

March 4, 2015*

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

**Content current as of February 27, 2015*

**Activities of the 114th Congress-
First Session**

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I. Appropriations

The government was funded through the remainder of fiscal year 2015 with the passage of a “CRomnibus” Appropriations bill, H.R. 83, in December 2014. The bill is a combination of a continuing resolution (CR) for the Department of Homeland Security, providing funding through 2/27/2015, and an omnibus bill that includes appropriations acts providing funds for all other agencies for the remainder of FY 2015. The House passed the bill by a vote of 219 to 206 on 12/11/2014. The House and Senate also passed two short-term CRs to allow the Senate time to act on the bill. The Senate passed the bill by a vote of 56 to 40 on 12/13/2014, and the President signed the bill into law on 12/17/2014.

The total FY 2015 appropriation for NIH is approximately \$30.1 billion. This is an increase for NIH of \$150 million over FY 2014 levels (an amount that does not keep pace with inflation), and it is \$50.3 million more than the President’s budget request for NIH for FY 2015. The FY 2015 appropriation for NCI is \$4.95 billion. This is an increase of \$27 million for NCI compared to the FY 2014 appropriation. The amount is \$20 million more than the President’s budget request for FY 2015.

The omnibus bill also appropriates \$12.6 million to NIH as authorized by the Gabriella Miller Kids First Research Act, signed into law in April 2014. The Act directs NIH conduct pediatric research through the Common Fund, and transfers the \$12.6 million from a Treasury account that the Gabriella Miller Kids First Research Act established. The NIH Common Fund presented a research program concept to the NIH Council of Councils on 1/30/2015 and continues to work to implement the Act. The Act authorizes \$12.6 million per year for ten years, but will require action by Appropriators to provide the authorized \$12.6 million for FY 2016 and any subsequent years. The President released his FY 2016 budget on February 2. It proposed a funding level of \$31.3 billion for NIH, an increase of 3.3 percent over FY 2015, and proposes a funding level of \$5.098 for NCI. These levels include a proposal to fund a Precision Medicine Initiative at NIH and in partnership with FDA, CMS, and the HHS Office of the National Coordinator (ONC). The President announced the initiative at an event at the White House on January 30, which NCI Director Dr. Harold Varmus and NIH Director Dr. Francis Collins attended. The audience included a number of cancer survivors, researchers, and advocates, and the President emphasized the potential of this initiative to continue to advance cancer research and cancer care. The President’s FY 2016 budget proposal includes a total of \$215 million for the initiative – \$130 million across NIH to support a national research cohort; \$70 million to NCI to support additional cancer genomics research efforts; \$10 million to FDA to support regulatory efforts related to precision medicine; and \$5 million to ONC to for data privacy and interoperability efforts, including the secure exchange of research data to support the initiative.

Appropriations leadership and new membership of the House and Senate Appropriations L-HHS Subcommittees are noted below. NIH expects both the House and Senate L-HHS Subcommittees will hold an NIH hearing this year, and the NIH House L-HHS Subcommittee Hearing has been scheduled for March 3. Only the NIH Director will be submitting testimony for the House Subcommittee hearing, and OGCR will post the NCI Director’s testimony for the Senate Subcommittee hearing on our website when it is available and will include summaries of the hearings in future CTAC Legislative Updates.

II. Committee and Subcommittee Leadership and New Members for the 114th Congress

House Energy and Commerce (E&C): Rep. Fred Upton (R-MI) will remain Chair of the E&C Committee in the 114th, and Rep. Joseph Pitts (PA) will remain Chair of the E&C Subcommittee on Health – Rep. Brett Guthrie (R-KY) will serve as Vice Chair of the Subcommittee. On 11/19/14 the full Democratic Caucus voted 100-90 for Rep. Frank Pallone, Jr. (D-NJ) over Rep. Anna Eshoo (D-CA) to serve as Ranking Member of the E&C Committee in the 114th Congress to replace Rep. Henry Waxman (D-CA) who retired. Rep. Gene Green (D-TX) is the Ranking Member of the E&C Subcommittee on Health. New members of the Subcommittee are Reps. Larry Bucshon (R-IN), Susan Brooks (R-IN), Chris Collins (R-NY), Kurt Schrader (D-OR), Joseph P. Kennedy, III (D-MA), and Tony Cardenas (D-CA).

