

November 2011

Legislative Update

for the

NCI Clinical Trials and Translational Research Advisory Committee

Activities of the 112th Congress-

First Session

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I. Appropriations

FY2012 Appropriations

Following months of contentious Congressional debate, the President signed the Budget Control Act (Public Law 112-25) on August 2. In addition to raising the debt ceiling and averting default on federal government-held debt, this legislation effectively created a budget resolution, or general framework within which appropriators can maneuver, capping the fiscal year 2012 discretionary spending level at \$1.043 trillion. This figure is about \$7 billion less than the current level, but \$34 billion more than was allowed by the budget resolution (H Con Res 34) the House proposed (and the Senate dismissed) in April.

A provision of the Budget Control Act requires that a joint deficit reduction committee, commonly known as the “Super Committee,” be created to provide recommendations to reduce the deficit by at least \$1.2 trillion. The committee, consisting of six Democrats and six Republicans, met for the first time on September 8 and has continued to deliberate in both public and behind-closed-doors forums. To date, no agreements have been announced, though there are some indications that areas of potential common ground are being explored. If the committee is unable to reach an agreement by November 25 that leads to enrolled legislation by December 23, cuts prescribed in the legislation will be triggered. These automatic cuts would total \$1.2 trillion over 10 years, encompassing an approximately 9% cut across the board for discretionary defense and non-defense programs.

The establishment of the Super Committee has affected both the substance and timing of appropriations legislation consideration for fiscal year 2012. Appropriators initially expressed reluctance to act before knowing what the Super Committee would propose, and there has been some uncertainty about when funding bills would be considered. After a number of fits and starts the Senate Appropriations Committee marked up and reported out its bill for funding the Departments of Labor, HHS, Education, and related agencies (Labor H; S. 1599) on September 21, while the House Appropriations Committee introduced its Labor H bill (H.R. 3070) on September 29 and has postponed markup indefinitely (see bill descriptions below).

Currently, the Senate is pursuing a strategy of clearing several small packages of spending bills, which they are calling “minibus” bills, rather than relying on a single catch-all omnibus bill to move FY2012 appropriations forward. The Senate passed the first of the minibus bills, encompassing appropriations for Agriculture, Commerce-Justice-Science, and Transportation-HUD on November 1, setting up the first conference committee on a spending measure in two years (the House-passed version of the Agriculture bill served as the vehicle for the legislation).

In the meantime, the Federal government is currently operating under a continuing resolution (CR) set to expire November 18, 2011. In September, as the beginning of fiscal year 2012 approached with no finalized appropriations measures in place, the Congress was obliged to approve a series of CRs. The current CR (H.R. 2608; PL 112-36), signed into law on October 5, funds the government at fiscal year 2011 levels as set forth in the Full Year Appropriations Act (PL 112-10), but with a 1.503 percent across-the-board reduction that brings the overall

funding level roughly in line with that of the Budget Control Act. It is likely that one or more additional CR's will be required to continue funding the government as negotiations proceed, and House appropriators have indicated that a new CR that would fund the government through mid-December will be attached to the first minibus bill during conference committee consideration.

FY2012 Appropriations Legislation

Making Continuing Appropriations for Fiscal Year 2012 (H.R. 2608; P.L. 112-36)

- This joint resolution provided stop gap government funding through 10/4/2011.
- Funding was at a rate 1.503% below FY2011 levels (PL 112-10), bringing funding levels roughly in line with the budget resolution set by the Budget Control Act (PL 112-25).
- The measure also extended SBIR/STTR programs through 10/4/2011.
- Introduced by Rep. Robert Aderholt (R-AL) on 5/26/2011 and became Public Law 112-33 on 9/30/11.

Making Continuing Appropriations for Fiscal Year 2012 (H.R. 2608; P.L. 112-36)

- This joint resolution provides stop gap government funding through 11/18/2011.
- Funding was set at a rate 1.503% below FY2011 levels (PL 112-10), bringing funding levels roughly in line with the budget resolution set by the Budget Control Act (PL 112-25).
- The measure also extends SBIR/STTR programs through 11/18/2011.
- Introduced by Rep. Sam Graves (R-MO) on 9/21/2011 and became Public Law 112-36 on 10/5/11.

