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

**Content current as of October 27, 2016*

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

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I. Budget and Appropriations

Current Status

On September 28, 2016, Congress passed a continuing resolution to fund the government at FY16 levels through December 9th. Funding the government for Fiscal Year 2017, whether in a single omnibus spending bill or in a series of smaller funding packages (“mini-buses”), will be the top priority when Congress returns on November 14th.

FY 2017 Labor-HHS Appropriations Bills

The Senate Appropriations Labor-HHS Subcommittee considered its FY2017 Labor-HHS Appropriations Act on June 7, including a \$2 billion increase for NIH for the second year in a row, and voted unanimously to advance the bill. The full Senate Appropriations Committee passed the bill out of committee with a vote of 29-1 (Sen. James Lankford, R-OK, was the only vote against the bill, citing concerns that the bill did not attempt to address recent Department of Labor overtime policies).

The House Labor-HHS Appropriations Subcommittee passed its bill by voice vote (non-recorded vote) out of the Subcommittee on July 6, and the full Committee advanced the bill on July 14. The House proposal includes a \$1.25 billion increase for NIH, and Chairman Tom Cole emphasized his interest in seeing that increase grow, stating, “I understand my friends in the other body have provided a \$2 billion increase for the NIH again this year. I want to be clear that I view the mark we set forth today as a floor, and not as a ceiling, for biomedical research funding, and I am hopeful that this number can increase as the process moves forward.”

Both the House and Senate bills propose a number of targeted increases for specific NIH initiatives, as well as an across-the-board increase for all NIH Institutes and Centers. However, neither bill provides specific funding for the Cancer Moonshot. This is not surprising based on both the specifics of the President’s budget request and the lukewarm reaction that the Appropriators have had to the proposal itself. It is important to note that the President’s budget proposal did not request additional funding for the Cancer Moonshot from the Appropriations Committees. To the contrary, the budget requested a \$1 billion decrease in the NIH appropriation, while simultaneously requesting an even larger increase in mandatory funding, of which \$680 million was specified for the Cancer Moonshot.

The appropriations committees manage the distribution of discretionary funds; they do not create new mandatory funding streams or disperse mandatory funds. Mandatory spending such as Medicare and Social Security are controlled by legislative committees (authorizers) and must be authorized by law.

Highlights from the Senate Proposal

The Senate bill proposes a \$2 billion increase for NIH over FY2016, from \$32.084 billion to \$34.084 billion. This includes a proposed increase to NCI of \$216 million over FY2016.

The Senate FY2017 Labor-HHS bill would provide the following for specific NIH initiatives:

- A \$400 million increase for Alzheimer's disease research (for a total of \$1.39 B)
- A \$100 million increase for the Precision Medicine Initiative Cohort (for a total of \$230 for the PMI cohort); funding for PMI Oncology is kept flat, at \$70 million, as proposed in the President’s request
- A \$100 million increase for the BRAIN initiative (for a total of \$250 million)
- A \$50 increase to Combat Antibiotic Resistant Bacteria (for a total of \$463 million)

- A \$12.5 million increase for NIH's IDeA (Institutional Development Award) program (for a total of \$333.4 million)
- \$12.6 million for the Gabriella Miller Kids First Research Program within the NIH Common Fund (this is the same funding level as FY2016, as authorized in the Gabriella Miller Kids First Research Act)

Highlights from the House Proposal

The House bill proposes a \$1.25 billion increase for NIH over FY2016, from \$32.084 billion to \$33.3 billion. This includes a proposed increase to NCI of \$124 million over FY2015.

