November 4, 2015*

Legislative Update

for the

NCI Clinical and Translational Research Advisory Committee

*Content current as of October 30, 2015

Activities of the 114th Congress-
First Session

MK Holohan, Director,
Office of Government and Congressional Relations
National Cancer Institute
Building 31-10A48
ncilegislative@mail.nih.gov
301-496-5217

Visit the Office of Government and Congressional Affairs website at:
http://legislative.cancer.gov
The House passed the Bipartisan Budget Act of 2015 (HR 1314) by a vote of 266-167 on October 28th, and the Senate passed the bill on October 30th by a vote of 64-35. The President has indicated he will sign the bill.

The bill suspends the U.S. debt limit until March 15, 2017, after the next presidential election. The agreement partially rolls back the sequester and increases discretionary spending caps for FY 2016 and FY 2017. The caps will increase by $50 billion in FY 2016 and $30 billion in FY 2017, split equally between defense and nondefense spending. Funding sequestration, a scheduled reduction in discretionary funding caps involving automatic cuts for mandatory programs, has been in place since the Budget Control Act of 2011 (BCA). Raising the discretionary funding caps will likely make it easier to enact an omnibus appropriations bill in December (see the Appropriations update, below, for more).

Under the budget act, discretionary spending would be capped at $1.067 trillion for FY 2016 and $1.070 trillion for FY 2017. To offset the cost of the budget, the agreement includes provisions related to the Social Security disability trust fund, Medicare Part B premiums, health insurance requirements for large employers, tax compliance, the strategic petroleum reserve, private pensions, the broadband spectrum, crop insurance, and the Justice Department’s Assets Forfeiture Fund and Crime Victims Fund. The agreement was negotiated by outgoing Speaker John Boehner (R-OH), Senate leadership, and the White House.

Of note, the strategic petroleum reserve has also been proposed as an offset for funding to NIH and FDA through the House 21st Century Cures Act. Reports indicate that use of the reserve funds for the budget deal will eliminate the potential for the reserve to be used as an offset for any possible Cures/Senate Innovation package (the Senate has yet to release its draft).

House Leadership Elections
Congressman Paul D. Ryan of Wisconsin was sworn in as the new Speaker of the House of Representatives on October 29, 2015.

On September 25th, Speaker of the House, John Boehner (OH) abruptly resigned from Congress effective October 31st, much to the surprise of his House colleagues. Speaker Boehner had been facing threats to his leadership from a group of conservative House members opposed to passing any long or short term spending bill without language defunding Planned Parenthood, and there did not seem to be a way forward him to avoid a shutdown and maintain his position as Speaker. Without a leadership position to defend, Speaker Boehner was free to pass a “clean” CR (without language defunding Planned Parenthood), which, as noted below, passed in both the House and Senate on September 30, and was signed into law by the President on the same day.

Speaker Boehner had originally set Republican Conference elections for October 8th to select a nominee for speaker, as well as the election of majority leader and majority whip. On October 5th, he postponed the majority leader and majority whip elections until October 29th. In an unexpected turn of events, Majority Leader Kevin McCarthy, the most likely nominee for Speaker, withdrew from the race on October
8th, the election for the Conference nominee was then postponed. After a period of uncertainty in mid-
October, and much encouragement from colleagues, Rep. Ryan indicated he would run for Speaker. The
Republican conference elected Rep. Ryan as its nominee on October 28th, and the full House elected him
as its new Speaker, with 236 votes, on October 29th.

I. Appropriations

Where we Stand –
The House and Senate reconvened on September 8th, following the August recess. After much
uncertainty and debate, on September 24th, Senate Majority Leader Mitch McConnell introduced a short
term Continuing Resolution that would fund the government through December 11th at approximately FY
2015 levels, and that also included language prohibiting any federal funds for Planned Parenthood. This
measure fell short of the 60 voted needed to advance for consideration on the Senate floor, and Sen.
McConnell introduced a clean version of the proposal, which no longer included the Planned Parenthood
provisions. On September 30th, the Senate passed the bill by a vote of 78-20, the House passed the bill by
a vote of 277-151, and the President signed the bill into law, preventing a government shutdown.

