November 6, 2013

Legislative Update
for the
Clinical Trials and Translational Research Advisory Committee
Activities of the 113th Congress-
First Session

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I. Appropriations
The federal government is currently operating under a continuing resolution (PL 113-46) that funds most agencies, including NIH and NCI, at the FY2013 level, at a rate of operations that reflects the sequestration cuts and all rescissions in the last continuing resolution (PL 113-6), excluding Hurricane Sandy supplemental funding. It provides for funding at this level through 1/15/14 or until enactment of new applicable appropriations, whichever occurs first. NCI's appropriation through 1/15/14 is approximately $1.4 billion.

The continuing appropriations act passed in the Senate by a vote of 81-18 and in the House by a vote of 285-144 on 10/16/13. It was signed into law by the President on 10/17/13, ending the October 2013 government shutdown.

The law also extends the debt limit through 2/7/14, and provides for pay and benefits for furloughed federal employees. It allows for funding flexibility for a number of agencies to ensure that certain activities are carried out, including funding for biological and chemical preparedness. It also extends through FY2014 certain federal agency reporting requirements for conferences costing more than $100,000.

Additionally, per the agreement negotiated by Senate Democratic and Republican leaders, House and Senate budget conferees have been appointed to continue negotiations aimed at reaching an agreement on a budget for the remainder of FY2014, with a deadline to deliver the spending plan to Congress by 12/13/13. Led by House Budget Chair Paul Ryan (R-WI), and Senate Budget Chair Patty Murray (D-WA), the 29 members of the conference committee have significant differences to resolve, with the House entering negotiations set on maintaining sequestration cuts and proposing an overall spending limit of $967 billion, and the Senate basing its proposal of $1.058 trillion on the assumption that Congress will repeal sequestration. The House budget proposal also protects funding for the Defense, Military Construction-VA, and Homeland Security, and as a result, imposes sharp cuts on non-defense discretionary spending, which includes NIH. For example, the Defense bill would increase 5.4%, while the Labor-HHS bill (which funds HHS/NIH/NCI) would be cut by 18.6% below the current, post-sequestration level (a $35 billion cut).

Despite this impasse, which was evident well ahead of the October shutdown, the appropriations committees continued to move FY2014 spending bills. Prior to the August recess, the House Appropriations Committee advanced all but two spending bills out of committee (Labor-HHS and Interior-Environment), and four bills – Military Construction-VA, Homeland Security (DHS), Defense, and Energy-Water – were passed by the House. The Senate Appropriations Committee advanced all but the Interior-Environment bill out of committee. The Senate Appropriations Committee passed a Labor-HHS Appropriations bill in July (providing $30.955 billion for NIH, an increase of $307 million from FY2013) – as noted, the House Appropriations Subcommittee has not released a Labor-HHS appropriations bill for comparison.

Also of note, during the government shutdown, the House passed a resolution that would have provided continuing appropriations specifically for the NIH. Referred to as the “Research for Lifesaving Cures Act,” the bill proposed continuing appropriations for the NIH through December 15, 2014 or until applicable appropriations are made for FY2014, whichever occurs first. Like the agreement that was ultimately reached to restore funding for the entire government, the act proposed funding at FY2013 levels, including reductions imposed by sequestration. The proposal also would have authorized compensation and benefits to avoid furloughs of NIH employees. The act was introduced by Rep. Jack Kingston (R-GA), Chairman of the House Labor-HHS Appropriations Subcommittee on 10/2/13 and passed in the House by a vote of 254-171 on the same day. The act was one of many House proposals to provide funding to re-open individual agencies or programs during the October 2013 government shutdown. The Senate never considered these proposals, as majority leadership indicated only a proposal to fund and re-open the entire government would receive consideration in the Senate.
Most recently, Rep. Allyson Schwartz (D-PA), introduced a bill to provide $3 billion in supplemental appropriations to the NIH for the remainder of FY2014. In an effort to be deficit neutral, the “Inspiring Scientific Research and Innovation Supplemental Appropriations Act, 2014” would offset this additional funding to NIH by eliminating a provision in the Internal Revenue Code that provides a tax break for corporate jet owners. Rep. Schwartz cited the support of various health systems and research organizations in her press release announcing the introduction of the bill, including the University of Pennsylvania Health System, the Children’s Hospital of Philadelphia, and the Sandy Rollman Ovarian Cancer Foundation.

