

March 2012

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

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

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I. Appropriations

FY2013 Appropriations

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 (approximately \$2.7 million more than the FY2012 Enacted level for the NCI).

The Congressional phase of the appropriations process began immediately after the release of the President's Budget. Secretary Sebelius testified before Senate Finance Committee on the overall HHS budget February 15, and will testify before multiple committees with jurisdiction over HHS programs including: House Ways and Means on February 28; House Energy and Commerce on March 1, House Appropriations Labor, HHS, Education subcommittee on March 6, and the Senate subcommittee on March 7.

The NIH FY2013 Appropriations hearing has been scheduled in the House for March 20. Committee staff have indicated the hearing will focus on the National Center for Advancing Translational Sciences (NCATS) and requested that Drs. Collins and Insel testify. The NIH FY2013 Appropriations hearing has been scheduled in the Senate for March 28. Dr. Collins will testify, and select IC Directors, including Dr. Varmus, will join him to address questions from Members of the committee.

FY2012 Appropriations

Finalizing FY2012 appropriations became a longer and more complex process than most years, with a number of continuing resolutions providing short-term funding while Appropriators negotiated a final bill. The following summary includes a number of key points throughout the process, and the final FY2012 appropriations for the NIH and the NCI.

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, 2011 while the House Appropriations Committee introduced its Labor H bill (H.R.3070) on September 29, without markup.

The Senate began its FY2012 appropriations efforts with a strategy of clearing several small packages of spending bills, called "minibus" bills, rather than relying on a single catch-all omnibus bill. The Senate passed one minibus bill, 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). The bill passed both chambers on November 17 and was signed by the President on November 18.

At that point, the minibus strategy was abandoned, and House and Senate appropriators addressed the remaining FY2012 appropriations bills, including the Labor H bill, through a nine-bill omnibus (using the Military Construction bill as a vehicle). On December 16, the

House adopted the conference report on the omnibus bill, and on December 17, the Senate cleared the bill with a 67-32 vote. The President signed the bill into law on December 23 (P.L. 112-74).

The legislation appropriates approximately \$30.69 billion to the NIH, approximately \$1.3 billion less than the FY2012 President's Budget Request for the NIH of \$31.99 billion. The bill appropriates \$5.08 billion to the NCI. The legislation includes a 0.189 percent rescission of funds, to be applied proportionately across all HHS discretionary programs. This amounts to an additional \$9.6 million reduction to the NCI's FY2012 appropriation, part of an overall reduction to the NIH's FY2012 budget of approximately \$58 million. The NCI's FY2012 Enacted funding level is approximately \$5.066 billion.

FY2012 Appropriations Legislation

Military Construction and Veterans Affairs and Related Agencies Appropriations Act 2012 (H.R.2055); Consolidated Appropriations Act 2012 (P.L. 112-74)

- The Consolidated Appropriations Act included Labor H in addition to the remaining eight FY2012 appropriations bills. The bill appropriates \$5.08 billion to the NCI. The legislation includes a 0.189 percent rescission of funds, to be applied proportionately across all HHS discretionary programs. This amounts to an additional \$9.6 million reduction to the NCI's FY2012 appropriation, part of an overall reduction to the NIH's FY2012 budget of approximately \$58 million.
- The bill creates the National Center for Advancing Translational Sciences (NCATS), at a funding level of approximately \$576.5 million. Up to \$10 million is provided within NCATS for the Cures Acceleration Network, an initiative originally authorized through the Patient Protection and Affordable Care Act.
- The conference report language directs the NIH to conduct a trans-NIH review of the applicability of the twelve Institute of Medicine recommendations to the NCI regarding clinical trials to all NIH ICs that conduct clinical trials.
- The conference report language also directs the NIH to conduct a three-year pilot study to assess the viability of third party reimbursement at the NIH by looking at one of the services commonly used by a significant number of outpatients at some point in the patient's protocol.
- The conference report provided for a change in allowable extramural salary support from Executive Level I (\$199,700) to Executive Level II (\$179,700), HHS-wide. This change is effective with grant awards with an Initial Issue Date on or after December 23, 2011.