House Appropriations L-HHS Subcommittee: On 11/20/14 House Appropriations Committee Chair Hal Rogers (R-KY) announced that Rep. Tom Cole (R-OK) will serve as Chair of the L-HHS Subcommittee. Rep. Rosa DeLauro (D-CT) will remain Ranking Member of the Subcommittee. Rep. Rogers will remain Chair of the full committee and Rep. Nita Lowey, D-NY, will remain Ranking Member. New members of the Subcommittee are Reps. Charlie Dent (R-PA),

Scott Rigell (R-VA), and Chaka Fattah (D-PA). Rep. Mike Simpson (R-ID) has returned to the committee (served in the 108th, 109th, 110th and the 112th Congresses but was not on Labor-H during the 111th and 113th).

Senate HELP Committee: Sen. Lamar Alexander (R-TN) is Chairman of the HELP Committee, after serving as Ranking Member in the 113th Congress. Sen. Patty Murray (D-WA) is Ranking Member of the Committee. New members of the Committee are Sens. Susan Collins (R-ME) and Bill Cassidy, MD (R-LA).

Senate Appropriations L-HHS Subcommittee: Sen. Roy Blunt (R-MO) is Chairman of the Labor-HHS Subcommittee, and Sen. Patty Murray is Ranking Member. Sen. Thad Cochran (R-MI) is Chairman of the full Committee, and Sen. Barbara Mikulski (D-MD), who served as Chair in the 113th Congress, is Ranking Member. New members of the L-HHS Subcommittee are Sens. Bill Cassidy, MD (R-LA), Shelley Moore Capito (R-WV), James Lankford (R-OK), Brian Schatz (D-HI), and Tammy Baldwin (D-WI).

III. Special Topics

Legislative Proposals to Provide Sustained Funding for Biomedical Research

Early into the 114th Congress, members of both the House and Senate are making moves aimed to increase funding in the area of biomedical research. Several pieces of legislation from the 113th Congress that did not receive a vote have been introduced again, along with a few new approaches. Rep. Rosa L. DeLauro (D-CT), along with cosponsors Reps. Brian Higgins (D-NY) and Peter King (R-NY), introduced the bipartisan legislation H.R.531, the Accelerating Biomedical Research Act, which was referred to the Committee on the Budget on January 26, 2015. That same week, Sens. Barbara Mikulski (D-MD) and cosponsor Benjamin Cardin (D-MD) introduced a companion bill, S.318, which was referred to the Committee on the Budget.

The goal of the legislation is to prioritize funding for the NIH to support discovery of treatments and cures, to maintain global leadership in medical innovation, and to restore NIH purchasing power after the historic doubling campaign that ended in FY 2003. In a press release announcing the bill, Rep. DeLauro commented, “Work supported by the NIH has saved the lives of countless Americans. Failure to invest in health research and disease prevention results in huge costs to our health, society, economy and knowledge itself...Congress must stop forcing the NIH to do more with less.”

If passed, the NIH would receive ‘additional new budget authority.’ Any funding provided in excess of \$29.4 billion would trigger a budget cap increase to accommodate the additional funding provided to the NIH. The legislation would allow Appropriators to increase NIH funding by ten percent for the first two years and approximately six percent each year thereafter through 2021. This is almost identical to H.R. 5580 introduced by Rep. DeLauro in the 113th Congress, which aimed to increase NIH appropriations to \$46.5 billion by the end of FY 2021. Currently, there are over 100 advocacy groups and research institutions in support of the legislation.

On January 28, 2015, Sen. Richard Durbin (D-IL) along with eight other democratic cosponsors introduced S.289, the American Cures Act, which was referred to the Committee on the Budget. This legislation takes a similar approach to that of Rep. DeLauro and Sen. Mikulski by providing ‘additional new budget authority’ to preserve America’s global leadership by investing in breakthrough biomedical research.

The American Cures Act would set a steady growth rate in federal appropriations for biomedical research conducted at the NIH, CDC, the DoD Health Program, and the VA Medical and Prosthetics Research Program. The bill would increase funding at a rate of GDP-indexed inflation plus five percent for each agency and program. Funds would come from an established Biomedical Research Fund to be administered by the Treasury to provide for an expanded and sustained national investment in biomedical research. The bill would also amend the Balanced Budget and Emergency Deficit Control Act to exempt the Fund from any sequestration order issued under the Act.