II. Special Topics

FDA Regulation of Tobacco: E-Cigarettes, Pending Legislation, and Trade Negotiations

Members of Congress, public health advocates, and the National Association of Attorneys General are now calling on President Obama and the FDA to assert regulatory authority over electronic cigarettes, or e-cigarettes, a cigarette-shaped product designed to deliver vaporized nicotine (derived from tobacco plants), along with little cigars, cigars, and other tobacco products yet to be regulated by the agency. At the same time, members of Congress are also calling on e-cigarette manufacturers to disclose more information on their marketing practices, including specific tactics shown to appeal to minors.

Four democrats on the House Energy and Commerce Committee, including Ranking Member Rep. Henry Waxman (D-CA), and Subcommittee on Health Ranking Member Rep. Frank Pallone (D-NJ), wrote to FDA Commissioner Margaret Hamburg on 9/16/13, urging the FDA to regulate e-cigarettes. The advocates’ letter, sent to the President on 9/19/13, makes a similar request, and points out that while fruit and candy flavors are prohibited in cigarettes, smokeless and roll-your-own (RYO) tobacco, these flavors are still permitted – and widely available – via cigars, little cigars and e-cigarettes (in flavors such as cotton candy, gummy bear, bubble gum, grape, and strawberry). The letter is signed by 14 organizations, including the American Academy of Pediatrics, the American Lung Association, the American Cancer Society Cancer Action Network, the American Heart Association, the American Public Health Association, and the Campaign for Tobacco-Free Kids.

On 9/24/13, Attorneys General from 41 states echoed the advocates’ call in a letter to Commissioner Hamburg, asking the FDA to issue proposed regulations by 10/31/13 to address e-cigarettes, and pointing to the growing e-cigarette market and the product’s appeal to youth. They emphasized the need for regulation by highlighting the lack of safety information available, noting, “Consumers are led to believe that e-cigarettes are a safe alternative to cigarettes, despite the fact that they are addictive, and there is no regulatory oversight ensuring the safety of the ingredients in e-cigarettes.”

The Family Smoking Prevention and Tobacco Control Act was signed into law on 6/22/09, giving the FDA the authority to regulate tobacco products – specifically cigarettes, smokeless and RYO tobacco – and the ability to expand its regulatory scope to include other tobacco-related products through its rule-making process. For example, in accordance with the Act, on 9/22/09, the FDA issued the rule banning cigarettes, smokeless and RYO tobacco with fruit, candy, and clove flavors. On 6/22/10 the FDA issued a rule restricting the sale and distribution of cigarettes and smokeless tobacco, in an effort to make these products less accessible and less attractive to children and adolescents.

The FDA had indicated its intention to issue a proposed rule regarding e-cigarettes, cigars, and other tobacco products by 10/31/13, however delays occurred due to the government shutdown, which postponed Office of Management and Budget review. In the meantime, legislation is still pending that would exempt cigars from FDA regulation. The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2013 was introduced in the House on 2/15/13, and in the Senate on 4/18/13. Similar legislation has been introduced in past sessions of Congress and has never moved out of committee. While e-cigarettes have not been the focus of federal legislation,
a number of states have passed and are considering legislation to restrict access to and use of e-cigarettes, with 23 states already prohibiting the sale of e-cigarettes to minors. Massachusetts prohibits the use of e-cigarettes in the workplace, and pending proposals include a bill that has already passed the California Senate that would ban e-cigarette use wherever smoking is banned. Connecticut has similar legislation pending, as does the District of Columbia.

Additionally, the Centers for Disease Control (CDC) reported survey results on 9/6/13 indicating e-cigarette use has doubled among middle and high school students in just one year, from 4.7% to 10.0% among high school students during 2011-2012. The CDC estimates that 1.78 million middle and high school students used e-cigarettes in 2012. Mitch Zeller, director of FDA’s Center for Tobacco Products, commented on the study, alluding to the expected FDA rule, “These findings reinforce why the FDA intends to expand its authority over all tobacco products and establish a comprehensive and appropriate regulatory framework to reduce disease and death from tobacco use.”

Twelve members of Congress, Democrats in both the House and Senate, expressed their concerns about these rising numbers in letters to the nine manufacturers of e-cigarettes, sent on 9/26/13. The letters focused specifically on the marketing and sale of e-cigarettes to minors, and noted the product’s lack of federal regulation, “Currently, e-cigarettes are not subject to federal laws and regulations that apply to traditional cigarettes. For example, federal laws and regulations prohibit traditional cigarettes from being sold to persons younger than 18, distributed as free samples, advertised on television and radio, and having characterizing fruit flavors that appeal to kids. . . . For more than four decades a federal ban on cigarette ads for radio and television has helped to deglamorize smoking for young people. We are concerned that e-cigarette makers are using a broad range of marketing techniques previously employed by traditional cigarette companies to entice youth to use their products.” The letter presented twenty questions to the companies, and requested written responses by 10/25/13. Signatories include Assistant Majority Leader Sen. Richard Durbin (D-IL) and Health, Education, Labor, and Pensions Chairman Sen. Tom Harkin (D-IA), as well as Reps. Waxman and Pallone.