II. Congressional Hearings, Briefings, and Visits

Briefings

House Appropriations Subcommittee Chairman Denny Rehberg (R-MT) Visits NIH (11/28/11): Chairman Rehberg spent several hours learning about NIH. Rehberg and 2 of his staff members met with the NIH Deputy Director and the Directors of NIAID and NINDS during a

visit to the NIH campus. He also met with NCI Deputy Director Dr. Doug Lowy, and researchers Drs. Bill Dahut and Alan Wayne, met an oncology patient taking part in an immunotoxin trial, and toured the Children's Inn.

Senator Scott Brown (R-MA) Visits NIH Clinical Center (12/13/2011): Senator Brown came to the NIH for a visit to the Clinical Center and was greeted by NIH Director, Dr. Francis Collins and Dr. John Gallin, Director, NIH Clinical Center. Sen. Brown met with Dr. William Gahl, Clinical Director, NHGRI and Director, NIH Undiagnosed Disease Program and a patient of Dr. Gahl's from Massachusetts. The Senator and his staff toured the CCR Molecular Imaging Clinic with Dr. Harold Varmus, NCI Director, Dr. Bill Dahut, CCR Clinical Director, and Dr. Pete Choyke, Molecular Imaging Program Director. Sen. Brown also met with Dr. Wyndham Wilson, Head of the Lymphoma Therapeutics Section, and a patient of Dr. Wilson's from Massachusetts.

HHS ASL and ASFR Visit the NIH Clinical Center (2/21/12): The HHS Assistant Secretary for Legislation, Jim Esquea and his staff, along with staff from the HHS Office of the Assistant Secretary for Financial Resources, visited the NIH to meet with senior leadership and to tour laboratory and clinical facilities at the NIH Clinical Center. ASL and ASFR met with the NIH Director, Dr. Francis Collins, and participated in a roundtable discussion with Dr. Harold Varmus, NCI Director, Dr. Anthony Fauci, NIAID Director, Dr. Griffin Rodgers, NIDDK Director, and Dr. Kathy Hudson, NIH Deputy Director for Science, Outreach, and Policy. ASL and ASFR also met with Dr. Marston Linehan, Chief of the CCR Urologic Oncology Branch, and visited his lab, as well as Dr. William Gahl, Clinical Director, NHGRI and Director, NIH Undiagnosed Disease Program, and one of his patients.

III. Issues of Interest

Shortages of Therapeutic Drugs:

On October 31, 2011, 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. 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.

Congressional interest in the drug shortage issues has focused on potential causes, including economic factors and increased regulatory pressures, of 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. Congressional activities on these issue include hearings held by the House Energy and Commerce Committee (September 23); the House Oversight and Government Reform Committee, Subcommittee on Health Care, District of Columbia, Census, and the National Archives (November 30); the Senate Finance Committee (December 7); and the Senate Committee on Health, Education, Labor, and Pensions (December 15).

Senator Amy Klobuchar (D-MN) also recently offered her legislation (S. 296, the Preserving Access to Life-Saving Medications Act of 2011, originally introduced in February 2011) as an amendment to the Senate’s authorization bill for federal highway aid (S.1813), on February 14, 2012. The amendment was not accepted, and Sen. Klobuchar has indicated that she intends to attach the bill to any legislative vehicle possible in an effort to offer immediate short-term steps to address drug shortages. In addition to Sen. Klobuchar’s proposal, S.296, Rep. Diana DeGette (D-CO) introduced similar legislation in 2011 (H.R.2245) and Rep. John Carney (D-DE) introduced H.R.3839, the Drug Shortage Prevention Act of 2012, on January 31, 2012. Additional detail on each bill is included in the “Legislation of Interest” section of this update.