Sen. Durbin first introduced this legislation in the 113th Congress and Rep. Anna Eshoo (D-CA) introduced the American HEALS (Helping Encourage Advancements in Lifesaving Science) Act as a companion bill which was identical in content. Also in the 113th Congress, Rep. Kathy Castor (D-FL) introduced H.R. 5724, the Permanent Investment in Health Research Act, which similarly proposed to appropriate increased funds annually based on a GDP percentage as well as exempt the NIH from sequestration orders. Rep. Castor recently introduced the bill in

the 114th Congress, H.R. 777, and it was again referred to the Committee on Energy and Commerce and also to the Committees on the Budget and Appropriations.

On January 29, 2015 Sen. Elizabeth Warren (D-MA) introduced S.320, the Medical Innovation Act, which aims to increase Federal investments in research at NIH and FDA. The bill was referred to the Committee on Health, Education, Labor, and Pensions. Cosponsors include Sens. Benjamin Cardin (D-MD), Sherrod Brown (D-OH) and Tammy Baldwin (D-WI). Maryland Congressman Chris Van Hollen (D) and colleagues introduced a companion bill on the House side. Rep. Van Hollen commented in a press release that he is “pleased to join Senator Elizabeth Warren in introducing the Medical Innovation Act, an innovative way to inject additional vital funds into medical research at no cost to taxpayers.”

The Act takes a very different approach from the above budget cap adjustment approaches. The bill would require that a pharmaceutical company that enters into a settlement with the government over alleged wrongdoing would have to set aside one percent of annual profits for each of its drugs that exceeds \$1 billion in annual sales and can be traced to federally funded research. Those funds would be allocated to NIH and FDA in amounts proportional to the funds appropriated to the agencies for the given fiscal year. Sen. Warren spoke on the Senate floor when introducing the bill, calling upon her colleagues to support this strategy:

“Increase NIH funding without raising taxes and without stealing support from other critical program. Instead support would come from blockbuster drug companies – only those that relied on government supported research to generate billions in sales, and only those that break the law and enter into major settlement agreements with the government. In such cases the government settlements would go forward as they normally do, but the offending company would also be required to reinvest a relatively small portion of the profits it has generated, as a result of tax-payer supported research, and put that money right back into the NIH.”

In the 113th Congress, Sens. Warren and Orrin Hatch (R-UT) quietly worked on the Invest for a Healthy Future Act. Although this bill was never formally introduced, the idea was to create a \$10 billion biomedical science fund that would be offset by cuts elsewhere that could only be tapped if appropriators keep the budgets at five major government agencies, including the NIH, at steady levels. This idea differs from others in that it created an incentive structure for lawmakers to support steady increases in research funding.

House Energy and Commerce 21st Century Cures Initiative and Senate HELP Innovation for Healthier Americans Report

The House Energy and Commerce Committee continues to move forward with its 21st Century Cures Initiative in the 114th Congress. Over the past year the effort, championed by Committee Chairman Fred Upton (R-MI), and Rep. Diana DeGette (D-CO), has convened a number of hearings and roundtable discussions at the Capitol and in members’ districts to explore opportunities to streamline and accelerate the drug and medical device discovery, development, and delivery process. NIH Director Dr. Francis Collins has participated in some of these events, as have a number of NCI-designated cancer center directors and other NIH and NCI grantees.

Most recently, Chairman Upton released a 21st Century Cures discussion draft bill from the Committee majority on 1/27/2015. Minority colleagues, including Rep. DeGette, have not endorsed the draft, and have indicated that continued discussion is needed to develop a bipartisan bill. Chairman Upton has noted that the draft is a starting point to incorporate input not only from his minority colleagues, but also stakeholders and other public comment. Much of the bill focuses on FDA and it also includes provisions affecting NIH and specific Institutes and Centers – all input to the Committee from NIH and FDA will be coordinated through HHS.

In a related effort, Sen. Lamar Alexander (R-TN), Chair of the Senate HELP Committee, and Sen. Richard Burr (R-NC), released a report on 1/29/2015, titled “Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation’s Medical Product Discovery and Development.” The report poses a number of questions regarding potential changes to FDA authorities and processes, and discusses a variety of challenges for NIH, but does not propose specific legislative or policy changes. Sen. Alexander has indicated the Committee will hold a number of hearings on these issues, and has referred to the report and the HELP Committee’s next steps as

parallel and complementary to the 21st Century Cures initiative. Sen. Alexander has also commented that he plans to introduce a Senate bill informed by this process that is separate from the House 21st Century Cures bill.

