are available on our website under Legislative Topics: <http://legislative.cancer.gov/topics>

Selected Bills with Recent Activity or Interest

Recalcitrant Cancer Research Act of 2012 (H.R. 733, S. 362, S. 3566 / 112th Congress)

- Initially, bills were introduced in February, 2011 as the **Pancreatic Cancer Research and Education Act** (HR 733 in the House; S 362 in the Senate). These bills were specific to pancreatic cancer and included provisions that would: require NCI to establish a pancreatic cancer initiative; require HHS to establish an Interdisciplinary Pancreatic Cancer Coordinating Committee with authority to make recommendations regarding the prioritization and award of NIH research grants relating to pancreatic cancer; require NCI and CDC to develop a communication tool kit for patients and their families focused on pancreatic cancer issues.
- Prior to consideration by the House Energy and Commerce Committee, HR 733 was modified. In action by the Health Subcommittee, on Sept. 11, 2012, an amendment was approved that replaced the original bill with new text and the title was changed to the Recalcitrant Cancer Research Act.

- The bill, as amended would require NCI to develop a scientific framework to conduct and support research for “recalcitrant cancers,” defined initially as cancers with a five-year survival rate of less than 20 percent and estimated to cause at least 30,000 deaths per year in the United States. Pancreatic cancer and a grouping of four types of lung cancer would qualify under this definition.
- For each recalcitrant cancer, NCI is directed to convene a working group of Federal and non-Federal entities to provide expertise and assistance in developing the scientific framework. The frameworks are to be completed within 18 months of enactment, then submitted to Congress and made publicly available on the HHS website within 30 days.
- The bill requires that actions undertaken to carry out each scientific framework be reported in the NIH Biennial report, with an assessment of progress made in improving outcomes for recalcitrant cancers.
- The bill further states that the NCI Director “shall consider” each relevant scientific framework when making recommendations for exception funding for grant applications.

Status Update:

- H.R. 733, titled the Pancreatic Cancer Research and Education Act, was introduced by Rep. Anna Eshoo (D-CA) on 2/16/11 and was referred to the House Committee on Energy and Commerce, Subcommittee on Health. In Sept. 2012, H.R. 733 had 294 cosponsors.
- S. 362, titled the Pancreatic Cancer Research and Education Act, was introduced by Sen. Sheldon Whitehouse (D-RI) on 2/16/11 and was referred to the Committee on Health, Education, Labor, and Pensions. In Sept. 2012, S.362 had 58 cosponsors.
- HR 733 as amended, titled the Recalcitrant Cancer Research Act, was passed by the House on 9/19/12.
- HR 733 was received in the Senate on 9/20/12
- S. 3566 was introduced by Sen. Tom Harkin on 9/19/12. This bill, including the new text of HR 733, titled the Recalcitrant Cancer Research Act, replaced S. 362. The Senate has not voted on the measure.

HHS Employee Compensation Reform Act of 2012 (H.R.2791 / 112th Congress)

- This bill would amend the Public Health Service Act to limit Title 42 hiring authority. It would prohibit more than 5% of the total number of HHS employees from serving as special consultants or fellowship recipients under Title 42.
- It would also limit, with exceptions determined by the HHS Secretary, the compensation payable to such an individual for a 12-month period to 150% of the annual rate payable under level 1 of the Executive Schedule, prorated for shorter periods.
- The bill calls for a report to Congress from the HHS Secretary, specifying the number of employees serving under Title 42 during the preceding year, and including a breakdown by each agency within HHS.
- H.R.2791 was introduced by Rep. Joe Barton (R-TX) on 7/26/2012 and was referred to the House Committee on Energy and Commerce, Subcommittee on Health on 7/27/2012.
- The Subcommittee held a hearing on 9/14/2012, “Title 42 – A Review of Special Hiring Authorities,” featuring the testimony of two witnesses from the Government Accountability Office (GAO), to discuss the GAO report, “HHS and EPA Can Improve Practices Under Special Hiring Authority,” which was released on 7/9/2012, shortly before Rep. Barton introduced his bill. During their testimony, the GAO witnesses Two GAO witnesses indicated that Title 42 is an important recruitment tool for HHS and EPA to attract and retain “highly skilled, in-demand personnel to government service in order to execute their missions;” however, they also noted that HHS does not have reliable data to manage and provide oversight of its use of Title 42.
- The bill has one co-sponsor to date, Rep. Cliff Stearns (R-FL), and a companion bill has not been introduced in the Senate.