Sen. Klobuchar’s original proposal 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. This would move beyond the voluntary notification called for by the President’s Executive Order, and would require six months notification from manufacturers to the FDA of planned discontinuances or interruptions, as well as advanced notice “as soon as practicable” for unplanned disruptions. The bill would also provide for enforcement authority, specifically punitive civil damages to be determined by the Secretary.

Sen. Klobuchar is also 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). Sen. Tom Harkin (D-IA), has also expressed interest in this issue, joining Sens. Casey and Blumenthal on a request that the Government Accountability Office (GAO) conduct a study of drug shortages in the U.S. The GAO study was released on December 15, and Dr. Marcia Crosse of the GAO testified about the report’s findings at the December 15 Senate HELP hearing. The bi-partisan group remains engaged with the Senate HELP committee as it continues to discuss opportunities to address drug shortages through the Generic Drug User Fee Act (GDUFA). Drug shortages were also addressed by a panel of witnesses at the House Energy and Commerce Committee, Subcommittee on Health’s recent hearing on GDUFA (February 9), including Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research.

On February 15, Secretary Sebelius testified before the Senate Finance Committee about the President’s FY2013 budget. Senator Ron Wyden (D-OR) questioned her about the shortage of methotrexate to treat ALL. The Secretary noted that the FDA is working with manufacturers and the shortage is expected to be resolved in the coming weeks. She cited market glitches at the primary cause of drug shortages and expressed interest in working with Congress to require mandatory notification of potential shortages to improve the ability of the FDA to pursue alternative strategies to avert future shortages. Sen. Wyden concluded by saying that drug shortages are also due to incentive issues at the manufacturing level and the gray market – both unlikely to be resolved by mandatory reporting requirements alone.

Additionally, the FDA announced on February 21 that it has been taking a number of steps to increase the available supply of both methotrexate and Doxil, two oncology drugs in

dangerously short supply in recent weeks. The FDA also issued draft guidance for industry regarding the scope and logistics of mandatory notification and voluntary notification. This draft was distributed for comment purposes only, and builds upon guidance that the FDA issued to follow-up on the President's Executive Order.

SBIR/STTR Reauthorization:

Congressional authorization for the SBIR/STTR programs expired on October 1, 2011 and authorization for the programs continued throughout 2011 via a series of continuing resolutions. A reauthorization of the SBIR/STTR programs for six years was included in the National Defense Authorization Act for Fiscal year 2012 (H.R.1540/P.L. 112-81), which the President signed into law on December 31.

The reauthorization provides for an incremental increase of set-aside funds for the SBIR program from 2.6 percent to 3.2 percent over five years, and for the STTR program from 0.35 percent to 0.45 percent over four years. The reauthorization also features increases in the guidelines for individual award levels: \$150,000 for Phase I and \$1,000,000 for Phase II, and contains a cap of 50% by which an individual award may exceed the award guidelines (i.e. a maximum of \$225,000 for Phase I and \$1,500,000 for Phase II).

The legislation allows the NIH, National Science Foundation and Department of Energy to award up to 25 percent of SBIR funds to small businesses majority-owned by multiple venture capital (VC) companies, and permits other federal agencies to award up to 15 percent of their SBIR funds to such small businesses.

Public Access to Federally Funded Research:

Members in the House and Senate have introduced legislative proposals addressing public access to federally funded research. Reps. Darrell Issa (R-CA) and Carolyn Maloney (D-NY) introduced H.R.3699, the Research Works Act, on 12/16/11. The proposal includes federally funded research products in its definition of "private-sector research work," so long as a commercial or nonprofit publisher has made a value-added contribution, including peer review or editing. The bill would limit public access to federally funded research by prohibiting a federal agency from engaging in activity that would disseminate private-sector research work.

On February 27, the science and health publishing company Elsevier announced it would no longer be supporting the Research Works Act. Later that day Reps. Maloney and Issa issued a statement indicating they would no longer be taking action on their bill.