IV. Congressional Hearings, Briefings, and Visits

Visit to NIH from Members of the House Appropriations, L-HHS Subcommittee: Representative Tom Cole (R-OK), Chairman of the House Appropriations Committee's Labor-HHS Subcommittee, visited NIH on 1/20/15 along with colleagues from the Committee. Reps. Rosa DeLauro (D-CT, Ranking Member of the Labor-HHS Subcommittee), Nita Lowey (D-NY, Ranking Member of the Full House Appropriations Committee), Charlie Dent (R-PA), Steve Womack (R-AR), and Dr. Andy Harris (R-MD), joined Chairman Cole. The members of Congress met with Dr. Collins, Dr. Varmus and a number of NIH IC Directors for a roundtable discussion. They then visited the Pediatric Oncology Branch and met with Drs. Lee Helman, Crystal Mackall and colleagues in her lab, and Dr. Malcolm Smith, DCTD. Dr. Helman provided an overview of the NCI intramural program, Dr. Mackall and her team focused on immunotherapy research and featured CAR T cell therapy as an example, and Dr. Smith provided background on the extramural pediatric portfolio. Following this discussion, the members visited NIAID's Vaccine Research Center.

Immunotherapy Briefing: Dr. James Gulley, CCR spoke at a Congressional briefing on 12/15/2014 organized by the Melanoma Research Alliance and the Society for Immunotherapy in Cancer (SITC). The briefing covered promising new areas of research involving immunotherapy and melanoma. Dr. Gulley's talk provided an introduction to immunotherapy for cancer, highlighting various immunotherapy approaches and featuring examples of NCI-supported research, including his work with colleagues in the NCI intramural program on therapeutic vaccines for prostate cancer.

Congressional Biomedical Research Caucus and Coalition for Life Sciences: On 12/17/2014 staff to Members of the Congressional Biomedical Research Caucus and Lynn Marquis and Kevin Wilson of the Coalition for Life Sciences, visited the NIH campus to meet staff and tour laboratories of NCI and NINDS. Staff attending include Molly Fishman, Health LA to Representative Jackie Speier (D-CA), Dan Martini, Health LA to Representative Charlie Dent (R-PA), Mark Gilbride, LA to Representative Steve Stivers (R-OH), Audrey Smith, Health LA to Representative David McKinley (R-WV), and Kristen Donheffner, Health Legislative Assistant to Representative Earl Blumenauer (D-OR). Dr. Brigitte Widemann of CCR and her research team gave a presentation about neurofibromatosis and promising results from a Phase I study of a MEK inhibitor, and met a patient who has had a very good response to treatment. NCI's Dr. Lee Helman, Dr. Lynn Austin, Susan Erickson, M.K. Holohan and Holly Gibbons attended the briefing.

Senate Cancer Coalition and ACS CAN Briefing on Building Opportunities in Cancer Research: The Senate Cancer Coalition and the American Cancer Society Cancer Action Network hosted a briefing on 12/10/14, focused on opportunities in cancer research to coincide with the release of the NCI Professional Judgment Budget. Senator Johnny Isakson (R-GA), co-chair of the Senate Cancer Coalition and a melanoma survivor gave opening remarks. Dr. Harold Varmus was the keynote speaker and highlighted central themes of the proposal. Dr. Otis Brawley, Chief Medical Officer at the American Cancer Society also spoke, along with Dr. Louis Weiner, Director of Georgetown's Lombardi Cancer Center, and Danielle Leach, co-chair of the Alliance for Childhood Cancer and Director of Government Relations for the St. Baldrick's Foundation.

V. Legislation of Interest

The following bills and resolutions 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 (113th Congress)

Consolidated and Further Continuing Appropriations Act of 2015 (H.R. 83; 113th Congress; P.L. 113-235)

- The bill is a combination of a continuing resolution (CR) for the Department of Homeland Security, providing funding through 2/27/2015, and an omnibus bill that includes appropriations acts providing funds for all other agencies for the remainder of FY 2015.
- The total FY 2015 appropriation for NIH is approximately \$30.1 billion, an increase for NIH of \$150 million over FY 2014 levels. The FY 2015 appropriation for NCI is \$4.95 billion. This is an increase of \$27 million for NCI compared to the FY 2014 appropriation.
- The House passed the bill by a vote of 219 to 206 on 12/11/2014. The House and Senate also passed two short-term CRs to allow the Senate time to act on the bill. The Senate passed the bill by a vote of 56 to 40 on 12/13/2014, and **the President signed the bill into law (P.L. 113-235) on 12/17/2014.**

Continuing Appropriations Resolution, 2015 (H.J. Res. 124; 113th Congress; P.L. 113-364)