Additionally, on 9/12/13, Sen. Sherrod Brown (D-OH), who also signed the September 26 letter, spoke on the Senate floor about ongoing negotiations of the Trans-Pacific Partnership (TPP) trade agreement, and also sent a letter to the U.S. Trade Representative (USTR) regarding this issue. In his floor remarks, Sen. Brown commented that the USTR had originally proposed a “safe harbor” clause for tobacco, which would limit the tobacco industry’s ability to challenge the tobacco control policies of the countries party to the agreement.

Sen. Brown voiced his concern that if the TPP proceeds without a tobacco safe harbor clause, the U.S. Family Smoking Prevention and Tobacco Control Act could be open to an “investor-state” trade dispute, where a company would be able to challenge the public health law in trade court. He cited examples of the tobacco industry bringing such suits in other countries, challenging Australia’s Tobacco Plain Packaging Act of 2011, and Uruguay’s graphic warning labels for tobacco products.

The TPP currently contains a general exception for matters necessary to protect human life or health, and the USTR has proposed a provision to clarify the parties’ understanding that this exception applies to tobacco health measures. The USTR has also proposed adding a provision to the TPP requiring that the health authorities of concerned parties to the agreement must meet to discuss any potential challenge to another party’s tobacco regulatory measure before formally initiating a challenge through the TPP dispute settlement process. HHS has stated that these proposals will make a difference for tobacco control and public health efforts, describing the inclusion of these provisions in the TPP as an “important step forward for public health in the international trade community.”

Most recently, on 10/30/13, more than 50 members of Congress wrote to President Obama expressing their concerns about the USTR’s position regarding tobacco and the TPP. They encouraged the President to urge USTR to reconsider its position and include a safe harbor provision.
STEM Education Legislation

Science, technology, engineering, and mathematics (STEM) education continues to be a topic of Congressional interest. Federal agencies, as well as the private and public sectors, rely on knowledgeable, properly trained, and skilled STEM workers to ensure a highly qualified workforce to fulfill organizational goals and advance science and innovation. Improvements to STEM education programs, from preschool to post-doctoral programs, are aimed at stimulating interest in STEM disciplines and providing the foundation to fulfill the growing demand for STEM workers within the United States.

Recognizing this need, many members of Congress are focused on improving STEM education and have introduced several bills in the 113th Congress. Sen. Tammy Baldwin (D-WI) introduced a STEM education bill on 9/26/13 of particular interest to NIH: the Next Generation Research Act (S. 1552). The main goal of this bill is to increase opportunities to develop future researchers through the establishment of the Next Generation of Research Initiative within the NIH. The proposed initiative would promote efforts aimed at improving opportunities for new researchers, including efforts to strengthen mentorship programs pairing new and veteran researchers, to enhance workforce diversity efforts, and to help improve new researchers’ success in obtaining renewal funding. The legislation would also call upon the NIH to study factors that affect the next generation of biomedical researchers and make recommendations for how to incentivize students to pursue research careers.

While none of the STEM education bills introduced during this Congress have been signed into law, some have gained several cosponsors – this suggests continuing interest in this area and the trend has been particularly apparent among Democrats. Rep. Mike Honda (D-CA) introduced two STEM education bills on 3/12/13. H.R. 1089, the Stepping up STEM Act of 2013, which currently has 42 cosponsors, includes provisions that would coordinate the nation’s STEM education initiatives and create an office of STEM Education in the Department of Education and an Advanced Research Projects Agency for Education (ARPA-ED). H.R. 1090, the Elementary Educator STEM Content Coach Act of 2013, has 10 cosponsors to date and would create a cohort of educators with deep content knowledge in STEM disciplines.

In addition, Sen. Jeff Merkley (D-OR) introduced S. 854, the STEM Education for the Global Economy Act of 2013, on 4/25/13, to improve student academic achievement in STEM subjects through a capacity-building competitive grant program. On 4/26/13, Rep. Marc Veasey (D-TX) introduced H.R. 1816, the Veterans’ STEM Education program, to provide additional assistance under the Post-9/11 GI Bill for veterans pursuing STEM degrees. H.R. 1816 was introduced as a companion bill to S. 514, introduced by Sen. Sherrod Brown (D-OH) on 3/11/13.