Rep. Michael Doyle (D-PA) and Sen. John Cornyn (R-TX), introduced the Federal Research Public Access Act of 2012 (FRPAA, H.R.4004/S.2096), on 2/9/12. Their proposal would expand public access to federally funded research by requiring each Federal agency with extramural research expenditures of over \$100 million dollars to develop a Federal research public access policy to require authors whose research is entirely or in part funded by the Federal

Government to submit final manuscripts of papers that are accepted for publication in peer-reviewed journals to the supporting Federal agency.

Additionally, FRPAA would require that public access to final peer reviewed or published versions of these papers must be made available as soon as practicable but no later than 6 months after journal publication. The bill also proposes the creation of an online bibliography of all publically accessible research papers providing free access to full-text publications.

The NIH Public Access Policy currently provides free public access via PubMed no later than 12 months after publication. The NIH policy was enacted through the Consolidated Appropriations Act of 2008, and went into effect on April 7, 2008. The Omnibus Appropriations Act of 2009 reaffirmed the policy, requiring it to remain a legislative mandate for FY2009 and beyond.

IV. Legislation of Interest

The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the CTAC 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/P.L. 112-80)

- 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.
- On 10/19/11, the Senate Homeland Security and Governmental Affairs Committee considered and reported the bill favorably to the full Senate. The bill was placed on the Senate calendar on 11/29/2011.
- The Senate passed the bill, without amendment, by unanimous consent on 12/5/11. The House passed the bill by a vote of 417-1 on 12/13/11. **The President signed the bill into law on 12/23/11, P.L. 112-80.**

Preserving Access to Life-Saving Medications Act of 2011 (S.296)

- 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. Requires six months advance notice of planned discontinuances/disruptions, and notice “as soon as practicable” for unplanned discontinuances/disruptions.

- Provides HHS with enforcement authority, specifically punitive civil damages to be determined by the Secretary.
- Instructs HHS to implement evidence-based criteria for identifying drugs vulnerable to shortages and 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 24 co-sponsors.

Preserving Access to Life-Saving Medications Act of 2011 (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. Requires six months advance notice of planned discontinuances/disruptions, and notice “as soon as practicable” for unplanned discontinuances/disruptions.
- Provides HHS with enforcement authority, defining specific penalty amounts not to exceed \$10,000 for each day on which a violation continues, and not to exceed \$1.8 million for all violations adjudicated in a single proceeding.
- Instructs HHS to implement evidence-based criteria for identifying drugs vulnerable to shortages and requires HHS to report to Congress to address actions taken to address drug shortages.
- Includes additional language, as compared to S.296, proposing that manufacturers can halt or interrupt production with less than six months notice if a continuation may create a liability problem for the manufacturer or may cause substantial economic hardship, among other justifications.
- H.R. 2245 was introduced by Reps. Tom Rooney (R-FL) and Diana DeGette (D-CO) on 6/21/11 and has 65 co-sponsors.

Selected New Bills

Drug Shortage Prevention Act (H.R. 3839)

- Provisions of H.R.3839 focus on HHS/FDA providing notification to manufacturers, and do not address notification requirements from manufacturers to HHS/FDA.
- The bill makes a number of proposals not included in S.296 or H.R.2245, such as further defining the terms “critical drug” and “critical drug shortage” and establishing a “National Critical Drug List.”
- The bill calls for expediting application review and for enhanced communication between the FDA drug shortage program and other offices overseeing the prescription drug regulatory process. It also calls upon the Attorney General to address the role of drug quotas and gray market activity, although without offering defined enforcement measures.
- The bill would require HHS to conduct a study on the feasibility of creating a national contingency plan for addressing drug shortages, including the feasibility of creating a national stockpile of critical drugs.
- Introduced by Rep. John Carney (D-DE) on 1/31/11 and was referred to the House Committees on Energy and Commerce and Judiciary, and to the Judiciary Subcommittees

on Crime, Terrorism, and Homeland Security; and on Intellectual Property, Competition, and the Internet. The bill has three co-sponsors.