Following passage of the Bipartisan Budget Act of 2015 in late October, Appropriators are working to
prepare an omnibus appropriations bill for consideration before the current continuing resolution expires
on December 11th. Prior to the budget deal, a full year continuing resolution was a more likely prospect.
The budget deal provides appropriators with additional resources beyond FY 2015 spending levels, and
makes it possible for Congress to enact appropriations bills with increases for discretionary accounts such
as the National Institutes of Health – as noted below, the Labor, HHS, Education, and Related Agencies
(LHHS) appropriations bills that were passed out of committee in both the House and Senate propose
increases to NIH funding (an increase of $1 billion in the House bill, and $2 billion in the Senate bill).

Action Prior to the August Recess
Prior to the August recess, the House and Senate Appropriations Committee passed their fiscal year (FY)
2016 LHHS appropriations bills, bringing back a glimmer of regular order to the appropriations process.
This is the first time since 2012 that a House LHHS appropriations bill has been introduced, marked up,
and passed by the Committee. Adding to the glimmer of hope, the House passed six of the 12
appropriations bills. However, it is likely that the remarkable progress made so far with the FY 2016
spending bills will be stymied for a number of reasons. First, the LHHS bill is the largest and often
considered the most contentious of all annual spending bills and as many as 28 Republicans have gone on
record stating that they will not vote for an appropriations bill or CR that provides funding for Planned
Parenthood. Meanwhile, the Administration and the Senate Democrats have pledged to reject all 12
appropriations spending bills until a deal is reached to provide relief from the spending caps imposed by
sequestration.

House and Senate Committee Action –
House Labor, HHS, Education and Related Agency Appropriations Bill –
On June 24, 2015, the House Appropriations Committee, Chaired by Hal Rogers (R-KY), approved the draft
FY 2016 LHHS Appropriations bill on a vote of 30-21. The bill includes funding for programs within the
Department of Labor, Department of Health and Human Services, the Department of Education, and
other related agencies.

For NIH, the bill proposes a FY 2016 Appropriation for of $31.2 billion, a $1.1 billion increase above FY
2015 enacted level and $100 million above the President’s budget request. Within the funding for NIH,
the bill provides increases for several research activities:
$480.6 million for the Clinical Translational Sciences Awards (CTSAs)
$311.8 million for the Institutional Development Awards (IDeA)
$164 million for the National Children’s Study
$12.6 million for the Pediatric Research Fund (Targeted funding within the Common Fund)
$9.947 million for the Cures Acceleration Network (CAN)

The bill also provides increases within NIH for several targeted research initiatives identified by the Administration. These include:

- $886 million for Alzheimer’s research, a $300 million increase
- $461 million for combating antibiotic resistant bacteria (CARB), a $100 million increase
- $150 million for BRAIN, a $95 million increase
- $200 million for Precision Medicine Initiative (PMI)

For NCI, the bill provides $5.081 billion, of which up to $16 million may be used for facilities repairs and improvements at NCI Frederick. This includes the $70 million increase for NCI PMI research activities.

The final bill reported by the Committee incorporated the manager’s amendment, which included a provision, offered by Representative Rosa DeLauro (D-CT), stating that none of the funds in the bill may be used to issue or facilitate the issuance of any recommendations of the United States Preventive Services Task Force with respect to breast cancer screening, mammography, and prevention.

**Senate Labor, HHS, Education and Related Agencies Appropriations Bill –**

On June 25, 2015, the Senate Appropriations Committee chaired by Thad Cochran (R-MS) approved the LHHS FY 2016 bill by a vote of 16-14. Like the House bill, the Senate bill provides funding for programs within the Departments of Labor, Health and Human Services, Education, and Related Agencies.