Accelerating the End of Breast Cancer Act of 2011 (H.R. 3067, S.3237 / 112th Congress)

- The bill provides for the establishment of a Commission to Accelerate the End of Breast Cancer with the mission to help end breast cancer by January 1, 2020.

- The duties of the Commission include identifying and promoting research opportunities to prevent and end breast cancer. The Commission would be composed of not more than ten members, appointed primarily by the President - at least one, but not more than three, to represent the biomedical research community; at least one, but not more than three, to represent disciplines outside of the biomedical research field; and at least two, but not more than four, educated patient advocates. H.R. 3067 calls for no more than eight members to be appointed by the President, and one each by the Speaker of the House of Representatives and the majority leader of the Senate.
- The Commission is tasked with identifying opportunities for study and recommending projects; it is also directed to work with Federal agencies to identify areas of concurrent interests. The bill directs the Commission to ensure its activities are coordinated with, and do not duplicate the efforts of, programs and laboratories of other government agencies.
- The bill gives the Chairperson the authority to approve study areas, develop criteria for assessing areas of study and study projects, and terminate areas of study that are not achieving the mission. The bill also directs the Commissioner to recommend proposals, projects, and collaborations based on scientific merit, but does not reference the National Institutes of Health (NIH) peer review process. H.R. 3067 also directs the Commission to identify opportunities for funding through awards, prizes, grants, and contracts, but again, does not reference NIH peer review.
- The bill requires the Commission to develop and submit to Congress a strategic vision, as well as an annual report.
- H.R. 3067 does not authorize funds to carry out the provisions of the bill; S. 3237 would establish the “Accelerating the End of Breast Cancer Fund” within the U.S. Treasury, and would authorize \$12 million for each of fiscal years 2013 and 2014, and such sums as might be necessary for each fiscal year thereafter (until termination of the Commission, as called for in the bill, on June 1, 2020).

Status Update:

- H.R. 3067 was introduced by Rep. Karen Bass (D-CA) on 9/26/11. The bill was referred to the House Energy and Commerce Committee, Subcommittee on Health on 9/26/11. H.R. 3067 has 235 cosponsors.
- S. 3237 was introduced by Sen. Sheldon Whitehouse (D-RI) on 5/24/12. The bill was referred to the Senate Health, Education, Labor and Pensions Committee on 5/24/12. S. 3237 has 23 cosponsors.

The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2011 (H.R. 1639, S. 1461 / 112th Congress)

- Amends the Federal Food, Drug, and Cosmetic Act to exempt traditional large and premium cigars from regulation by the Food and Drug Administration (FDA) and from user fees assessed on tobacco products by the FDA.
- The bill would ultimately exempt traditional large and premium cigars from regulations and user fees established by the Family Smoking Prevention and Tobacco Control Act of 2009 (Public Law 111-31). As enacted, the law’s provisions require FDA regulation of cigarettes and smokeless tobacco. Cigars are considered tobacco products under the Act, however, the Act does not automatically apply to cigars. The FDA must issue a regulation deeming cigars to be subject to the law, and the Act gives the FDA the authority to do so. H.R. 1639/S. 1461 would prohibit the FDA from extending these provisions to apply to cigars.
- Additional information about PL 111-31, including a link to the full text of the law, is included on the FDA’s website (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm>).