III. Congressional Briefings and Visits

NCI Staff Spoke at Childhood Cancer Summit (9/19/13) – At the request of Representatives Michael McCaul (R-TX) and Chris Van Hollen (D-MD), co-chairs of the House Childhood Cancer Caucus, Dr. Crystal Mackall, Chief, Pediatric Oncology Branch, Center for Cancer Research, NCI, spoke about pediatric cancer research. Representatives Michael McCaul, Chris Van Hollen, and Dana Rohrabacher (R-CA) provided brief remarks. Representative John Carney (D-DE) also attended but did not make remarks.

NCI Staff Spoke at Press Event (9/19/13) – At the request of Hyundai Hope on Wheels, Dr. Crystal Mackall, Chief, Pediatric Oncology Branch, Center for Cancer Research, NCI, gave a brief presentation about the importance of public/private partnerships in advancing biomedical research. Representatives Chris Van Hollen (D-MD), Mike Kelly (R-PA), Chaka Fattah (D-PA), Janice Hahn (D-CA), and G.K. Butterfield (D-NC) gave remarks. This event was linked to, but separate from, the Childhood Cancer Summit.

NCI Staff Spoke at Senate Cancer Coalition Forum (9/18/13) – At the request of Senators Dianne Feinstein (D-CA) and Johnny Isakson (R-GA), chair and co-chair, respectively, of the Senate Cancer Caucus, Lou Staudt, Director,
Center for Cancer Genomics, NCI, participated in a panel discussion entitled, “Innovative Treatment Options and Breakthroughs in Cancer Care. Senator Feinstein moderated the event and Senator Richard Blumenthal (D-CT) made brief remarks.

NCI Staff Spoke at Congressional Lunch Briefing on Ovarian Cancer (9/17/13) – At the request of the Society for Women’s Health Research, Dr. Elise Kohn, Head, Gynecologic Cancer Therapies, Division of Cancer Treatment and Diagnosis, NCI, spoke about ovarian cancer research. Representative Rosa DeLauro (D-CT) sponsored the event.

HELP Committee Staff Visited NCI (8/20/13) – At the request of Barbara Damron, Health Policy Fellow, staff members from the Senate Committee on Health, Education, Labor and Pensions (HELP) visited the NIH campus to meet with NCI investigators. The group met with Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research (CCR), and visited a clinic setting with Dr. Ola Landgren, Senior Investigator, Metabolism Branch, CCR, and toured the lab of Dr. Carole Parent, Deputy Laboratory Chief, Laboratory of Cellular and Molecular Biology, CCR.

NCI Staff Spoke at Congressional Briefing on Cancer Health Disparities (7/24/13) – At the request of the American Association of Cancer Research, Dr. Worta McCaskill-Stevens, Director, Community Oncology Research Program, NCI, spoke at a briefing entitled, “Reducing Cancer Health Disparities Through Research.” Representatives Elijah Cummings (D-MD), Barbara Lee (D-CA), Raul Grijalva (D-AZ), and Rodney Davis (R-IL), sponsored the event with Representative Davis providing remarks. Howard Koh, Assistant Secretary for Health, HHS, also was a featured speaker.

Representative Peters Visited NIH (7/19/13) – Rep. Scott Peters (D-CA) and staff visited NIH. They met with Drs. Francis Collins, Director, NIH, and Eric Green, Director, NHGRI, and toured two labs in the Clinical Center: the NHGRI Undiagnosed Disease Program and the NCI Molecular Imaging Clinic.

Senator Tammy Baldwin Visited NIH (7/15/13) – Sen. Tammy Baldwin (D-WI) visited the NIH campus and met with Drs. Francis Collins, Director, NIH, and Eric Green, Director, NHGRI, and toured two labs in the Clinical Center: the NHGRI Undiagnosed Disease Program and the NCI Molecular Imaging Clinic.

III. Legislation of Interest
The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the BSA 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 (113th Congress)

CHIMP Act Amendments of 2013 (S. 1561)
- This bill would amend provisions in the Public Health Service Act relating to the federal sanctuary system for surplus chimpanzees. Specifically, the bill provides the authority for the NIH to continue to fund the sanctuary system beyond the current $30 million cap if the Secretary of HHS determines that it would enable the NIH to operate more efficiently and economically by decreasing the overall federal cost of supporting and maintaining chimpanzees from FY 2014 through FY 2023.
- In addition, the bill amends a provision so that the Secretary, in consultation with the federal sanctuary Board of Directors, determines if another facility meets the standards of care in the NIH regulations instead of the Board of Directors solely making that determination.
- The Act was introduced by Senator Tom Harkin (D-IA) on 9/30/13, and was referred to the HELP
Committee. The bill was passed in the Senate by unanimous consent on 10/30/13.