Research Works Act of 2012 (H.R.3699):

- This bill would limit public access to federally funded research. It would prohibit a federal agency from adopting, maintaining, or otherwise engaging in any policy, program, or activity that: (1) causes network dissemination of any private-sector research work without the prior consent of the publisher; or (2) requires the author or the author's employer assent to such network dissemination.
- The bill defines "private-sector research work" as an article intended to be published in a scholarly or scientific publication, or any version of such an article, that is not a work of the U.S. government, describing or interpreting research funded in whole or in part by a Federal agency and to which a commercial or nonprofit publisher has made a value-added contribution including peer review or editing.
- Network dissemination is defined as distributing, making available, or otherwise disseminating a private-sector research work through the internet or by a closed or limited digital or electronic network.
- H.R.3699 was introduced by Rep. Darrell Issa (R-CA) on 12/16/11. The bill was referred to the House Committee on Oversight and Government Reform. As of 2/22/12, the bill has one co-sponsor, Rep. Carolyn Maloney (D-NY).
- On February 27, Reps. Maloney and Issa issued a statement indicating they would no longer be taking action on their bill.

Federal Research Public Access Act of 2012 (H.R.4004/S.2096):

- This bill would expand public access to federally funded research. It would require each Federal agency with extramural research expenditures of over \$100 million dollars to develop a Federal research public access policy consistent with and advancing the purposes of the agency.
- Each Federal research public access policy requires authors whose research is entirely or in part funded by the Federal Government to submit final manuscripts of papers that are accepted for publication in peer-reviewed journals to the supporting Federal agency.
- Free public access to final peer reviewed or published versions of these papers must be made available as soon as practicable but no later than 6 months after journal publication. (The NIH Public Access Policy currently provides free public access via PubMed no later than 12 months after publication.)
- The bill also requires the creation of an online bibliography of all publically accessible research papers with each entry linking to online full text, long-term preservation of the articles, and continued free access to these published research findings.
- H.R.4004 was introduced by Rep. Michael Doyle (D-PA) on 2/9/12 and referred to the House Committee on Oversight and Government Reform. As of 2/16/12, the bill is co-sponsored by Rep. Lacy Clay (D-MO) and Rep. Kevin Yoder (R-KS).
- S.2096 was introduced by Sen. John Cornyn (R-TX) on 2/9/12 and referred to the Committee on Homeland Security and Governmental Affairs. S.2096 is co-sponsored by Sen. Kay Bailey Hutchison (R-TX) and Sen. Ron Wyden (D-OR) as of 2/22/12.

Building Better Business Partnerships Act of 2012 (H.R.3985):

- The purpose of this bill is to improve and streamline mentor-protégé programs for small businesses. These programs pair small businesses interested and eligible to enter into federal prime contracts and subcontracts with for-profit concerns of any size that are able to assist the small business compete for federal contracts.
- H.R. 3985 was introduced by Rep. Robert Schilling (R-IL) on 2/8/12. The bill was referred to the House Committee on Small Business. As of 2/22/12, the bill has one co-sponsor, Rep. Judy Chu (D-CA).

Spending Reductions through Innovations in Therapies Agenda (SPRINT) Act of 2012 (H.R. 3891/S. 2069):

- This bill would amend the Public Health Service Act to speed American innovation in research and drug development for the leading causes of death that are the most costly chronic conditions in the U.S., to save American families and the Federal and State governments money, and to help family caregivers.
- The bill establishes the Spending Reductions through Innovations in Therapies Program (SPRINT) to support development of therapies and encourage innovation in technologies that may assist in advanced research and development to reduce spending by Federal health care programs for high-cost chronic conditions.
- H.R. 3891 was introduced by Rep. Edward Markey (D-MA) and referred to the House Committee on Energy and Commerce on 2/2/2012. As of 2/22/12, the bill is co-sponsored by Rep. Christopher Smith (R-NJ).
- S.2069 was introduced by Sen. Barbara Mikulski (D-MD) on 2/2/12 and referred to the Senate Committee on Health, Education, Labor, and Pensions.