Status Update:

- H.R. 1639 was introduced by Rep. Bill Posey (R-FL) on 4/15/2011 and was referred to the Committee on Energy and Commerce, Subcommittee on Health. H.R.1639 has 220 cosponsors.
- S. 1461 was introduced by Sen. Bill Nelson (R-FL) on 4/15/11 and was referred to the Committee on Health, Education, Labor, and Pensions. S. 1461 has 13 cosponsors.

Selected New Bills

Verifying Authority and Legality in Drug Compounding Act of 2012 (H.R. 6584/112th Congress)

- The bill would amend Section 503A of the Federal Food, Drug, and Cosmetic Act to clarify the Food and Drug Administration's (FDA) authority over compounding pharmacies. Provisions under the legislation would specify when the FDA can regulate compounding pharmacies and when they would be exempt from the regulations; grant waivers for compounding pharmacies that are not manufacturers but want to compound drugs before receiving prescriptions, such as hospital pharmacies; and allow the FDA to waive requirements for a limited time in the event of a drug shortage or to protect human health.
- House and Senate hearings on this topic took place on November 14 and 15, respectively. FDA Commissioner Dr. Margaret Hamburg and Dr. Lauren Smith, interim commissioner of the Massachusetts Department of Public Health testified at each hearing, among other witnesses. Barry Cadden, co-owner of the New England Compounding Center was subpoenaed to appear at the House hearing, however he invoked his 5th Amendment rights and refused to answer any questions. He was invited to testify at the Senate hearing but did not attend.
- Additionally, on November 15, Representatives Edward Markey (D-MA), Henry Waxman (D-CA), Diana DeGette (D-CO), John Dingell (D-MI), Frank Pallone, Jr. (D-NJ), and Anna Eshoo (D-CA), wrote to the Government Accountability Office calling for an investigation into the link between drug shortages and increased reliance on compounding pharmacies.
- H.R.6584 was introduced by Representatives Edward Markey (D-MA), Steve Cohen (D-TN), Louise Slaughter (D-NY), Stephen Lynch (D-MA), and John Olver (D-MA) on 11/2/12, and was referred to the Committee on Energy and Commerce. A companion bill has not been introduced in the Senate.

Discussion Proposal to Improve Drug Distribution Security (Discussion Draft/112th Congress)

- On October 24, 2012, the Senate HELP Committee and House Energy and Commerce Committee released a discussion draft of a proposal to improve drug distribution security, often referred to as "track and trace." The deadline for written comments was November 7, 2012, and a formal proposal has yet to be introduced.
- Proposals for a system to track and trace prescription drugs through the supply chain were discussed during the negotiations of the FDA user fee reauthorization, but were not included in the final law.
- Reports indicate that negotiations are still ongoing, and as currently drafted, the proposal includes tracking and tracing requirements for manufacturers, wholesalers, dispensers, repackagers, and third-party logistics providers. Each entity would be required to provide a product's transaction history before the next owner could accept it, and each product would have an identifier that includes the lot number and expiration date.
- The proposal calls for the HHS Secretary to create standards for exchanging transaction information about drugs within two years of the proposal being enacted. It would allow the Secretary to issue proposed regulations requiring the use of electronic systems for tracking, tracing and verifying products, and to require pedigrees on the unit level of products.

Triple-Negative Breast Cancer Research and Education Act of 2011 (H.R. 6417 / 112th Congress)

- This bill would provide for research and education with respect to triple-negative breast cancer, and for other purposes.
- Under this bill, the Director of NIH would be required expand, intensify, and coordinate programs for the conduct and support of research with respect to triple-negative breast cancer through the appropriate institutes, offices, and centers.
 - For the purposes of carrying out this section, \$500,000 would be appropriated for each of the fiscal years 2013 through 2015.
- This bill would also require the Centers for Disease Control to carry out an education program and HRSA would be required to develop information for health care providers.
- The bill does not mention the National Cancer Institute.