- The continuing resolution (CR) would provide funding for federal government operations at FY 2014 levels through 12/11/2014 at an annualized rate of \$1.012 trillion.
- Among other measures, it would provide \$88 million for government efforts to fight the Ebola virus.
- It would also allow the FDA to collect fees for the inspection of compounded drugs.
- Rep. H. Rogers (R-KY) introduced the CR on 9/9/2014. The CR was referred to the House Appropriations and the House Budget Committees; passed by the House on 9/17 and passed by the Senate on 9/18. **The President signed it into law (P.L. 113-364) on 9/19/2014.**

EARLY Act Reauthorization of 2014 (H.R. 5185/S. 2655; 113th Congress; P.L. 113-265)

- The bill aims to reauthorize the Young Women’s Breast Health Education and Awareness Requires Learning Young (EARLY) Act of 2009 for a period of 5 years. The EARLY Act was originally signed into law as section 10413 of the Patient Protection and Affordable Care Act (Public Law 111-148) on 3/23/10.
- Consistent with the original law, the reauthorization proposes to increase awareness of breast cancer risks in young women (15 – 39 years old) and to provide support for those diagnosed with breast cancer.
- The reauthorization would direct CDC to continue implementation of the EARLY Act provisions signed into law in 2010 and does not include new provisions. The bill would direct the CDC to continue to conduct a national evidence-based education campaign to increase public awareness regarding breast cancer in young women, especially regarding risks faced by ethnic and cultural groups. Additionally, the bill would direct the CDC, in consultation with HRSA, to continue an education campaign to increase awareness among physicians and other health care professionals of risk factors, risk reduction strategies, early diagnosis and treatment of breast cancer in young women.
- The bill would also direct the CDC to continue to conduct prevention research on breast cancer in younger women; continue to support research aimed at measuring their awareness of the disease; and continue the activities of its Advisory Committee on Breast Cancer in Young Women.
- The bill would authorize \$9 M for each fiscal year from 2015 through 2019.
- Reps. Debbie Wasserman Schultz (D-FL) and Renee Ellmers (R-NC) introduced H.R. 5185 on 7/24/2014, and Sens. Amy Klobuchar (D-MN) and David Vitter (R-LA) introduced S. 2655 on 7/24/14. H.R. 5185 was referred to the Committee on Energy and Commerce, and S.2655 was referred to the Committee on Health, Education, Labor, and Pensions.
- The House passed the bill on 12/9/2014 and the Senate on 12/15/2014. **The President signed it into law (P.L. 113-265) on 12/18/2014.**

Sunscreen Innovation Act (H.R. 4250/S. 2141; 113th Congress; P.L. 113-195)

- The bills aim to accelerate FDA review and approval of sunscreens with new active ingredients. FDA’s Center for Drug Evaluation and Research would be required to complete its review of eligible applications within 300 days of the request being filed. If the center did not act within that time, the request would be transferred to the FDA Commissioner for review within 60 days.
- Provisions in the bills are specific to FDA, and NCI would not have any responsibility for implementation.
- The House passed H.R. 4250, the Sunscreen Innovation Act on 7/28/14 and the bill was received in the Senate on 7/29/14. H.R. 4250 was originally introduced by Rep. Ed Whitfield (R-KY) on 3/13/14, and Sens. Jack Reed (D-RI) and Johnny Isakson (R-GA) introduced a companion bill, S. 2141 on the same date. The Senate passed S.

2141 on 9/17/14, agreeing to the measure by Unanimous Consent. The House passed S. 2141 by unanimous consent on 11/13/14. **The President signed it into law (P.L. 113-195) on 11/26/2014.**

Selected New Bills in the 114th Congress

Sequestration Relief Act of 2015 (S.515; 114th Congress)

- The bill aims to revise discretionary spending limits (both non-defense discretionary and defense discretionary), to allow for increased spending. The bill findings note the negative effects of sequestration on the National Institutes of Health, and the bill aims to express the sense of the Senate that biomedical research is among the top priorities to be addressed by providing additional spending authority.
- Sens. Brian Schatz (D-HI) and Dick Durbin (D-IL) introduced S.515 on 2/12/2015 and the bill was referred to the Committee on the Budget.