The House FY2017 Labor-HHS bill would provide the following for specific NIH initiatives:

- A \$350 million increase for Alzheimer's disease research (for a total of \$1.26 B)
- The requested \$100 million increase for the Precision Medicine Initiative Cohort (for a total of \$230 for the PMI cohort); funding for PMI Oncology is kept flat, at \$70 million, as proposed in the President's request
- A \$45 million increase for the BRAIN initiative (for a total of \$195 million)
- A \$12.4 million increase for NIH's IDeA (Institutional Development Award) program (for a total of \$333.3 million)
- \$12.6 million for the Gabriella Miller Kids First Research Program within the NIH Common Fund (this is the same funding level as FY2016, as authorized in the Gabriella Miller Kids First Research Act)

Review of FY2017 President's Budget and Appropriations Activity to Date

The [President's FY2017 Budget Request](#), released in February 2016, proposed an overall funding level for NIH of \$33.1 billion, in a mix of discretionary and mandatory funds. Of note, that calculation included a \$1 billion discretionary cut to NIH's base, balanced by an equivalent increase in mandatory funds. In addition, the budget included \$680 million for the Cancer Moonshot supported through mandatory funding streams, which would require authorizing legislation (and offsets for the costs). As noted above, this is a process that falls outside of the jurisdiction of the Appropriations Committees.

Appropriators, who spearheaded the \$2 billion increase that NIH received for FY16, immediately voiced opposition to any cuts to discretionary funding for NIH, and many members of Congress expressed misgivings about a plan to increase mandatory spending. At the House Labor-HHS Subcommittee hearing on the NIH budget held on March 16, Chairman Rep. Tom Cole (R-OK) emphasized his position on the proposal in his opening remarks at the NIH hearing, noting, "I'm proud that last year this Congress was able to increase NIH funding by two billion dollars. And I'm confident that through these efforts, one day we'll find cures for diseases like cancer and Alzheimer's. I was therefore especially disappointed to see the proposed budget cut to the National Institute of Health this year by the administration. A proposal to divert one billion dollars of biomedical research funds to the mandatory side of the budget ledger and rely on new and possibly unlikely authorizations to continue the advances that we've made in increasing the research funding is disheartening. Frankly, I do not plan to let the one billion dollar cut stand." Similarly, House Appropriations Chairman Hal Rogers (R-KY) stated, "We don't like mandatory spending. It's grown completely out of control...when I came to Congress, we appropriated two-thirds of federal spending. Now it's one-third. Entitlements were one-third and now they're two-thirds and growing. Unless we deal with it, we can't even pay the interest on the debt with discretionary funds. So that's why we are so dead set against mandatory."

Rep. Nita Lowey (D-NY), ranking Member of the full House Committee commented "[W]hile

representing a net increase of \$825 million, your budget will result in a one billion dollar cut in discretionary funding for NIH. And I assure you, that this Chair and Ranking Member and the big Chair and I will just not let that happen.” She also voiced skepticism about the likelihood of success of the Administration’s request, commenting, “if you can get it [mandatory funding], good luck to you on that one.”

Comments at the Senate Labor-HHS hearing for NIH echoed these concerns, as did language the Senate Committee included in the report that accompanied the Labor-HHS bill. The introduction to the NIH section of the report reads as follows:

“The Committee rejects the administration’s budget request to reduce discretionary funding for medical research at the NIH by \$1,000,000,000. A continued commitment to NIH is essential to address our Nation’s growing health concerns, spur medical innovation, sustain America’s competitiveness, and reduce healthcare costs. After last year’s historic increase of \$2,000,000,000, the largest increase for the NIH in this bill in over a decade, the administration chose to take a step backwards by reducing discretionary funding for NIH. Instead of accepting this misguided budget request, the Committee increases funding by \$2,000,000,000 above fiscal year 2016.”

The House report addresses the Cancer Moonshot more directly:

“The Committee strongly supports the goals of the Cancer Moonshot initiative, to find cures for cancer and to reduce cancer mortality in the United States. While death rates have declined for all cancers combined, the disease continues to have a devastating impact on too many families. In fiscal year 2016, NIH expected to spend \$5,700,000,000 on cancer research. The Committee continues the \$195,000,000 used in fiscal year 2016 for this initiative. The Committee looks forward to the Cancer Moonshot spending details once the taskforce completes its work at the end of the calendar year.”

While bipartisan support for NIH and for cancer research remains strong, Appropriators clearly disagreed with the administration’s approach to the FY2017 budget proposal for NIH.