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2012 (S.1599/H.R.3070)

- S.1599 proposes a \$190 million reduction in funding to the NIH as compared to FY2011 levels (a reduction of approximately 0.6%). The bill proposes a reduction of approximately \$57 million to NCI compared to FY2011 (a reduction of approximately 1.1%).
- S.1599 was introduced by Sen. Tom Harkin (D-IA) on 9/22/11. This bill was referred to the Senate Committee on Appropriations, and was reported by Sen. Harkin with written report No. 112-84.
- H.R.3070 proposes NIH funding at the President's Budget level (a 3.3% increase from FY2011); decreases for other HHS components are as high as 8% (CMS and SAMHSA), and the bill proposes to eliminate funding for implementation of the Patient Protection and Affordable Care Act (PL 111-148).
- H.R.3070 was introduced by Rep. Denny Rehberg (R-MT) on 9/29/11, and was referred to the House Committee on Appropriations.

II. Congressional Hearings, Briefings, and Visits

Briefings

Ovarian Cancer Briefing (9/15/2011): Dr. Jennifer Loud, Assistant Branch Chief, Clinical Genetics Branch, Human Genetics Program, Division of Cancer Epidemiology and Genetics,

was invited by the Ovarian Cancer National Alliance to join a panel of speakers at a Members-only briefing on ovarian cancer. Reps. Lois Capps (D-CA), Rosa DeLauro (D-CT), and Debbie Wasserman Schulz (D-FL) attended.

Senator Jerry Moran (R-KS) Visits NIH Clinical Center (9/22/2011): Senator Moran came to the NIH for a brief visit to the Clinical Center where he was greeted by NIH Director, Dr. Francis Collins. The Senator and his staff spoke with a young patient and toured clinic and laboratory areas with Drs. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research, and Marston Linehan, Chief, Urologic Oncology Branch, Center for Cancer Research.

Seventh Annual African American Prostate Cancer Disparity Summit (9/22/2011): At the request of Dr. Thomas Farrington, Prostate Health Education Network, Drs. Kathy Cronin and Angela Mariotto, Division of Cancer Control and Population Sciences, presented data and statistics on prostate cancer disparities from the NCI Surveillance Epidemiology and End Results Program.

AACR Breakfast Briefing on NCI Activities (9/22/2011): At the request of Representative John Culberson (R-TX), Dr. Harold Varmus, NCI Director, addressed Republican Study Committee Members and staff to talk about current NCI activities of interest to the group, including the use of nanotechnology in cancer research and advancements in personalized medicine.

Congressional Staff and Advocates Visit NIH (9/27/2011): In collaboration Research!America, NIH hosted twenty congressional staff and eleven advocacy group representatives on a tour of the NIH Clinical Center to provide a firsthand view of the research underway in the intramural program and that funded across the country. NIH presenters included Drs. Francis Collins, Director, NIH; Marston Linehan, Chief, Urologic Oncology Branch, Center for Cancer Research, NCI; Monica Skarulis, Clinical Endocrinology Section, Chen Wong, Metabolic Research Clinical Units, and Marc Reitman, Chief, Diabetes Branch, NIDDK; Ronald Germain, Chief, Laboratory of Systems Biology, NIAID; and Richard Childs, Chief, Section on Transplantation Immunotherapy, Hematology Branch, National Heart, Lung, and Blood Institute, and a patient with a story of recovery.

Multiple Myeloma Briefing (10/25/2011): At the invitation of the International Myeloma Foundation (IMF), Dr. Ola Landgren, Head of the Multiple Myeloma Section in the Metabolism Branch, Center for Cancer Research, presented an overview of NCI-supported myeloma research, including advances in the monitoring and treatment of the disease and its precursor state. Rep. Jackie Speier (D-CA) offered opening remarks, and other panelists included Ms. Arin Assero, IMF; Dr. Barbara Klencke, Onyx Pharmaceuticals, Inc.; and Mr. Michael Katz, Patient Advocate and Member, IMF Board of Directors.

III. Issues of Interest

Shortages of Therapeutic Drugs:

On October 31, President Obama issued an Executive Order directing the FDA and Department of Justice (DOJ) to take action to reduce and prevent drug shortages, protect

consumers, and prevent price gouging. Under this order, the FDA is directed to broaden its efforts to promote earlier notification by drug manufacturers of anticipated shortages and to expedite review processes that may affect the creation of additional manufacturing capacity. In addition the FDA has been asked to work with the DOJ to assess the degree to which some market participants may be responding to drug shortages by illegally hoarding medications or raising prices to gouge consumers.