For NIH, the bill proposed an appropriation of $32 billion, an increase of $2 billion above the FY 2015 enacted level. This represents the largest increase for NIH since 2003. Some of the specifics of the bill include:

- $200 million for Precision Medicine ($70 million of which goes to NCI);
- $350 million increase for the National Institute on Aging;
- $135 million, an increase of $70 million, for the BRAIN Initiative to map the human brain;
- $461 million, an increaser of $100 million, for the CARB Initiative;
- $300 million, an increase of $26.7 million, for IDeA; and
- Increases to every Institute and Center to continue investments in innovative research that will advance fundamental knowledge and speed the development of new therapies, diagnostics, and preventive measures.

For NCI, the bill provides $5.204 billion, of which $16 million may be used for facilities repairs and improvements at NCI-Frederick.

Additionally, Sen. Cochran introduced S.2132, on October 5, 2015, which proposes to arrange spending bills into groups of “mini-omnibus” packages requiring additional votes. The LHHS measure, as reported out of Committee and described above, is grouped with the Department of Interior-Environment and Financial Services bills for FY 2016. This is the first of a number of procedural steps in the Senate to get four spending bills that combine multiple regular appropriation measures to the floor for potential votes.
II. Special Topics
Update: House Passes 21st Century Cures Act Senate HELP Innovation for Healthier Americans
Discussion Draft Expected

The House passed H.R. 6, the 21st Century Cures Act, on July 10th by a vote of 344-77. As summarized in the last NCRA legislative update, the bill includes a number of provisions directed at NIH and FDA. The bill would reauthorize NIH for FY 2016-2018 and would establish an “NIH and Cures Innovation Fund” with funding of $1.75 billion in mandatory funds per year for five years for NIH, and $110 million per year for FDA. Notably, an amendment that would have made the additional funding for NIH and FDA a discretionary spending program, rather than mandatory funds, failed by a vote of 281-141.

The bill directs a number of specific efforts to be supported through the Fund, including a program administered through the NIH OD that would require matching funds from the ICs for “high-risk, high-reward” research, awards to early stage investigators, and the Small Business Innovation Research program, as well as allowing for some resources in the Fund to support investigator initiated research projects. The bill also calls for the NIH Director to develop a strategic plan for the Fund, and a separate strategic plan for NIH, to also be used by each IC in development of IC-specific strategic plans. The NIH Director would also be given expanded authority to appoint, review, and remove IC directors every five years (an exception is noted for the presidential appointment of the NCI Director). The bill would also require each IC director to “review and approve” R-series awards.

The Senate HELP Committee continues with its parallel but independent effort entitled “Innovation for Healthier Americans” and reports indicate that a discussion draft may be released in the coming weeks. The draft is expected to include a focus on electronic health records and may address proposed FDA regulation of laboratory developed tests. It is still unclear as to whether the Senate draft will include provisions to provide mandatory funding to NIH and FDA.

Senator Lamar Alexander (R-TN), Chair of the HELP Committee, and a member of the Senate LHHS Appropriations Subcommittee, brought this issue up at an October 7th LHHS Subcommittee hearing, NIH: Investing in a Healthier Future. Sen. Alexander commented, “Our visceral reaction is against new mandatory funding but I am convinced that this is a critical time in science and a critical time of opportunity, so I am willing to think about that.”

Given that the budget deal utilized potential offsets, prospects for mandatory funding through a 21st Century Cures/Innovation for Healthier Americans package are looking less promising.

III. Congressional Hearings, Briefings, and Visits

Briefing: Advances in Precision-Based Cancer Prevention and Detection: Dr. Sudhir Srivastava, Chief of the Cancer Biomarkers Research Group, Division of Cancer Prevention, NCI, spoke on a panel at a congressional briefing organized by the National Coalition for Cancer Research (NCCR). The briefing, “Advances in Precision-Based Cancer Prevention and Detection,” is part of NCCR’s “Cancer 101” Congressional Briefing Series. Dr. Srivastava focused on biomarker research in the context of cancer prevention and NCI’s Early Detection Research Network (EDRN). He was joined by his colleague Daniel Chrichton from NASA’s Jet Propulsion Laboratory, a key informatics partner in the EDRN. Other panelists

1A detailed summary is available on NCI’s website at: http://legislative.cancer.gov/topics, under “21st Century Cures, H.R. 6”.
included Dr. Clifford Hudis of the Memorial Sloan Kettering Cancer Center; Dr. Mitchell Schnall of the University of Pennsylvania, and Co-Chair of ECOG-ACRIN; and Carolyn Aldigé, founder of the Prevent Cancer Foundation.