Tobacco Tax Equity Act of 2015 (S.450; 114th Congress)

- S.450 would require changes to the tax code to establish tax parity across tobacco products, setting the tax rate on all tobacco products at the same per unit level as cigarettes (currently products including pipe tobacco, cigars, and smokeless tobacco are taxed at a lower rate). The bill proposes that this tax rate also apply to new products determined by the FDA to be tobacco products, such as electronic cigarettes.
- Sen. Dick Durbin (D-IL) introduced S.450 on 2/11/2015 and the bill was referred to the Committee on Finance.

Permanent Investment in Health Research Act of 2015 (H.R. 777, 114th Congress)

- The bill proposes to amend the Public Health Service Act to provide additional funding for the NIH by appropriating \$32 billion for FY 2016. The proposal calls for an increase in NIH appropriations for fiscal years 2017 through FY 2025 adjusted by the percentage increase in nominal gross domestic product during the preceding calendar year.
- The bill would also provide for appropriations to remain available until expended, and would exempt the NIH from sequestration orders.
- Rep. Kathy Castor (D-FL) introduced H.R. 777 on 2/5/2015. The bill was referred to the Committees on Appropriations, Budget, and Energy and Commerce.

Traditional Cigar Manufacturing and Small Business Jobs Preservation Act (H.R.662/S. 441, 114th Congress)

- The bill would amend the Federal Food, Drug and Cosmetic Act to exempt traditional large and premium cigars from regulation by the FDA and would also exempt such cigars from user fees assessed on tobacco products by the FDA.
- H.R. 662 was introduced by Rep. Bill Posey (R-FL) on 2/2/2015 and referred to the Committee on Energy and Commerce. S. 441 was introduced by Sen. Bill Nelson (D-FL) on 2/10/2015 and referred to the HELP Committee.

Breast Density and Mammography Reporting Act (H.R. 716/S. 370, 114th Congress)

- The bill would amend the Mammography Quality Standards Act (MSQA) of 1992 to require mammography results to include information about a patient's breast density, and for that information to be reported to patients in their mammography results summary.
- The bill directs the Health and Human Services (HHS) Secretary to establish reporting requirements based on current scientific knowledge, and also requires that the summary communicate the effect of dense breast tissue in masking breast cancer on mammography. For women with results indicating they have dense breast tissue, the summary must also include language encouraging them to consult with their physician regarding whether additional screening would be beneficial.
- The bill also directs the HHS to "expand and intensify" HHS programs related to (1) applied research on breast density; (2) research on the cost-effectiveness, effectiveness, and feasibility of reimbursement models for supplemental imaging related to breast density; (3) research supporting clinical guidelines and best practices for mammography screening for women with dense breasts.

- Rep. Rosa DeLauro (D-CT) and Sen. Dianne Feinstein (D-CA) introduced the Breast Density and Mammography Reporting Act on 2/5/15, along with colleagues Reps. Steve Israel (D-NY) and Mike Fitzpatrick (R-PA) and Sen. Kelly Ayotte (R-NH). H.R. 716 was referred to the Committee on Energy and Commerce, and S. 370 was referred to the Committee on Health, Education, Labor and Pensions.

Additional Information: Rep. DeLauro introduced similar legislation in the 111th, 112th, and 113th Congresses. She introduced this version of the bill in the 113th Congress in July 2014, and Sen. Feinstein introduced the companion bill. Neither bill moved out of Committee. The section directing HHS to expand and intensify relevant research efforts was not included in the proposals introduced in the 111th and 112th Congress, nor in an earlier version of the bill Rep. DeLauro introduced in the 113th Congress in October 2013.

Clinical Trial Cancer Mission 2020 Act (H.R. 617; 114th Congress)

- The bill would amend the Public Health Service Act to enhance clinical trial registry data bank reporting requirements and enforcement measures, including a clarification that reporting requirements would apply regardless of whether a clinical trial resulted in a positive or negative outcome.
- H.R. 617 would also extend these requirements to Department of Defense (DoD) supported trials, and would give NIH and DoD additional enforcement authorities: withholding remaining award amounts, requiring repayment of awards by grantees not in compliance, and designating a grantee ineligible for future awards.
- Rep. Tom Reed (R-NY) introduced H.R. 617 on 1/28/2015 and the bill was referred to the Committee on Energy and Commerce. Rep. Reed has introduced similar proposals in previous sessions of Congress and they have not moved out of Committee.