Concurrently with the issuance of the Executive Order, the FDA sent a letter to drug manufacturers encouraging them to notify FDA of potential prescription drug shortages even in cases where they are not required to do so. The Administration also released an FDA report describing its role in monitoring, preventing, and responding to drug shortages, and a report by the Department of Health and Human Services describing the underlying factors, including economic pressures, that lead to these shortages.

Recent Congressional interest in the drug shortages issues has focused, in part, on economic factors influencing drug shortages, and the impact of “gray market” companies that buy and stockpile drugs and often sell them to the hospitals at significantly marked up prices. Rep. Elijah Cummings (D-MD), ranking member of the House Oversight and Government Reform Committee, recently called for an oversight investigation into “gray market” activities related to drugs in short supply. In addition, Sen. Charles Schumer (D-NY) held a press conference on October 9 and called upon the Federal Trade Commission to investigate drug shortage gray market distributors for price gouging.

Additional Congressional activities around the drug shortage issue include a September 23 hearing held by the House Energy and Commerce Committee. The Preserving Access to Life-Saving Medications Act of 2011 (S. 296, H.R. 2245) was introduced earlier this year to address drug shortages, and would require manufacturers of all prescription drugs, including biologics, to notify the FDA of a discontinuance, interruption, or other disruption that would likely result in a shortage of the drug (a bill summary is included below under “Legislation of Interest”).

Sen. Amy Klobuchar, a lead sponsor of the bill, is working with a bi-partisan group in the Senate that includes her lead co-sponsor Sen. Robert Casey (D-PA), as well as Sens. Richard Blumenthal (D-CT), John McCain (R-AZ), Richard Burr (R-NC), and Bob Corker (R-TN). On October 20, Sen. Casey, also on behalf of Sens. Klobuchar and Blumenthal, introduced an amendment to the Agriculture-Rural Development-FDA appropriations bill to provide an additional \$10 million in appropriations for the Office of the Commissioner of the Food and Drug Administration to support efforts to address and prevent drug shortages. Sen. Tom Harkin (D-IA), has also expressed interest in this issue, joining Sens. Casey and Blumenthal on a request, issued in the spring, that the Government Accountability Office (GAO) conduct a study of drug shortages in the U.S. The GAO study is underway and a report is expected in late fall.

SBIR/STTR Reauthorization:

The SBIR/STTR programs were extended by the Congress (PL 112-17) on June 1, with no changes to the set-asides, through the end of FY2010. Disagreement over the shape of these

programs persists. The House bill, H.R. 1425, authorizes the programs through 9/30/2014, and increases the sizes of the awards (and allows for periodic adjustments due to inflation). It also allows certain agencies, including HHS agencies, to award up to 45% of available SBIR/STTR funds to companies with substantial venture capital investment. The bill would not increase the set-asides, but would not prevent agencies from supplementing SBIR/STTR awards with other funds. The Senate has taken issue with several provisions – most notably the venture-capital ownership issue – and the House bill, as is, is seen as a non-starter in the Senate.

The current CR (see Appropriations) extended the SBIR/STTR programs through November 18, 2011.

Patent Reform:

The 112th Congress passed patent reform legislation on September 8th. The central feature of the measure, known as the America Invents Act (H.R. 1249; P.L. 112-29), is a movement from the “first to invent” patent system, favored by the U.S. since the inception of its patent system, to a “first to file” system. The first-to-file approach is used in all other patent-issuing countries and is viewed as a way to streamline and clarify the patent process.

An important attribute of the first-to-file provision that may be of particular interest to NIH grantees is the grace period. Inventors have a one-year protected period following publication of their work to file their patent applications. Another feature that may be of interest concerns is the prior user rights defense, which generally applies to inventors who choose to protect their inventions as trade secrets rather than patent them. The new law adopts the House provision expanding the invocation of prior user rights for infringement cases to include those relating to all types of patents, except those owned by universities (with the exception of university-owned patents in which the underlying inventions were solely funded by non-Federal dollars).