To repeal the Patient-Centered Outcomes Research program and comparative effectiveness research funding (H.R.3827):

- This bill would repeal the Patient-Centered Outcomes Research program and comparative effectiveness research funding as added by section 6301 of the Patient Protection and Affordable Care Act.
- The bill would rescind any unobligated ARRA funds for comparative research and deposit the funds into the general fund of the Federal Treasury for Federal budget deficit reduction.
- H. R. 3827 was introduced by Rep. Brett Guthrie (R-KY) on 1/25/12. The bill was referred to the Committees on Ways and Means, Appropriations, the Budget, and Energy and Commerce. As of 2/22/12, the bill has six co-sponsors.

Comprehensive Cancer Care Improvement Act of 2011 (H.R.3705/S.2097):

- The bill would amend title XVIII of the Social Security Act to provide for coverage of comprehensive cancer care planning under the Medicare Program and to improve the care furnished to individuals diagnosed with cancer by establishing grants programs for provider education, and related research.
- The bill would support a research program on topics related to coordination of care, symptom management, and palliative care for cancer patients through a \$5,000,000 annual appropriation for each of the fiscal years 2012 through 2016.

- H.R.3705 was introduced by Rep. Lois Capps (D-CA) on 12/16/12 and referred to the Subcommittee on Health. As of 2/22/12, the bill has one co-sponsor, Rep. Charles Boustany (R-LA).
- S.2097 was introduced by Sen. Mary Landrieu (D-LA) on 2/9/12 and referred to the Committee on Finance.

Unlocking Lifesaving Treatments of Rare Diseases Act (ULTRA, H.R.3737):

- The purpose of this bill is to amend the Federal Food, Drug, and Cosmetic Act to fast track approval of certain orphan drugs to serve the unmet needs of individuals with ultra rare diseases. Drugs could be fast tracked if they are designated for a rare disease or condition that affects a small number of patients in the U.S.
- If fast tracked, the Secretary can use a surrogate endpoint for the approval of the drug based on the existence of reasonable scientific data that support and qualify the relevance of the surrogate endpoint to the disease state and treatment.
- In addition, the Secretary shall not require clinical treatment data or historical clinical data on the surrogate endpoint as a prerequisite to assessment of the surrogate endpoint if such data are not available.
- H.R.3737 was introduced by Rep. Cliff Stearns (R-FL) on 12/20/11. The bill was referred to the House Energy and Commerce Committee, Subcommittee on Health. As of 2/22/12, the bill has three co-sponsors.

Comprehensive Cancer Care Improvement Act of 2011 (H.R.3705/S.2097):

- The bill would amend title XVIII of the Social Security Act to provide for coverage of comprehensive cancer care planning under the Medicare Program and to improve the care furnished to individuals diagnosed with cancer by establishing grants programs for provider education, and related research.
- The bill would support a research program on topics related to coordination of care, symptom management, and palliative care for cancer patients through a \$5,000,000 annual appropriation for each of the fiscal years 2012 through 2016.
- H.R.3705 was introduced by Rep. Lois Capps (D-CA) on 12/16/12 and referred to the Subcommittee on Health. As of 2/22/12, the bill has one co-sponsor, Rep. Charles Boustany (R-LA).
- S.2097 was introduced by Sen. Mary Landrieu (D-LA) on 2/9/12 and referred to the Committee on Finance.

Assuring and Improving Cancer Treatment Education and Cancer Symptom Management Act of 2011 (H.R.3622); Improving Cancer Treatment Education Act of 2012 (H.R.3790):

- H.R.3622 was introduced by Rep. Steve Israel (D-NY) on 12/8/11, and H.R.3790 was also introduced by Mr. Israel, on 1/18/12.
- Both proposals would require Medicare to cover the provision of a one-hour treatment education session delivered by a registered nurse following initial cancer diagnosis and/or any significant modifications to the treatment plan.
- The proposals also call for the NIH to conduct research geared toward improving treatment and management of symptoms and side-effects associated with cancer and

cancer treatment, and evaluating the role of nursing interventions in the mediation of symptoms and side-effects.