National Prostate Cancer Plan Act (S. 222; 114th Congress)

- The bill would establish the National Prostate Cancer Council on Screening, Early Detection, Assessment, and Monitoring of Prostate Cancer (Council) within the HHS.
- The bill directs the Council to implement a national 5-year strategic plan for the accelerated creation, advancement, and testing of diagnostic tools, to improve screening; early detection of aggressive prostate cancer; monitoring of tumor response to treatment, including recurrence and progression; and accurate assessment and surveillance of indolent disease to reduce unnecessary biopsies and treatment.
- The bill directs the Council to provide coordination for prostate cancer research and services across all Federal agencies; evaluate all current programs in prostate cancer, including Federal budget requests and approvals and public-private partnership; and submit an annual report to Congress regarding the implementation of the 5-year plan.
- The bill would require that the first annual report include recommendations to expand, eliminate, coordinate, or condense federal programs based on the performance, mission and purpose of the programs; subsequent reports would identify specific roles for NCI, NIMHD, and the HHS Office of Minority Health.
- Federal members of the Council would include a representative of the NCI, NIBIB, CDC, CMS, FDA, AHRQ, the HHS Office of Minority Health, and the DoD Congressionally Directed Medical Research Program. Non-Federal members of the Council would consist of six prostate cancer patient advocates and eight experts in prostate cancer research, including medical oncologists, radiologists, radiation oncologists, urologists and pathologists.
- The bill would authorize appropriations of \$2 million for the five year period of 2016 through 2020.
- Sens. Barbara Boxer (D-CA) and Jim Sessions (R-AL) introduced S. 222 (also filed as S.216) on 1/21/2015. The bill was referred to the Committee on Health, Education, Labor, and Pensions. Sens. Boxer and Sessions introduced the same proposal in the 113th Congress but it did not move out of Committee.

Triple-Negative Breast Cancer Research and Education Act of 2015 (H.R. 45; 114th Congress)

- The bill would provide for research and education with respect to triple-negative breast cancer (TNBC), and for other purposes.
- The bill would require the NIH Director to expand, intensify and coordinate programs for the conduct and support of research on TNBC through appropriate institutes, offices and centers.
- \$500,000 would be appropriated for each of the fiscal years 2016 through 2018.

- The bill would also require the Centers for Disease Control to conduct an education program would require the Health Research Services Administration to develop information for health care providers. The bill does not mention the NCI.
- H.R. 45 was introduced by Rep. Sheila Jackson Lee (D-TX) on 1/6/2015 and was referred to the Committee on Energy and Commerce.

Accelerating Biomedical Research Act (H.R. 531/S. 318; 114th Congress)

- The bills aim to prioritize funding for the NIH and to restore the purchasing power the NIH had at the end of FY 2003.
- The bill would activate a budget cap increase for any appropriation of funds to NIH beyond \$29.4 billion. The NIH would receive an initial increase of 10% in each of the first two fiscal years, FY 2016 and FY 2017; and thereafter an increase of approximately 6% annually through FY 2021.
- Reps. Rosa DeLauro (D-CT), Brian Higgins (D-NY), and Peter King (R-NY) introduced H.R. 531 on 1/26/2015. Sens. Barbara Mikulski (D-MD) and Benjamin Cardin (D-MD) introduced S. 318 on 1/29/2015. The bills were referred to the House and Senate Committees on the Budget.

American Cures Act (S. 289; 114th Congress)

- The bill would establish Biomedical Research Fund to be administered by the Treasury, and authorizes funding to be appropriated to support an expanded and sustained national investment in biomedical research by increasing funding for eligible programs within NIH, CDC, the DoD Health Program, and the VA Medical and Prosthetics Research Program.
- The bill proposes \$150 billion in mandatory funding over 10 years, starting with \$1.8 billion in the first year, and would provide for an increase in funding for each program at a rate of GDP-indexed inflation plus five percent.
- Sen. Richard Durbin (D-IL) introduced S. 289 on 1/28/2015. The bill was referred to the Budget Committee. Sen. Durbin introduced the same bill during the 113th Congress - it was referred to the HELP Committee, and did not move out of Committee.