The Senate passed its version of the bill (S. 23) on March 8 overwhelmingly. The House overcame significant opposition to the first-to-file provision and passed its version on June 23. However, there were significant differences between the two versions, most notably the objection by House appropriators to a popular provision of the Senate’s version that would allow the Patent and Trademark Office (PTO) to keep all of the revenue generated from patent process fees (which is generally a greater sum than its annual appropriation) to help the PTO address its massive backlog and meet new requirements imposed by the legislation. House appropriators were concerned that this would interfere with Congressional oversight of the PTO, but the Senate indicated that elimination of this provision was a deal-breaker. An agreement was reached to continue funding the PTO through appropriations, with excess revenues collected through fees set aside in an “escrow” account that could be tapped via further appropriations. Senate bill managers decided to move the House-passed version in the Senate rather than convene a conference committee over concerns that sending an amended measure back to the House would result in the demise of the legislation. Despite reservations about the fee diversion issue voiced by several Senators, the House-passed version of the bill passed the Senate by an 89 - 9 vote. The President signed the bill on September 16, 2011.

IV. Legislation of Interest

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

Reauthorization of the Breast Cancer Stamp (H.R. 466/S. 384)

- Extends authority of the United States Postal Service to issue the breast cancer semipostal stamp to raise funds for breast cancer research through 2015.
- Maintains the annual reporting requirement for the NIH and the Department of Defense.
- Introduced in the House by Rep. Joe Baca (D-CA) on 1/26/11 and referred to the committees on Armed Services, Energy and Commerce, and Oversight and Government Reform.
- Introduced in the Senate by Sen. Diane Feinstein (D-CA) on 2/17/11 and referred to the Homeland Security and Governmental Affairs Committee. The bill has 65 co-sponsors (D-36, R-27, I-2).
- On 10/19/11, the Senate Homeland Security and Governmental Affairs Committee considered and reported the bill favorably to the full Senate.

Preserving Access to Life-Saving Medications Act of 2011 (S.296, H.R. 2245)

- Requires manufacturers of all prescription drugs, including biologics, to notify the FDA of a discontinuance, interruption, or other disruption that would likely result in a shortage of the drug.
- Instructs HHS to implement evidence-based criteria for identifying drugs vulnerable to shortages.
- The House bill calls for a GAO study to examine possible causes of drug shortages, including manufacturing problems, breakdowns in supply chain and delivery systems, and restrictive regulatory requirements.
- Requires HHS to report to Congress to address actions taken to address drug shortages.
- S.296 was introduced by Sens. Amy Klobuchar (D-MN) and Bob Casey (D-PA) on 2/7/11. The bill has 11 co-sponsors.
- H.R. 2245 was introduced by Reps. Tom Rooney (R-FL) and Diana DeGette (D-CO) on 6/21/11 and has 9 co-sponsors.

SBIR/STTR Reauthorization Act of 2011 (S. 493):

- Reauthorizes SBIR/STTR programs for 8 years; through FY 2019.
- Increases SBIR set aside by 0.1 % per year, from FY 2013-2023; and increases the STTR set aside from 0.3% to 0.6% by 0.1% every two years from FY2013-2017.
- Increases individual SBIR/STTR award levels from \$100,000 to \$150,000 for Phase I and from \$750,000 to \$1 million for Phase II.
- Authorizes the NIH, DOE, and NSF to award up to 25% of SBIR funds to small businesses majority-owned by multiple venture capital (VC) companies. Permits other federal agencies to award up to 15% of their SBIR funds to such small businesses.

- Introduced by Senators Mary Landrieu (D-LA) and Olympia Snowe (R-ME) on 3/4/11 and has 8 cosponsors.
- The Senate Committee on Small Business & Entrepreneurship held a hearing on 3/9/11, where NIH witness, Sally Rockey (Deputy Director for Extramural Research- NIH), testified. During the hearing, Rockey reported that the Administration is currently reviewing the set aside percentages. Since the set asides are percentages of the budget, the SBIR/STTR budget increases alongside the NIH budget. However, in flat funding, the set aside takes away from the larger NIH portfolio.
- On 3/9/11, the Senate Committee reported the bill with amendments. The amendment allows a federal agency to transfer an amount equal to any amount awarded to a 'covered small business concern' from non-SBIR and non-STTR funds of the federal agency not later than 90 days after which the federal agency makes the award. A 'covered small business concern' is defined as companies that were not majority-owned VCs at the time they submitted their application, but changed their status to VC by the time of award. In essence it expands the SBIR/STTR pool and preserves the 25% limit on awards to VC companies.
- On 4/6/11, the Senate considered the bill. However, numerous amendments not germane to the bill were added to it. The bill was then set aside along with the amendments to be considered at a later date.
- On 5/4/11, the Senate considered the bill and failed to invoke cloture on the bill to limit debate and end the dispute over numerous amendments to the bill.