- H.R.3622 includes a provision directing the NIH to make nursing intervention research grants, with a registered nurse as the principal investigator, and for the purpose of studying cancer symptom management care and services delivered by registered nurses to cancer patients; as well as a provision calling for an Institute of Medicine study on the provision of symptom management and supportive care in people with cancer. H.R. 3790 does not include these provisions.
- H.R.3790 and H.R. 3622 were referred to the House Energy and Commerce Committee, Subcommittee on Health; and H.R.3622 was also referred to the House Ways and Means Committee. As of 2/22/12, H.R.3790 has seven co-sponsors, and H.R.3622 has five co-sponsors.

Modernizing Our Drug and Diagnostics Evaluation and Regulatory Network Cures Act of 2011 (MODDERN Cures Act; H.R. 3497)

- The main purpose of the bill is to promote the development of “meaningful treatments” for patients by providing special regulatory considerations for innovative diagnostic tests paired with therapeutic agents, and for therapeutic agents that would address unmet medical needs.
- Additional provisions include the establishment of the Advanced Diagnostics Education Council to create a standard lexicon and develop guidance on key concepts related to innovative diagnostics (the NIH Director or his/her designee would have an *ex officio* membership on this Council), and a requirement for an IOM study of intellectual property laws and their impact on therapy and diagnostic development.
- Introduced by Rep. Lance Leonard (R-NJ) on 11/18/11 and referred to the House Committees on Energy and Commerce, and Ways and Means, and Judiciary.

Taxpayers’ Cancer Research Funding Act of 2011 (H.R. 3466)

- The bill would establish a trust fund called the Breast and Prostate Cancer Research Fund and would amend the Internal Revenue Code to provide a check-off on income tax forms to allow individuals to designate \$5 to contribute to the fund.
- Revenue from this fund would be used to pay for research approved and administered by the NCI.
- Introduced by Rep. Peter King (R-NY) on 11/17/11 and referred to the House Committees on Energy and Commerce, and Ways and Means. It has 17 cosponsors.

Grant Reform and New Transparency Act of 2011 (GRANT Act; H.R. 3433)

- The purpose of the GRANT Act is to provide transparency and require certain standards in the award of federal grants.
- The bill would require, for each competitive grant awarded by a federal agency, the public posting of the full grant application, award decision documentation and rankings, justification for deviation from rankings, and disclosure of information on individuals who served as peer reviewers on the grant.
- The bill would also require the posting of grant performance information within 60 days after the end of the period allowed for completion of the grant.

- Introduced by Rep. James Lankford (R-OK) on 11/16/11 and has 4 cosponsors. The bill was referred to the House Committee on Oversight and Government Reform.

Selected Recent Resolutions

40th Anniversary of the National Cancer Act (H. Res.531 /S.Res.347):

- Recognizing the 40th anniversary of the National Cancer Act of 1971 and the more than 12,000,000 survivors of cancer alive today because of the commitment of the United States to cancer research and advances in cancer prevention, detection, diagnosis, and treatment.
- The House of Representatives celebrates and reaffirms the commitment embodied in the National Cancer Act of 1971, specifically, that support for cancer research continues to be a national priority to address the scope of this pressing public health concern.
- Introduced by Rep. Steve Israel (D-NY) and referred to the Committee on Energy and Commerce on 1/31/12. As of 2/22/12, the resolution has 42 co-sponsors.

National Cancer Prevention Day (H. Res.538):

- A resolution expressing support for the designation of February 4, 2012, as National Cancer Prevention Day.
- The House of Representatives recognizes all efforts to raise the awareness for the reduction of cancer risks and recognizes the devastating effect cancer has on families and wishes to expand knowledge, encourage early detection, and work with friends in the medical and scientific fields to put an end to this deadly disease.
- Introduced by Rep. Steven Israel (D-NY) and referred to the Committee on Energy and Commerce on 2/3/12. As of 2/22/12, the resolution has 32 co-sponsors.