**Senate LHHS Appropriations Subcommittee Hearing, NIH: Investing in a Healthier Future:** Dr. Doug Lowy, NCI Acting Director, and other NIH IC Directors joined Dr. Francis Collins, NIH Director, at the Senate LHHS hearing on October 7th. Dr. Collins emphasized the importance of basic research in his oral testimony, using cancer immunotherapy as an example of the “long arc of medical research” leading to new effective treatments, and shared the story of a young girl who benefitted from CAR T-cell therapy for acute lymphoblastic leukemia. Dr. Lowy responded to a number of questions, including an opening question from Subcommittee Chairman Senator Roy Blunt (R-MO) about the promise of targeted immunotherapy approaches for cancers. Ranking Member Senator Patty Murray (D-WA) also asked about immunotherapy research. Dr. Lowy also addressed questions about supporting young investigators, electronic cigarette research, plans for the Pediatric MATCH precision medicine trial, opportunities for additional investment, and his vision for NCI – he highlighted three key areas: continuing to support basic research; leveraging advances in precision medicine for cancer treatment, screening, and prevention; and focusing on health disparities.

**Dr. Elise Kohn speaks at Congressional Ovarian Cancer Caucus Event:** Dr. Elise Kohn, Head of Gynecologic Cancer Therapeutics in NCI’s Cancer Therapy Evaluation Program, spoke at a Congressional briefing on September 29th that launched the Ovarian Cancer Caucus. Dr. Kohn joined the Caucus Co-Chairs, Congresswoman Rosa DeLauro (D-CT) and Congressman Sean Duffy (R-WI), and representatives of the Ovarian Cancer National Alliance. Dr. Kohn provided an update on ovarian cancer research, including exciting clinical trials underway with NCI support and a focus on early detection research. Rep. DeLauro, a 29-year ovarian cancer survivor, commented that she is alive “by the grace of God and biomedical research” and stressed the need for increased, and sustained, funding for NIH. Rep. Duffy’s sister is an ovarian cancer survivor, and he lost a friend to ovarian cancer last year. Rep. Sheila Jackson Lee (D-TX) also attended.

**Congressman Chris Van Hollen (D-MD) visits NIH and the NCI Pediatric Oncology Branch:** Congressman Van Hollen visited NIH on September 22nd and met with Dr. Collins; hosted a round-table discussion with NIH employees; and hosted a press event to highlight the threat a potential government shutdown poses to NIH. Rep. Van Hollen also serves as a Co-Chair of the Congressional Childhood Cancer Caucus and requested that his visit include at the NCI Center for Cancer Research Pediatric Oncology Branch (POB). The Congressman and his staff met with Dr. Lee Helman, Acting Director of NCI’s Center for Cancer Research, Dr. Brigitte Widemann, and child with relapsed rhabdomyosarcoma who participated in a POB study and is now four years in remission, who was joined by his mother.

**Dr. Lee Helman Speaks at Congressional Childhood Cancer Caucus Summit:** Dr. Lee Helman, Acting Director of NCI’s Center for Cancer Research, and a Senior Investigator in the Pediatric Oncology Branch, gave the keynote address at the Congressional Childhood Cancer Caucus Summit. The summit was hosted by caucus co-chairs, Congressmen Michael McCaul (R-TX) and Chris Van Hollen (D-MD), along with caucus member Congresswoman Jackie Speier (D-CA). Dr. Helman spoke about unique challenges in childhood cancer research, as well as research opportunities, with a focus on individualized therapy for pediatric cancers. He highlighted the importance of basic research, recent advances in immunotherapy approaches, the NCI Pediatric Preclinical Testing Consortium, childhood cancer survivorship research, and plans for the NCI Pediatric MATCH precision medicine trial.
Senate Appropriations Clerks Visit NCI Center for Cancer Research and Frederick National Laboratory for Cancer Research: On July 29th, Majority Clerk to the Senate LHHS Appropriations Subcommittee, Laura Friedel, and Minority Clerk, Alex Keenan, met with Drs. Doug Lowy and Lee Helman for a brief tour of NCI’s CCR at the NIH Clinical Center, and then traveled to NCI’s FNLCR to meet with Drs. Jim Doroshow, Craig Reynolds, Lynn Austin and NCI colleagues to tour FNLCR facilities, learn more about the research underway in FNLCR labs, and discuss facility repairs and improvements.