Creating Jobs Through Small Business Innovation Act of 2011 (H.R. 1425):

- Reauthorizes SBIR/STTR programs for 3 years; through FY 2014.
- Increases individual SBIR/STTR award levels from \$100,000 to \$150,000 for Phase I and from \$750,000 to \$1 million for Phase II.
- Authorizes the NIH, DOE, and NSF to award up to 45% of SBIR funds to small businesses majority-owned by multiple venture capital companies. Permits other federal agencies to award up to 35% of their SBIR funds to such small businesses.
- Introduced by Rep. Renee Ellmers (R-NC) on 4/7/11 and has 23 cosponsors.
- On 3/16/11, House Small Business Committee Chairman, Rep. Sam Graves (R-MO), held a hearing titled "Spurring Innovation and Job Creation: The Small Business Innovation Research (SBIR) Program."
- On 4/7/11, Rep. Ellmers, Chair of the House Small Business Subcommittee on Healthcare & Technology held a hearing and introduced H.R.1425 "Creating Jobs through Small Business Innovation Act of 2011."
- On 4/13/11, the Subcommittee on Technology and Innovation held a mark-up of H.R. 1425 and approved the bill by voice vote.
- On 5/3/11, the bill was re-referred to the committees on Small Business, Armed Services and Science, Space & Technology for consideration.
- On 5/4/11, the full Committee on Science, Space & Technology considered the bill.
- On 5/11/11, the full Small Business Committee reported the bill, as amended, favorably to the full House.
- On 5/26/11 the Committee on Science, Space, and Technology reported the bill, amended, favorably to the House (H. Rept. 112-90).

- On 7/1/11 the House Armed Services Committee discharged the bill and placed in on the Union Calendar.

Selected New Bills

Consistency, Accuracy, Responsibility, and Excellence (CARE) in Medical Imaging and Radiation Therapy Act of 2011 (H.R. 2104)

- The purpose of this Act is to require personnel who perform or plan the technical component of either medical imaging examinations or radiation therapy procedures for medical purposes to possess, to hold certification designated by the Secretary of DHHS, or state certification or licensure that meets or exceeds DHHS standards.
- The Act also directs DHHS to establish and implement a certification process, and would only allow Medicare payment for medical imaging and radiation services performed by personnel who meet the certification requirements of the Act.
- H.R.2104 was introduced by Rep. Ed Whitfield (R-KY) on 6/2/11.

Prostate Research, Outreach, Screening, Testing, Access and Treatment Effectiveness (PROSTATE) Act of 2011 (S. 1190 / H.R. 2159):

- The purpose of this legislation is to improve prostate cancer screening and treatment, particularly in medically underserved communities, by establishing the Interagency Prostate Cancer Coordination and Education Task Force, intensifying prostate cancer research; utilizing telehealth programs to reach medically underserved communities, and carrying out a national education campaign.
- VA is designated as the lead on most provisions. Several provisions require that the VA work with HHS and other agencies.
- S. 1190 was introduced by Sen. Jon Tester (D-MT) and referred to the Committee on Health, Education, Labor and Pensions on 6/14/11. The bill has 5 cosponsors.
- H.R. 2159 was introduced by Rep. Edolphus Towns (D-NY) and referred to the Committees on Armed Services, Energy and Commerce, and Veterans' Affairs on 6/14/11. The bill has 31 cosponsors.

Stem Cell Research Advancement Act of 2011 (H.R. 2376)

- The purpose of this Act is to require the Secretary of DHHS to conduct and support research that utilizes human stem cells, including human embryonic stem cells. The Act limits this research to the use of specific sources of human embryonic stem cells.
- The Act prohibits DHHS support of human cloning, and requires the NIH Director to include information on human stem cells in the biennial report to Congress.
- H.R. 2376 was introduced by Rep. Diana DeGette (D-CO) on 6/24/11 and was referred to the House Committee on Energy and Commerce, Subcommittee on Health. The bill has 19 cosponsors.

Cancer Drug Coverage Parity Act of 2011 (H.R. 2746)

- The bill would require group and individual health insurance coverage and group health plans to provide coverage of oral anticancer drugs on terms no less favorable than the coverage provided for intravenously administered anticancer medications.

- Introduced by Rep. Brian Higgins (D-NY) on 8/1/11 and has 3 cosponsors. The bill was referred to the House Subcommittee on Health, Employment, Labor, and Pensions on 9/8/11.