- H.R. 6417 was introduced by Rep. Sheila Jackson Lee (D-TX) on 9/14/2012 and was referred to the House Committee on Energy and Commerce.

Cell Phone Right to Know Act (H.R. 6358 / 112th Congress)

- This bill would allow for examination, labeling, and communication of adverse human biological effects associated with exposure to electromagnetic fields from cell phones and other wireless devices.
- Under this bill, NIEHS and EPA are required to jointly support a comprehensive research program to determine whether exposure to electromagnetic fields from mobile communication devices causes adverse biological effects in humans. Information resulting from this program should be made available regularly to the public and reports should be provided to Congress 4 and 8 years after the date of enactment.
 - A total of \$50,000,000 per year will be appropriated for the first 7 fiscal years after the enactment of the bill for this program.
- The EPA would be required to establish maximum exposure level goals and maximum exposure levels for exposure to electromagnetic fields generated by mobile communication devices as well as set regulations to provide for labeling of such devices.
- This bill would require the Secretary to expand and intensify the activities of HHS to train, and support the training of, scientists in the field of examining the relationship between electromagnetic fields and human health by increasing the number and size of grants to institutions for such training and increasing the number of career development awards for such training for health professionals who intend to build careers in pediatric basic and clinical research.
- In addition, NIH would be required to establish a program to enter into contracts with qualified individuals under which such individuals agree to conduct research in the field of examining the relationship between electromagnetic fields and human health of which the Federal Government will repay not more than \$35,000 of the graduate student loans.
- H.R. 6358 was introduced by Rep. Dennis Kucinich (D-OH) on 8/3/2012 and was referred to the House Subcommittee on Health.

Trial and Experimental Studies Transparency Test (TEST) Act of 2012 (H.R. 6272 / 112th Congress)

- This bill would amend title IV of the Public Health Service (PHS) Act to expand the clinical trial registry data bank specifically relating to registration and results reporting on clinicaltrials.gov.
- Provisions of this bill would amend Section 402(j) of the PHS Act to:
 - Require all interventional biomedical studies on humans to be registered with the clinical trial registry data bank before the first participants are enrolled in the trial and not later than 30 days after such trial is determined to meet the quality criteria established by the Director of NIH;
 - Require that results from all covered trials are posted on the database within one year of completion of the trial;
 - Provide for delayed submission of results (up to two years after trial completion) for trials on medical interventions that have never before been approved for any use;
 - Instruct the Secretary of HHS to undergo rulemaking to require foreign trials that are used to support an application for marketing in the United States to comply with the registration and reporting requirements of the database; and
 - Instruct NIH and the FDA to provide a report to Congress regarding the implementation and compliance with the database requirements. H.R. 6272 was referred to the Committee on Energy and Commerce.
- H.R. 6272 was introduced by Rep. Edward Markey (D-MA) on 8/2/2012 and was referred to the House Committee on Energy and Commerce, Subcommittee on Health on 8/3/2012.

Cancer-Free Label Act of 2012 and Carcinogen-Free Label Act of 2012 (H.R. 6191, H.R. 6601 / 112th Congress)

- H.R.6191 would establish a program within Federal regulatory agencies (such as the Food and Drug Administration) to permit manufacturers to label covered products that do not contain known or probable carcinogens as "Cancer-Free." H.R. 6601 proposes the label "carcinogen-free" rather than "cancer-free." Both bills also call for any product qualifying for the label also include a notice stating "This product does not contain known or likely carcinogens that increase your risk of cancer."
- H.R. 6191 was introduced by Rep. Theodore Deutch (D-FL) on 7/25/12 and was referred to the House Committee on Agriculture on 7/25/12, and the Subcommittee on Nutrition and Horticulture on 8/13/12. The bill was also referred to the House Committee on Energy and Commerce on 7/25/12, and the Subcommittee on Health on 7/27/12. Rep. Deutch introduced H.R. 6601 on 11/16/12, and the bill was referred to the Committee on Energy and Commerce and the Committee on Agriculture. Rep. Deutch introduced H.R. 6601 on 11/16/12, and the bill was referred to the Committee on Energy and Commerce and the Committee on Agriculture.