IV. Legislation of Interest
The following bills and resolutions were selected for inclusion in this update due to anticipated interest among the NCRA membership. More detailed information about these bills and others are available on our website under Legislative Topics: http://legislative.cancer.gov/topics.

Selected New Bills in the 114th Congress

Breast Cancer Awareness Commemorative Coin Act (H.R. 2722/S. 2185)
- The bill aims to establish a Breast Cancer Awareness Commemorative Coin by requiring the Secretary of the Treasury to mint up to 50,000 $5 gold coins (to be sold for $35 per coin), up to 400,000 $1 silver coins (to be sold for $10 per coin), and up to 750,000 half-dollar coins (to be sold for $5 per coin) in 2018. Once the cost of design and issuance of the coins is covered, the surcharge would be paid to the Breast Cancer Research Foundation to further research funded by the organization.
- The bill was introduced by Sen. Heidi Heitkamp (D-ND) and referred to the Committee on Banking, Housing, and Urban Affairs on 10/20/15. The bill is companion to H.R. 2722, introduced by Rep. Carolyn Maloney (D-NY) on 6/10/2015 and passed by the House on 7/15/2015. H.R. 2722 was amended before passage to remove Susan G. Komen as a co-recipient after a number of Republican Members of the House objected to the organization’s support for breast cancer screening services provided by Planned Parenthood.

Tobacco to 21 Act (S. 2100/H.R.3646)
- The bill would prohibit the sale or distribution of tobacco products to anyone under the age of 21.
- The bill would also authorize the HHS Secretary to enforce such prohibition, including undercover compliance checks, retailer inspections, and initiating enforcement actions for non-compliance.
- The bill would not preempt State or local government laws prohibiting tobacco sale to minors if such laws were at least as restrictive as the Federal law.
- S. 2100 was introduced by Sen. Brian Schatz (D-HI) and referred to the Committee on Commerce, Science and Transportation on 9/29/2015. H.R.3646 was introduced by Rep. Diane DeGette (D-CO) and referred to the Committee on Energy and Commerce on 9/30/2015.

- The bill would extend the authority of the U.S. Postal Service to issue a semipostal to raise funds for breast cancer research, and for other purposes for another 5 years, through 2019.
- The bill would ensure that an agency receiving funds generated by the special postage stamp sales, use them for breast cancer research.
- Rep. Jackie Speier (D-CA) introduced H.R. 2191 on 4/30/2015. The bill was referred to the Committees on Armed Services; Energy and Commerce; and Oversight and Government Reform. Sen. Dianne Feinstein (D-CA) introduced S. 1170 on 4/30/2015. The bill was referred to the Committee on Homeland Security and Governmental Affairs.
- The Senate passed S. 1170 by unanimous consent on 9/22/2015.
Prevent a Government Shutdown Act of 2015 (H.R. 3476)

- The bill would amend the Balanced Budget and Emergency Deficit Control Act of 1985 to provide for an increase in the discretionary spending limits for fiscal years 2016 and 2017. The bill calls for a bipartisan measure to be negotiated by individuals appointed by the Speaker, the Minority Leader of the House of Representatives, the Majority Leader of the Senate, and the Minority Leader of the Senate. The measure would require the approval of a majority of the individuals appointed to negotiate the measure and, if approved, the measure would be considered under the procedures set forth in Section 402 of the Budget Control Act of 2011, with the following changes: “September 25, 2015” shall be substituted for December 23, 2011."
- H.R. 3476 was introduced on 9/10/2015, by Representative Chris Van Hollen (D-MD).