Access to Medical Treatment Act (H.R. 2736)

- This bill would enable an individual to be treated by a health care practitioner with any medical treatment that the individual desires - including a treatment that is not approved, certified, or licensed by the Secretary of Health and Human Services - if the practitioner has personally examined the individual and agrees to treat the individual, and the administration of such treatment does not violate licensing laws.
- H.R. 2736 was introduced by Rep. Dan Burton (R-IN) on 8/5/11. The bill has one cosponsor and was referred to the House Committee on Energy and Commerce, Subcommittee on Health.

Health Equity and Accountability Act of 2011 (H.R. 2954)

- This broad bill addresses a variety of health-related issues, and includes the following directives which authorize the NCI to take a leadership role:
 - The implementation of a Lung Cancer Mortality Reduction Program (see Lung Cancer Mortality Reduction Act of 2011 – H.R. 1394/S. 752); and
 - The expansion of prostate cancer research, outreach, screening, testing, access, and treatment effectiveness (see PROSTATE Act – H.R. 2159/S. 1190).
- Various provisions included in the bill also address ongoing research conducted by NIH, including NCI research on disease states such as liver cancer caused by hepatitis B and C, and acquired bone marrow failure diseases.
- Introduced by Rep. Barbara Lee (D-CA) on 9/15/11 and has 72 cosponsors. The bill was referred to the House Subcommittee on Health on 10/3/11.

Patients First Act of 2011(H.R. 2951)

- The purpose of this Act is to require the Secretary of DHHS to conduct and support basic and applied research to develop techniques for the isolation, derivation, production, testing, and human clinical use of stem cells, including pluripotent stem cells.
- The Act prohibits the creation of a human embryo for research purposes; the destruction or discarding of, or risk of injury to, a living human embryo; or the use of any stem cell derived or provided in a way inconsistent with the provisions of the Act.
- H.R. 2951 was introduced by Rep. J. Randy Forbes (R-VA) on 9/15/11 and was referred to the House Committee on Energy and Commerce. The bill has 23 cosponsors.

Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act of 2011 (S. 1613/H.R. 3015)

- The purpose of this Act is to improve and enhance research and programs on childhood cancer survivorship.
- It amends the Public Health Service Act to require the Secretary of Health and Human Services (HHS) to make grants to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer

survivors; and requires the Secretary to convene a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer.

- It reauthorizes and expands the NCI's pediatric cancer research program to include research on survivors within medically underserved populations, health disparities in survivorship outcomes, and follow-up care for survivors.
- S. 1613 was introduced by Sen. Jack Reed (D-RI) on 9/22/11 and was referred to the Senate Committee on Health, Education, Labor, and Pensions. The bill has one cosponsor.
- H.R. 3015 was introduced by Rep. Jackie Speier (D-CA) on 9/22/11 and was referred to the House Committee on Energy and Commerce. The bill has 10 cosponsors.

Creating Hope Act of 2011 (H.R. 3059/S. 606)

- The legislation would authorize the FDA to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases, including pediatric cancers.
- The bill would allow the FDA to incentivize drug manufacturers to develop therapies for tropical or rare pediatric diseases, including pediatric cancers. Under this authority, the FDA could offer, to those companies developing these therapies, vouchers for expedited review of other, potentially more profitable, drug products.
- H.R. 3059 was introduced by Rep. Michael McCaul (R-TX) on 9/23/11 and has 55 cosponsors. The bill was referred to the House Energy and Commerce Committee on 9/23/11.
- S. 606 was introduced by Sen. Robert P. Casey (D-PA) on 3/17/11 and has 8 cosponsors. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions on 3/17/11.

Accelerating the End of Breast Cancer Act of 2011 (H.R. 3067)

- 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.
- Introduced by Rep. Karen Bass (D-CA) on 9/26/11 and has 16 cosponsors. The bill was referred to the House Energy and Commerce Committee on 9/26/11.

Breast Density and Mammography Reporting Act of 2011 (H.R. 3102)

- The bill requires that every mammography summary delivered to a patient after mammography examination, as required by the Mammography Quality Standards Act of 1992, contain information regarding the patient's breast density and language communicating that individuals with more dense breasts may benefit from supplemental screening tests.
- Introduced by Rep. Rosa DeLauro (D-CT) on 10/5/11 and has 20 cosponsors. The bill was referred to the House Energy and Commerce Committee on 10/5/11.