Medical Innovation Act of 2015 (S. 320/H.R. 744; 114th Congress)

- The bill aims to provide addition support for research at NIH and FDA and would require that a pharmaceutical company that enters into a settlement with the government over alleged wrongdoing would have to set aside one percent of annual profits for each of its drugs that exceeds \$1 billion in annual sales and can be traced to federally funded research. Those funds would be allocated to NIH and FDA in amounts proportional to the funds appropriated to the agencies for the given fiscal year.
- The bill would require that the payments be used to supplement existing NIH and FDA funding in the following categories:
 - Radically innovative research to develop treatments for unmet and under-met medical needs, evaluate new approaches to disease treatment, or to identify new biomarkers.
 - Fundamental research to advance the understanding of cellular processes, protein science, immunology, genetics or neurology to lay the foundation for the next generation of drugs.
 - Money-saving research that focuses on diseases that disproportionately impact government spending through programs such as Medicare, Medicaid, and the Affordable Care Act.
 - Supporting the next generation of scientists through research grants for young, independent investigators and universities with innovative training programs.
- The bill also directs HHS to submit annual reports to Congress that would include a description of supplemental payments assessed, collected, and distributed, and a list of the covered manufacturers that were assessed supplemental payments and the amount of such assessments. The bill would direct NIH and the FDA to report on the use and impact of the supplemental payments in their annual budget submission.
- Sen. Elizabeth Warren (D-MA), along with Sens. Ben Cardin (D-MD), Tammy Baldwin (D-WI), and Sherrod Brown (D-OH), introduced the S.320 on 1/29/2015. Rep. Chris Van Hollen (D-MD), joined by Reps. Jan Schakowsky (D-IL), Peter Welch (D-VT), and Kathy Castor (D-FL), introduced H.R. 744 on 2/4/2015. S. 320 was referred to the HELP Committee, and H.R. 744 was referred to the Energy and Commerce Committee.

Protecting Children from Electronic Cigarette Advertising Act of 2015 (H.R.478/S.430; 114th Congress)

- The bill would direct the Federal Trade Commission to use existing authorities to prohibit unfair and deceptive marketing practices of e-cigarettes to children under 18 years of age (while protecting the FDA's authority to regulate tobacco products, including e-cigarettes).
- The bill would cover States where the sale of an electronic cigarette to a child under 18 years of age is prohibited by a provision of Federal or State Law. It also would require a civil penalty to be imposed by an amount not greater than \$16,000, depending on the number of days that the violator of the rule was not in compliance.
- Rep. Elizabeth Esty (D-CT) introduced H.R. 478 on 1/22/2015. The bill was referred to the Committee on Energy and Commerce. Sen. Barbara Boxer (D-CA) introduced S. 430 on 2/10/15 and the bill was referred to the HELP Committee.

Child Nicotine Poisoning Prevention Act of 2015 (S. 142; 114th Congress)

- The bill would require the Consumer Product Safety Commission to require child safety packaging for liquid nicotine containers, to be implemented within a year after the enactment of the Act.
- Senator Bill Nelson (D-FL) introduced S. 142 on 1/8/2015. The bill was referred to the Committee on Commerce, Science, and Transportation. The Committee passed the bill by a voice vote on 2/26/15. The Committee passed the same proposal from Sen. Nelson in the 113th Congress, but it did not reach the Senate floor for a vote.

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 not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Supporting Quality of Life for Prostate Cancer Patients (H. Res.106; 114th Congress)

- The resolution expresses support for protecting Medicare or Veterans' Administration benefits for medical device treatments for male incontinence and impotence that result from treatment for prostate cancer and other diseases.
- H. Res. 106 was introduced by Rep. Erik Paulsen (R-MN) on 2/11/2015 and was referred to the Committees on Veterans' Affairs; Ways and Means; and Energy and Commerce.

Designation of September 25, 2015 as National Pediatric Bone Cancer Awareness Day (H.Res. 102; 114th Congress)

- The resolution expresses support for designating September 25, 2015 as National Pediatric Bone Cancer Day.
- H. Res. 102 was introduced by Rep. Blake Farenthold (R-TX) on 2/10/2015 and referred to the Committee on Energy and Commerce.

National Cancer Prevention Day (H. Res. 86; 114th Congress)

- A resolution expressing support for designating February 4, 2015 as National Cancer Prevention Day.
- H. Res. 86 was introduced by Rep. Steve Israel (D-NY) on 2/4/2015 and was referred to the Committee on Energy and Commerce.

Importance of Transformative Breakthroughs in Biomedicine (H.Res. 95; 114th Congress)

- A resolution "Recognizing the importance of transformative breakthroughs in biomedicine, biotechnology, and life sciences in the diagnosis, management, curing, and treatment of illness and the existence of a 'Valley of Death' in biotechnology and life sciences funding that stifles innovation and impedes translational medical research."
- H.Res. 95 was introduced by Rep. Juan Vargas (D-CA) introduced on 2/5/2015, and was referred to the Energy and Commerce Committee. The resolution does not address NIH directly, but does include language recognizing a "need for bipartisan reform" of the FDA.