Next Generation Researchers Act (S. 2014/H.R. 3466)

- The bill would create within the NIH Office of the Director the next generation of researchers’ initiative and require the National Academy of Sciences to prepare a report evaluating barriers for entry into biomedical research for early-stage investigators.
- S. 2014 was introduced on 9/9/2015, by Senators Tammy Baldwin (D-WI) and Susan Collins (R-ME). A companion bill, H.R. 3466, was introduced in the House by Representative Mark Pocan (D-WI).


- The bill would allow individuals, pharmacists, and wholesalers to import prescription drugs from licensed Canadian pharmacies. In addition the legislation would require the Secretary of HHS to negotiate drug prices under the Medicare Part D prescription drug program and to issue regulations already required under current law by January 1, 2016. Provisions of the bill would delay regulations on the destruction of imported drugs until the rule for legally importing drugs is finalized. The bill also requires greater transparency on the part of pharmaceutical companies by requiring that companies report information on the total costs incurred by research and the development of clinical trials, as well as the portion of the drug development expense offset by tax credits and federal grants.
- S. 2023 was introduced on 9/10/2015, by Senator Bernie Sanders (I-VT), and it was referred to the Senate Finance Committee. Rep. Elijah Cummings (D-MD) introduced H.R. 3513 on 9/16/2015, and it was referred to the Committees on Energy and Commerce, Ways and Means, and the Judiciary.

Protecting Access to Lifesaving Screenings Act (PALS) Act (S.1926/H.R.3339)

- The bill would prevent for two years (ending January 1, 2018) the adoption of the draft recommendations of the United States Preventive Services Task Force (USPSTF) with respect to breast cancer screening, mammography, and prevention. The bill would also require the Government Accountability Office to conduct a study on the methodologies and processes by which the USPSTF develops its recommendations.
- S. 1926 was introduced by Sen. Barbara Mikulski (D-MD), Vice Chairwoman of the Senate Appropriations Committee, and Sen. Kelly Ayotte (R-NY) on 8/4/2015 and was referred to the Committee on Finance. H.R. 3339 was introduced by Renee Ellmers (R-NC) and Debbie Wasserman Shultz on 7/29/2015 and was referred to the Committees on Energy and Commerce, and Ways and Means.

Additional Background: Current USPSTF draft guidelines recommend biennial mammograms for women age 50 to 74 that are not at high-risk of developing breast cancer. If the USPSTF guidelines are finalized as currently drafted, health insurance plans would no longer be required to cover mammograms without charging a copayment for women under the age of 50. Current policy is that women aged 40 -74 are
eligible for an annual free mammogram. This policy is a result of Senator Mikulski’s “Women’s Preventive Health Amendment” to the Affordable Care Act.

Scientific Research in the National Interest Act (H.R. 3293)

- The bill would require the National Science Foundation (NSF) to provide publicly a written justification for each grant or cooperative agreement it funds. The justification must include how the grant or cooperative agreement would promote the progress of science in the United States; is consistent with the NSF mission; is worthy of Federal funding; and is in the national interest.
- The bill defines “in the national interest” as indicated by having the potential to increase economic competitiveness; advance health and welfare of the American public; develop a competitive STEM workforce; increase public scientific literacy and engagement with science and technology; increase partnerships between academia and industry in the U.S.; support national defense; or promote the progress of science.
- The bill also indicates that the provisions in the bill shall not be construed as altering NSF’s “intellectual merit or broader impacts criteria for evaluating grant applications.”
- Rep. Lamar Smith (R-TX) introduced H.R. 3293 on 7/29/2015. The bill was referred to the Committee on Science, Space, and Technology.