Nanotechnology Regulatory Science Act of 2011 (S. 1662)

- This bill would establish a nanotechnology regulatory science program for the investigation of nanomaterials, which would include addressing the toxicity of these materials, and potential effects on and interactions with biological systems.

- The Act requires DHHS consultation with the Secretary of Agriculture, and encourages DHHS/FDA coordination with agencies participating in the National Nanotechnology Initiative
- S. 1662 was introduced by Sen. Mark Pryor (D-AR) on 10/6/2011 and referred to the Senate Committee on Health, Education, Labor, and Pensions. The bill has one cosponsor.

Federal Advisory Committee Act Amendments of 2011 (H.R. 3124)

- The bill would amend the Federal Advisory Committee Act to extend the provisions of the Act to apply to each advisory committee, including any subcommittee or subgroup, to include working groups, task forces, or other entities formed for the purpose of assisting any committees or subcommittees.
- Specific provisions include requiring that appointments be made without regard to political affiliation or activity and requiring a public nomination process of committee members.
- The bill would also require that advisory committee members be designated “special government employees” or “representatives” and that any recommendation from advisory committees be accompanied by a statement describing the process used in formulating the recommendation.
- Introduced by Rep. William Lacy Clay (D-MO) on 10/6/11 and has 16 cosponsors. The bill was referred concurrently to the House Committees on Oversight and Government Reform, and Ways and Means.
- On 10/13/2011, the Committee on Oversight and Government Reform considered and reported the bill favorably to the full House.

Modernizing Laboratory Test Standards for Patients Act of 2011 (H.R. 3207)

- The purpose of the bill is to create a pathway for premarket notification and review of laboratory tests.
- The bill would require the Secretary, in consultation with the Director of NIH, to establish a single, publicly accessible test registry and data bank, which would be administered by the Centers for Medicare and Medicaid Services.
- The bill specifically states that the Secretary shall not require a test-offering entity to include (for purposes of demonstrating clinical validity) evidence of clinical utility.
- Introduced by Rep. Michael Burgess (R-TX) on 10/14/11 and has 3 cosponsors. The bill was referred to the House Energy and Commerce Committee on 10/14/11.

Selected Recent Resolutions

Recognizing that the occurrence of prostate cancer in African-American men has reached epidemic proportions (H. Res. 313)

- Recognizing that the occurrence of prostate cancer in African-American men has reached epidemic proportions and urging Federal agencies to address that health crisis by designating additional funds for research, education, awareness outreach, and early detection.

- Introduced by Rep. Gregory Meeks (D-NY) on 6/16/11 and has no cosponsors. The resolution was referred to the House Energy and Commerce Committee, Subcommittee on Health, on 6/22/11.

National Prostate Cancer Awareness Month (H. Res. 336)

- A resolution expressing support for designation of September 2011 as “National Prostate Cancer Awareness Month.”
- Calls for efforts to increase awareness of, access to, and research to improve, prostate cancer screening and treatment.
- Introduced by Rep. Randy Neugebauer (R-TX) and referred to the House Energy and Commerce Committee, Subcommittee on Health, on 6/24/11. The resolution has 13 cosponsors.

National Ovarian Cancer Awareness Month (S. Res. 242)

- Expressing the Senate’s support for the designation of September 2011 as National Ovarian Cancer Awareness Month.
- Introduced by Sen. Debbie Stabenow (D-MI) and agreed to in the Senate on 7/29/11.

Supporting Stomach Cancer Awareness Month (S. Res. 245)

- Designates November 2011 as Stomach Cancer Awareness Month, and expresses the Senate’s support of efforts to educate the public about stomach cancer.
- Introduced by Sen. John Kerry (D-MA) and referred to the Judiciary Committee on 7/29/11.

National Ovarian Cancer Awareness Month (H. Res. 407)

- A resolution expressing support for designation of September 2011 as “National Ovarian Cancer Awareness Month.”
- Introduced by Rep. Dan Burton (R-IN) and referred to the House Oversight and Government Reform Committee on 9/20/11. The resolution has 43 cosponsors.

National Prostate Cancer Awareness Month (S. Res. 278)

- A resolution designating September 2011 as “National Prostate Cancer Awareness Month.”
- Calls for efforts to increase awareness of, access to, and research to improve, prostate cancer screening and treatment.
- Introduced by Senator Jeff Sessions (R-AL) and agreed to on 9/23/11.