Grant Reform and New Transparency (GRANT) Act of 2013 (H.R. 3316)

- The bill would amend title 31, United States Code, to provide transparency and require certain standards in the award of federal grants. The provisions include requirements for posting grant award information for each competitive grant awarded by a federal agency on a public web site. Specifically, the bill would require the posting of:
  o The executed grant agreement;
  o A copy of the grant proposal, application or plan;
  o The award decision documentation and rankings;
  o A justification for deviating from rankings; and
  o The disclosure of information on individuals who served as peer reviewers on the grant.

- The bill does include an exception to the requirement for posting grant applications if posting the full proposal would adversely affect an applicant or agency.

- In addition, the bill would require the posting of grant performance information within 60 days after the end of the period for completion of the grant.

- The Act was introduced by Rep. James Lankford (R-OK) on 10/23/2013 and was referred to the House Committee on Oversight and Government Reform. A committee consideration and mark-up session was held on 10/29/13 and the bill was voted out of committee.

Additional Information: To date, no companion bill has been introduced in the Senate.

Drug Quality and Security Act (H.R. 3204)

- The bill aims to clarify laws related to human drug compounding, and to strengthen the drug supply chain.

- Regarding drug compounding, the bill:
  o Distinguishes compounders engaged in traditional pharmacy practice from those making large volumes of compounded drugs without individual prescriptions.
  o Allows compounders who prefer to practice outside the scope of traditional pharmacy practice to register as outsourcing facilities. Compounders who choose to remain traditional pharmacies will continue to be primarily regulated by State Boards of Pharmacy as they are in current law.
  o Defines the FDA’s role in oversight of outsourcing facilities, with these facilities subject to FDA oversight in much the same way as traditional manufacturers.
  o Gives providers and patients the option of purchasing products from outsourcing facilities that comply with FDA quality standards.
  o Requires the FDA to list FDA-regulated outsourcing facilities on its website, requires detailed labeling on compounded drugs, and prohibits false and misleading advertising.
  o Clarifies current federal law regarding pharmacy compounding by resolving the patchwork of current federal regulation and applying a uniform standard nationwide.

- Regarding a “track and trace” system for prescription drugs, the bill:
  o Replaces the current state product tracing laws with a uniform standard, in an effort to implement electronic, interoperable unit-level product tracing throughout the country over a ten year implementation period.
  o Requires, over seven years, that the major sectors of the pharmaceutical supply chain share and track key information about each drug’s distribution history. Within ten years, supply chain stakeholders will be required to participate in electronic, interoperable product tracing.
  o Strengthens licensure requirements for wholesale distributors and third-party logistics providers. In addition, the bill would require the FDA to keep a database of wholesalers that will be available to the public through the FDA’s website.
  o Establishes nationwide drug serial numbers, to be implemented by four years after the date of enactment.

- The Act was introduced by Rep. Fred Upton (R-MI), Chairman of the House Energy and Commerce Committee, on 9/28/13 and passed in the House by a voice vote on 9/28/13.
Next Generation Research Act (S. 1552)

- The main goal of this bill is to increase opportunities for the development of our next generation of researchers through the establishment of the Next Generation of Research Initiative within the National Institutes of Health (NIH).
- The proposed initiative would promote efforts aimed at improving opportunities for new researchers including efforts to strengthen mentorship programs pairing new and veteran researchers, to enhance workforce diversity efforts, and to help improve new researchers’ success in obtaining renewal funding.
- The bill would require the National Academy of Sciences (NAS) to conduct a comprehensive study of legislative, administrative, educational, and cultural barriers to providing for a successful next generation of biomedical researchers.
- In addition, a report to Congress would be required within five years of the date of enactment concerning the results of the NAS study including an evaluation of the impact of sequestration on the next generation of researchers and recommendations for the implementation of policies to incentivize, improve entry to, and sustain careers in research.
- The bill was introduced by Sen. Tammy Baldwin (D-WI) on 9/26/13 and was referred to the HELP Committee.

Additional Information: During her July visit to NIH, Sen. Baldwin discussed her concerns about the limited opportunities for young scientists – at the time of her visit she was considering introducing legislation to incentivize careers in science.