Childhood Cancer STAR (Survivorship, Treatment, Access, Research) Act (H.R.3381/S.1883)

- The bill is in part a consolidation of legislative proposals introduced in recent and current sessions of Congress focused on childhood cancer research and care (including biorepositories and biospecimen research, and survivorship research), as well as childhood cancer surveillance and issues surrounding access to investigational therapies.
- The bill authorizes NCI to support and expand collection of biospecimens from children, as well as adolescents and young adults (AYAs), diagnosed with cancer in an effort to build upon biorepositories and biospecimen research already underway with NCI support.
- The bill also directs NIH, with guidance from the NCI Director and in coordination with ongoing research activities, to support grants focusing on the cause of health disparities in pediatric cancer survivorship; and focusing on late effects and follow-up care for pediatric cancer survivors.
- Other provisions specific to NIH and NCI include requiring that at least one member appointed to the National Cancer Advisory Board be knowledgeable in pediatric oncology; establishing specific reporting requirements for NIH in addressing pediatric oncology research within its annual Pediatric Research Initiative Report to Congress; and expressing the sense of Congress that the NCI Director should ensure that all applicable study sections, committees, advisory groups, and panels at NCI should include one or more qualified pediatric oncologists, as appropriate.
- The bill also authorizes HHS, through the Centers of Disease Control and Prevention, to award grants to State cancer registries to expand surveillance infrastructure to track the epidemiology of cancer in children and AYAs.
- Additional provisions in the bill focused on pediatric cancer survivorship direct the HHS Secretary to: establish pilot programs to evaluate model systems for monitoring and caring for childhood cancer survivors; establish a task force on long-term follow-up services for pediatric cancer survivors; and carry out a 3-year demonstration project to improve quality and coordination of childhood cancer survivorship care as survivors transition to adult care. The bill would also require the Government Accountability Office to submit recommendations to Congress regarding barriers to obtaining and paying for childhood cancer survivorship care.
- The bill would also require HHS to finalize its May 2013 draft guidance on expanded access to investigational drugs for treatment use, and would require the manufacturer or distributor of an
investigational drug to make its policy on evaluating and responding to expanded access requests publicly available.

- H.R. 3381 was introduced by Reps. Michael McCaul (R-TX) and Chris Van Hollen (D-MD), co-chairs of the Congressional Childhood Cancer Caucus, along with Rep. Jackie Speier (D-CA), on 7/29/2015 and was referred to the Committee on Energy and Commerce. S. 1883 was introduced by Sens. Jack Reed (D-RI) and Shelley Moore Capito (R-WV), on 7/29/2015 and was referred to the Committee on Health, Education, Labor, and Pensions.

Child Nicotine Poisoning Prevention Act of 2015 (H.R. 3242)
- The bill would require the Consumer Product Safety Commission to promulgate a rule to require child safety packaging for liquid nicotine containers.
- Rep. Susan Brooks (R-IN) introduced H.R. 3242 on 7/28/2015. The bill was referred to the Committee on Energy and Commerce.

Mary Jo Lawyer-Spano Mesothelioma Patient Registry Act of 2015 (H.R. 3284; 114th Congress)
- The bill would create, through the Agency for Toxic Substances and Disease Registry within HHS, a national mesothelioma patient registry for mesothelioma data collection and research.
- The bill specifies data to be collected to include incidence, prevalence, treatment outcomes, and information regarding the number of people receiving treatment for mesothelioma disaggregated by hospital. The proposal also indicates that additional data may be collected, such as information regarding natural history, prevention, detection and treatment approaches, and outcome measures.
- The bill directs the HHS Secretary to consult with experts on mesothelioma including those from national voluntary associations, clinicians and research scientists, on the development of the registry.
- The bill encourages the Secretary to make information and analysis from the registry available to other federal agencies and departments including NIH, FDA, CMS, the Department of Veterans Affairs, and the Department of Defense. Registry data, that is not individually identifiable, would also be made available to the public for research purposes.
- The bill was introduced by Rep. John Katko (R-NY) on 7/20/2015 and was referred to the Committee on Energy and Commerce. Cancer. Summary.

Stop Tobacco Sales to Youth Act of 2015 (H.R. 3042)
- The bill would amend current law (15 U.S.C. 375) to prevent the interstate sale and delivery of electronic cigarettes, cigars, and pipe tobacco to minors. The bill would not affect any agreements, compacts, or other intergovernmental arrangements between any State or local government and any government of an Indian tribe on matters in the Indian country, such as the collection of sales tax; regulatory authority on the sale, use, or distribution of cigarettes and smokeless tobacco; and enforcement actions.
- The bill was introduced by Rep. Rosa DeLauro (D-CT) on 7/13/2015 and was referred to the Committee on the Judiciary.

