

Legislative Update
For the
Board of Scientific Advisors
November 2012

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. 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 will be considered during a lame duck session after the November election. We are currently operating under a Continuing Resolution (CR) which is in effect through March 27, 2013.

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 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 Buffer, Chief Administrative Officer; and Mitzi Guarino, Senior Project Officer.

III. Legislation of Interest

The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the BSA 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

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 (H.R. 6191 / 112th Congress):

- This bill 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. 6191 was introduced by Rep. Theodore Deutch (D-FL) on 7/25/2012 and was referred to the House Subcommittee on Nutrition and Horticulture on 8/13/2012.

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.