PEPFAR Stewardship and Oversight Act of 2013 (S.1545/H.R.3177)

- The bill would extend authorities related to global HIV/AIDS and promote oversight of the United States Programs. The reported version of the bill would add to the requirement for an annual report a description, globally and by country, of specific efforts to address co-infections and comorbidities of HIV/AIDS, including the number and percent of people in HIV care or treated who started tuberculosis treatment; and the number and percentage of eligible HIV positive patients starting isoniazid preventative therapy.
- The Senate Committee Report indicates that the description of efforts to limit co-morbidities should include a discussion on AIDS-related cancers, including trends with respect to cervical cancer, and efforts to address such cancers.
- The Act was introduced by Sen. Robert Menendez (D-NJ) on 9/24/13 and was reported favorably out of the Senate Committee on Foreign Relations on October 2, 2013. The Act was introduced in the House by Rep. Eliot Engel on September 25, 2013, and was referred to the House Committee on Foreign Affairs.

MODERN Cures Act of 2013 (H.R. 3116)

- The bill’s full title is the Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2013, and it aims to address potential regulatory and reimbursement challenges that may be precluding new treatments from reaching patients, particularly those with rare and/or chronic conditions, and to remove the disincentives for the development of therapies for these unmet needs.
- If passed, the Act would establish an Advanced Diagnostics Education Council within the Department of Health and Human Services, to promote an improved understanding of key concepts related to innovative diagnostics by recommending standard terms and definitions. Members of the council would include an NIH representative.
- The bill encourages the development of drugs abandoned in the development process by creating a new category of drugs known as dormant therapies for compounds with insufficient patent protection that offer the promise to treat conditions with unmet medical needs, and also proposes steps toward creating incentives for companion diagnostics.
- The bill calls on the Secretary HHS to consider various factors in determining payment for diagnostics under the Centers of Medicare and Medicaid Services fee schedule – this includes input from patients, clinicians, and technical experts through the establishment of an independent advisory panel. The Secretary would also be required to issue public justifications of payment determinations for new diagnostic tests.
• The Act was introduced by Rep. Leonard Lance (R-NJ) on 9/17/13 and was referred to the House Committees on Energy and Commerce, Ways and Means, and Judiciary. On 9/20/13 the bill was referred to the Energy and Commerce Subcommittee on Health.

FOIA Oversight and Implementation Act of 2013 (H.R. 1211)
• The bill proposes to amend the Freedom of Information Act to provide for greater public access to information, specifically in an electronic, publicly accessible format.
• The bill would require OMB to establish a single FOIA website, accessible to the public at no cost, which allows the public to submit requests for public records and to receive automated information about the status of a request.
• The bill would also require agencies to post online all records that have been released through FOIA three or more times.
• The bill was introduced by Rep. Darrell Issa (R-CA) on 3/15/13 and was amended and approved by the Committee on Oversight and Government Reform on 3/20/13. The bill was reported to the full House on 7/16/13.

Additional Information: If enacted, these amendments would change current procedures as all FOIA requests are currently received by mail, fax, or email and requested records are not generally made available online.

Selected New Bills (113th Congress)

Breast Density and Mammography Reporting Act of 2013 (H.R. 3404):
• The bill would amend the Mammography Quality Standards Act (MSQA) of 1992 to require mammography results to include the patient’s relative breast density, and for that information to be reported to patients.
• The Act was introduced by Rep. Rosa DeLauro (D-CT), along with Rep. Steve Israel (D-NY), on 10/30/13 and was referred to the Committee on Energy and Commerce.

Additional Information: Reps. DeLauro and Israel introduced a similar bill in the 112th Congress and it did not move out of committee. Bill text is not yet available for H.R. 3404. Based on Rep. DeLauro’s press release, the bill appears to be similar to her earlier proposal, which would have also required patients be informed of their relative risk of developing breast cancer associated with their level of breast density, as well as communication to patients that individuals with more dense breasts may benefit from supplemental screening. The release also notes that Sen. Dianne Feinstein (D-CA) plans to introduce a companion bill in the Senate. Additionally, independent of this legislative proposal, the FDA has already scheduled a notice of proposed rule making for a breast density reporting amendment to the MSQA for December 2013.