Planning Actively for Cancer Treatment (PACT) Act of 2015 (H.R. 2846)
- The bill aims to amend the Social Security Act to provide for Medicare coverage of cancer care planning and coordination. It proposes that the planning service would be provided to patients at the time of cancer diagnosis, at the end of active treatment and beginning of long-term survivorship, and if there is a significant change in treatment or follow-up care.
- The bill would require providers and patients to jointly develop a cancer care treatment plan that addresses both treatment and symptom management, as well as a survivorship care plan, to be
revised as necessary. The bill calls for the plans to be provided in writing and presented, in person, to the patient, and to take into account the cultural and linguistic needs of the patient.

- Unless otherwise indicated by the DHHS, the payment rate specified under the physician fee schedule for transitional care management services would be applicable to the cancer care planning and coordination services.
- Rep. Lois Capps (D-CA) introduced H.R. 2846 on 6/23/2015 and the bill was referred to the Committees on Energy and Commerce and Ways and Means. Rep. Capps introduced a similar bill in the 113th Congress and it did not move out of Committee.

Medicare Patient Access to Treatment Act of 2015 (H.R. 2895)

- The bill aims to amend the Social Security Act to establish payment parity under the Medicare program for ambulatory cancer care services provided in the hospital outpatient department and the physician office setting, including the administration of chemotherapy.
- Rep. Mike Pompeo (R-KS) introduced H.R. 2895 on 6/25/2015 and the bill was referred to the Committees on Energy and Commerce and on Ways and Means. Former Rep. Mike Rogers (R-MI) introduced a similar bill in the 113th Congress and it did not move out of Committee.

Selected Recent Resolutions (114th Congress)

This section highlights resolutions introduced to raise awareness about specific diseases or issues. 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 no not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Passed

Designating September 2015 as National Prostate Cancer Awareness Month (S. Res. 248)

- Supports the designation of September 2015 as National Prostate Cancer Awareness Month.
- The bill was introduced by Sen. Jeff Sessions (R-AL) on 8/5/2015 and was passed in the Senate by unanimous consent on the same day.

Designation of September 2015 as National Ovarian Cancer Awareness Month (S. Res. 228)

- Supports the designation of September 2015 as National Ovarian Cancer Awareness Month.
- The resolution was introduced by Sen. Kelly Ayotte (R-NH) on 7/23/2015 and was referred to the Committee on the Judiciary. The Senate passed H.Res. 228 on 8/6/2015 by unanimous consent.

Introduced

Designation of October 2015 as "National Breast Cancer Awareness Month"

- Supports the designation of October 2015 as National Breast Cancer Awareness Month.
- The resolution was introduced by Rep. Tim Murphy (R-PA) on 10/27/15 and was referred to the Committee on Energy and Commerce.

Recognizing the Importance of Cancer Program Accreditation in Ensuring Comprehensive, High Quality, Patient-centered Cancer Care (H.Res. 487)

- The resolution notes the role of the American College of Surgeons Commission on Cancer (CoC) in ensuring that cancer patients have access to quality diagnosis, treatment, and rehabilitation through its accreditation of cancer programs, and calls for an appreciation of the importance of accredited cancer programs.
• The resolution was introduced by Rep. Lynn Jenkins (R-KS) and was referred to the House Committee on Energy and Commerce on 10/22/2015.

Designating September 2015 as National Prostate Cancer Awareness Month (H. Res. 425)
• Supports the designation of September 2015 as National Prostate Cancer Awareness Month.
• The bill was introduced by Rep. Randy Neugebauer (R-TX) on 9/17/2015 and was referred to the Committee on Energy and Commerce.

Designation of September 2015 as National Ovarian Cancer Awareness Month (H. Res. 378)
• Supports the designation of September 2015 as National Ovarian Cancer Awareness Month.
• The resolution was introduced by Rep. Steve Israel (D-NY) on 7/23/2015 and was referred to the Committee on Oversight and Government Reform.