National Pediatric Research Network Act of 2012 (H.R. 6163, S. 3461 / 112th Congress)

- The bill would authorize the Director of the National Institutes of Health (NIH), to act through the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to establish a National Pediatric Research Network.
- The legislation authorized the NICHD Director to award funding to public or private nonprofit entities, also recognized as pediatric research consortia in the bill language, which would then make up the Network.
- The bill authorizes the Director of NIH to make awards for not more than 20 pediatric research consortia, and indicates a specific research focus on rare pediatric diseases, including any such diseases or conditions that are genetic disorders (such as spinal muscular atrophy and Duchenne muscular dystrophy) or are related to birth defects (such as Down syndrome and fragile X).
- The award recipients would be responsible for (1) planning, establishing, or strengthening pediatric research consortia; and (2) providing basic operating support for such consortia, including to meet unmet needs for pediatric research and train researchers in pediatric research techniques. Provisions of the bill direct the consortia members to focus primarily on pediatric rare diseases or conditions; conduct or coordinate multi-site clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of pediatric rare diseases or conditions; and rapidly and efficiently disseminate scientific findings from such trials.
- H.R. 6163 was introduced by Rep. Cathy McMorris Rodgers (R-WA) on 7/19/12 and was referred to the House Committee on Energy and Commerce, Subcommittee on Health. On 9/19/12 the bill was considered by the House under suspension of the rules, and the bill was agreed to by voice vote. The bill was received in the Senate on 9/20/12 and was referred to the Committee on Health, Education, Labor, and Pensions.
- S. 3461 was introduced by Sen. Sherrod Brown (D-OH) on 7/31/12 and was referred to the Committee on Health, Education, Labor, and Pensions.

Patient Centered Quality Care for Life Act (H.R. 6157 / 112th Congress)

- This bill would establish various national efforts to improve care coordination and quality of life factors for patients facing cancer and other serious diseases. The efforts are focused on increasing access to palliative care, which provides patients with relief from the symptoms, pain, and stress of illness.
- The initiative would be realized through the establishment of a national stakeholder summit, training of doctors and healthcare workers, a grants program to encourage patient-centered care, and a coordinated strategy to expand research in palliative care, including the creation of a Quality of Life Cross-Agency Advisory Committee.
- Duties of the committee would include summarizing recent advances in symptom management and survivorship research and making recommendations to NIH on gaps in research. The committee would also have to look at developing new and enhancing current health surveillance tools, including the Health Information National Trends Survey, the Surveillance Epidemiology and End Results (SEER) cancer registry, and the SEER-Medicare Linked Database.

- The bill would also require the Trans-NIH Research Report (which is required by Section 402A(c)(2)(B)(i) of the PHS Act) to include research on quality of life and survivorship.
- H.R. 6157 was introduced by Rep. Emanuel Cleaver (D-MO) on 7/19/2012 and was referred to the House Subcommittee on Health on 7/20/2012.

Prostate Cancer Detection Research and Education Act (H.R.6033, S.3345 / 112th Congress)

- Requires the NIH Director to establish an advisory council, which will provide an annual report that includes: 1) an evaluation of Federally funded prostate cancer research relating to diagnostic tests; 2) a plan for the development and validation of accurate tests to detect and diagnose prostate cancer; and 3) a set of standards for prostate cancer screening, created in coordination with the United States Preventive Services Task Force.
- Calls for the NIH Director, in consultation with the Department of Defense, to coordinate and intensify research in accordance with the plan.
- Compels the DHHS Secretary, in coordination with NIH and CDC, to launch a national campaign to increase the awareness and knowledge of prostate cancer, with particular emphasis on addressing racial disparities.
- H.R.6033 was introduced by Rep. Elijah Cummings (D-MD) on 6/27/2012 and was referred to the Committee on Energy and Commerce, Subcommittee on Health.
- S.3345 was introduced by Sen. Barbara Boxer (D-CA) on 6/27/2012 and was referred to the Committee on Health, Education, Labor, and Pensions.