Eliminating Disparities in Breast Cancer Treatment Act of 2013 (H.R. 3295)
• The bill would amend title XVIII of the Social Security Act to require development of a uniform set of consensus-based breast cancer treatment performance measures for a 6-year quality reporting system and value-based purchasing system under the Medicare program (with an aim of eliminating disparities in treatment based on race, level of education, income, and health insurance status).
• The bill would establish that beginning in October 2017 Medicare base payments would be tied to the quality of care provided as assessed by the standards established through the quality reporting system. Additionally, if providers fail to submit data in accordance with the bill’s requirements, the Secretary HHS shall reduce their payments.
• The proposal also calls for reporting every six months, beginning 10/1/15, that would include an evaluation of the number of health care providers submitting data, an analysis of whether the system is successful in reducing disparities in breast cancer treatment, and recommendations on whether and to what extent to extend the system.
• The Act was introduced by Rep. Kathy Castor (D-FL) 10/16/13 and was referred to the Committee on Ways and Means and the Committee on Energy and Commerce.
Biennial Budgeting and Appropriations Act of 2013 (HR 3059)
- The bill proposes a biennial budget process that will authorize and appropriate funds for both fiscal years within each biennium beginning on October 1 of every odd-numbered year.
- The bill was introduced on 8/2/13 by Rep. Ed Whitfield (R-KY) and was referred to the Committees on Budget, Oversight and Government Reform, and Rules.

The Conference Accountability Act of 2013 (S 1347)
- The bill seeks to provide transparency, accountability, and limitations on Government sponsored conferences.
- The bill would:
  - Not allow any agency to pay travel expenses for more than 50 employees to attend an international conference;
  - Limit annual travel expenses for FY 2014 through FY 2018 to not more than 80 percent of the aggregate amount of travel expenses in FY 2010;
  - Limit agencies to $500,000 to support a single conference and to funding only one conference by an outside organization during any fiscal year; and
  - Require a report to be posted on the agency’s public website outlining all travel expenses paid during the preceding quarter.
- The bill was introduced on 7/23/13 by Sen. Tom Coburn (R-OK) along with Sens. McCain (R-AZ), Chiesa (R-NJ), Enzi (R-WY), and Ayotte (R-NH) and was referred to the Committee on Homeland Security and Governmental Affairs.

Critical Care Assessment and Improvement Act of 2013 (H.R. 2651)
- The bill would require the HHS Secretary to coordinate with the Institute of Medicine and submit a report to Congress on the current national state of critical care services and develop recommendations to strengthen critical care capabilities.
- The bill directs the NIH to establish a Critical Care Coordinating Council specifically requiring representation from NHLBI, NINR, NICHD, NIGMS, and NIA, but allowing the inclusion of additional ICs as appropriate. Directives for this council include coordinating and catalyzing funding opportunities, coordinating and analyzing current research on critical care issues, and providing an annual report with recommendations to the NIH director.
- Additional provisions include:
  - HRSA – update a 2006 study on of critical care workforce, and expand it to address supply and demand regarding the spectrum of health care professionals involved in critical care.
  - CMS – implement a project designed to improve the quality and efficiency of care provided to critically ill patients.
- The bill was introduced by Rep. Erik Paulsen (R-MN) on 7/10/2013 and referred to the House Committees on Energy and Commerce, and Ways and Means. The bill was then referred to the Energy and Commerce Subcommittee on Health on 7/12/13.

Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act (H.R. 2607/S. 1251)
- This bill is a reauthorization of the original Caroline Pryce Walker Conquer Childhood Cancer Act that was passed unanimously in the House and the Senate in 2008 (named in honor of former Representative Deborah Pryce's daughter, Caroline).
- The bill would authorize appropriations through 2018 (the Senate version offers such sums as necessary; the House version caps the authority at $10 million per year), and changes the authorized activities, substituting the following:
  - The bill would expand on existing childhood cancer biorepository resources to include specimens and clinical and demographic information from children, adolescents, and young adults (CAYA) diagnosed with cancer (not just those enrolled in NCI-sponsored studies) in comprehensive pediatric cancer biorespositories with the goal of including 90 percent of CAYA in the effort.
The bill would also authorize the CDC to award grants for state cancer registries to enhance and expand infrastructure for identifying and tracking incidences of CAYA cancers. The bill would direct a GAO study to investigate the feasibility of expanding FDA requirements for pediatric studies of adult oncologic drugs and make recommendations for overcoming any research barriers.

- H.R. 2607 was introduced by Rep. Chris Van Hollen (D-MD) on 6/28/13 and was referred to the House Energy and Commerce Committee. On 7/5/13, the bill was referred to the Subcommittee on Health. S. 1251 was introduced by Sen. Jack Reed (D-RI) on 6/27/13 and referred to the Senate Committee on Health, Education, Labor, and Pensions.

Additional Information: This bipartisan reauthorization was introduced in the House by Rep. Chris Van Hollen (D-MD) and Rep. Michael McCaul (R-TX), co-chairs of the Childhood Cancer Caucus.

Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act (S. 1247) and Childhood Cancer Survivors’ Quality of Life Act of 2013 (H.R. 2058)

- Both bills would authorize $15 million each year for five years for the HHS Secretary to award grants for pilot programs to develop or evaluate model systems for monitoring and caring for childhood cancer survivors.
- Both bills would authorize an additional $5 million each year for five years for the HHS Secretary to establish a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer Survivors. The collaborative would include educators, consumer and family advocates, and providers of psychosocial and biomedical health services.
- The House bill would also authorize $10 million each year for five years for the NIH Director to award grants for research on the causes of health disparities in pediatric cancer survivors and conduct or support research on follow-up care for pediatric cancer survivors.
- S. 1247 was Introduced by Sen. Jack Reed (D-RI) on 6/27/13 and referred to the Committee on Health, Education, Labor, and Pensions. H.R. 2058 was introduced by Rep. Jackie Speier (D-CA) on 5/20/13 and was referred to the Energy and Commerce Committee, Subcommittee on Health on 5/24/13.

Additional Information: Both bills are similar to the Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act of 2011 which was introduced by Rep. Speier and Sen. Reed in the 112th Congress. The legislation was never considered in the House or the Senate in the 112th Congress.

Planning Actively for Cancer Treatment (PACT) Act of 2013 (H.R. 2477)

- The bill states that people diagnosed, treated, or having survived cancer should, with a medical professional, have the ability to construct, modify, and re-examine, a treatment/survivorship plan of action for a primary or re-occurring diagnosis of cancer.
- The bill was introduced by Lois Capps (D-CA) on 6/25/13 and was referred to the House Committee on Energy and Commerce, and the Committee on Ways and Means. On 6/28/13, the bill was referred to the Subcommittee on Health.

Additional Information: Sen. Mark Warner introduced a similar bill, the Care Planning Act of 2013 (S 1439), on 8/1/13. This bill encompasses a broad range of late-stage diseases (not limited to cancer) and would provide for advanced illness care coordination services, including the development of a care plan, for Medicare beneficiaries. This bill was referred to the Committee on Finance on 8/1/13.

Women’s Preventive Health Awareness Campaign (H.R. 2457)

- This bill directs the HHS Secretary to carry out a national public outreach and education campaign to raise awareness of women’s preventive health measures including cancer screenings (e.g. cervical and breast), immunizations, and prenatal visits.
- The bill would require a media and website component, information dissemination about screening and prevention services, and address health disparities in women’s prevention.
- Funding would come from existing DHHS monies.
- The bill does not mention any component of the NIH.
The bill was introduced by Rep. Ami Bera (D-CA) on 6/20/13 and was referred to the House Committee on Energy and Commerce. On 6/21/13 the bill was referred to the Subcommittee on Health. The bill has 47 co-sponsors.

Selected Recent Resolutions (113th Congress)
This section highlights resolutions introduced to raise awareness about specific diseases. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Passed
Designating September 2013 as National Ovarian Cancer Awareness Month (S. Res. 205)
- This resolution designates September 2013 as National Ovarian Cancer Awareness Month.
- S. Res. 205 was introduced by Sen. Debbie Stabenow (D-MI) on 7/30/13 and was adopted by unanimous consent.

Additional Information: A similar resolution was introduced in the House on 7/16/13 by Rep. Steve Israel (D-NY). The resolution was referred to the Committee on Oversight and Government Reform, but it has not been adopted.

Designating September 2013 as National Prostate Cancer Awareness Month (S. Res. 206)
- This resolution designates September 2013 as National Prostate Cancer Awareness Month.
- S. Res. 206 was introduced by Sen. Jeff Sessions (R-AL) on 7/30/13 and was adopted by unanimous consent.

Introduced
Expressing Support for Designating September 26, 2014 as “National Pediatric Bone Cancer Awareness Day” (H. Res. 362; 113th Congress)
- This resolution expresses support for the designation of September 26, 2014 as “National Pediatric Bone Cancer Awareness Day.”
- H. Res. 362 was introduced by Rep. Blake Farenthold (R-TX) on 9/27/13 and was referred to the Energy and Commerce Committee.

A resolution expressing the sense of the Senate that the USPSTF should reevaluate its recommendations against PSA-based screening for prostate cancer (S. Res. 251; 113th Congress)
- A resolution expressing the sense of the Senate that the United States Preventive Services Task Force should reevaluate its recommendations against prostate-specific antigen-based screening for prostate cancer for men in all age groups in consultation with appropriate specialists.
- This resolution was introduced by Sen. Jeff Sessions (R-AL) on 9/23/13 and was referred to the Committee on Health, Education, Labor, and Pensions.