United States Preventative Services Task Force (USPSTF or Task Force) Transparency and Accountability Act of 2012 (H.R. 5998 / 112th Congress)

- The legislation would amend United States Preventative Services Task Force provisions and the process by which the group makes formal recommendations regarding preventive care services.
- The bill would require the USPSTF be made up of members with expertise in health sciences research, health economics and clinical care, and include balanced representation of practicing primary and specialty care providers, patient/health care consumers and medical products manufacturing community.
- The bill seeks to strike language added by the 2010 Patient Protection and Affordable Care Act that directly ties Medicare coverage of a particular preventive service to the grade given by the USPSTF.
- This bill would establish criteria for grades (A, B, C, D, I) that Task Force must follow; the current authorizing language does not address a grading system.
- H.R. 5988 was introduced by Rep. Marsha Blackburn (R-TN) on 6/21/12 and referred to the Committee on Energy and Commerce, and the Committee on Ways and Means.

Breast Cancer Patient Education Act of 2012 (H.R. 5937, S.3628/ 112th Congress)

- This bill seeks to amend the Public Health Service Act to raise awareness of, and to educate breast cancer patients anticipating surgery regarding, the availability and coverage of breast reconstruction, prostheses, and other options.
- H.R. 5937 was introduced by Rep. Leonard Lance (R-NJ) on 6/8/12 and was referred to the House Committee on Energy and Commerce.
- S. 3628 was introduced by Sen. Roy Blunt (R-MO) on 11/14/12 and was referred to the Senate Committee on Health, Education, Labor, and Pensions.

The Melanoma Research Act of 2012 (H.R.5716/ 112th Congress)

- This bill seeks to establish a Skin Cancer Research Fund to increase funding for the conduct or support of research relating to skin cancer by the National Institutes of Health. The Skin Cancer Research Fund would be funded by taxes related to the use of indoor tanning services (26 U.S.C. 5000B).
- In addition to melanoma, this legislation would cover NIH research for the following types of skin cancers: Actinic keratosis, Basal cell carcinoma, Kaposi's sarcoma, and Squamous cell carcinoma.
- Introduced by Rep. Brian Bilbray (R-CA) on 5/10/12. The bill was referred to the Committee on Energy and Commerce on 5/10/12, and in addition to the Committee on Ways and Means on 5/10/12.

Armed Forces Breast Cancer Research Act of 2012 (H.R.4869/ 112th Congress)

- This bill would direct the Secretaries of Defense and Veterans Affairs to jointly conduct a study on the incidence of breast cancer among members of the Armed Forces and veterans.
- The legislation requires that study results are reported to Congress within 18 months of enactment.
- H.R.4869 was introduced by Rep. Leonard Boswell (D-IA) on 04/26/2012 and referred to the Committee on Armed Services, and in addition to the Committee on Veterans' Affairs on 04/26/12. Referred to the Veteran's Affairs subcommittee on health on 5/11/2012.

CT Colonography Screening for Colorectal Cancer Act of 2012 (H.R.4165/S.2265)

- The bill amends the Social Security Act to cover screening computed tomography colonography as a colorectal cancer screening test under the Medicare program.
- H.R.4165 was introduced by Rep. Ralph Hall (R-TX) on 3/8/12 and was referred to the House Subcommittee on Health and the House Ways and Means Committee.
- S.2265 was introduced by Sen. James Inhofe (R-OK) on 3/29/12 and was referred to the Senate Finance Committee.