Additionally, during the full House Appropriations Committee markup of the Labor-HHS bill, Rep. Rosa DeLauro (D-CT, Ranking Member of the House Labor-HHS Subcommittee) offered an amendment that proposed providing a \$2 billion increase to NIH (as the Senate bill proposes), and that this increase include full funding of the Cancer Moonshot at the Administration’s proposed level. Rep. DeLauro, a 30-year ovarian cancer survivor, and Rep. Debbie Wasserman Schultz (D-FL), a breast cancer survivor, spoke passionately about the importance of cancer research and the opportunity of the Cancer Moonshot. Other members voiced their support for cancer research, including Chairman Cole. While he did not support the amendment, which failed along party lines, he indicated that additional cancer research funding is something he expects to continue to discuss as Congress finalizes funding plans for FY2017 and once additional details are available about specific Cancer Moonshot efforts.

II. Special Topics

Update: Senate HELP *Innovation for Healthier Americans* and House 21st Century Cures

Although both House Speaker Paul Ryan and Senate Majority Leader Mitch McConnell have indicated that passing the 21st Century Cures Bill (with mandatory funding for NIH) is a top priority in the lame duck session, it appears that prospects for its passage are increasingly uncertain. Over the past several weeks it has been reported that negotiations on mandatory funding and proposed offsets were gaining

momentum, and that both parties see passage of the bill as a priority in the lame duck session. However, just last week it was reported that liberal groups including the Center for American Progress sent a letter to Democratic leaders urging them to delay consideration of the Cures bill until the next Congress to enable the legislation to be developed as a vehicle to address prescription drug costs. It is unclear to what extent this may erode Democratic support for advancing the bill in the lame duck.

III. Congressional Hearings, Briefings, and Visits

Dr. Lowy visited Eastern Kentucky with Dr. Nora Volkow and Rep. Hal Rogers (October 6): Dr. Lowy joined Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA), and Rep. Hal Rogers, Chair of the House Appropriations Committee, in learning about Kentucky's research and healthcare landscape on October 6. In addition to visits to Primary Care Centers of Eastern Kentucky and the Appalachian Regional Healthcare (ARH) Cancer Center, Drs. Lowy and Volkow participated in a luncheon with local health care leaders, a roundtable on substance abuse in Kentucky, a discussion of the Center of Excellence in Rural Health (CERH) at the University of Kentucky, and the SOAR and MIT Hack-a-Thon.

Dr. Doug Lowy spoke at the One Voice Against Cancer (OVAC) Briefing (September 27): Dr. Lowy spoke at a briefing on September 27 organized by One Voice Against Cancer focused on the National Cancer Moonshot Blue Ribbon Panel (BRP) Report. Dr. Lowy was joined by fellow panelists Dr. Clifford Hudis, CEO, American Society of Clinical Oncology; Dr. Deborah Mayer, UNC Lineberger Director of Cancer Survivorship; Danielle Leach, Director of Government Relations and Advocacy, St. Baldrick's Foundation; and Ellen Sigal, Chairperson and Founder of Friends of Cancer Research. Dr. Lowy also delivered remarks, in which he shared the "4 P's" of the BRP report: patients, pediatrics, prevention, and promotion.

Rep. Mark DeSaulnier (D-CA) Visit to NIH (September 26): Representative DeSaulnier, who was successfully treated for chronic lymphocytic leukemia (CLL) in 2015 at the Georgetown Lombardi Comprehensive Cancer Center, visited the NIH Main Campus on September 21, where he met with Dr. Lawrence Tabek, Principal Deputy Director of NIH; Dr. John Gallin, Director, Clinical Research Center; Dr. Bill Dahut, Clinical Director for NCI's Center for Cancer Research; Dr. Baris Turkey and colleagues in NCI's Molecular Imaging Program in the CCR; and Dr. Adrian Wiestner and colleagues in the Hematology Branch of NHLBI. The visit focused on providing a general overview of NIH and its mission, as well as discussion of advances in cancer imaging and CLL research.

Dr. Doug Lowy spoke at the Congressional Childhood Cancer Caucus Summit (September 23): Dr. Lowy spoke at this summit, widely attended by childhood cancer advocates and organized by the Congressional Childhood Cancer Caucus, on September 23. Dr. Lowy provided an overview of NCI pediatric oncology initiatives, including the Pediatric Oncology Branch (POB), the Pediatric Provocative Questions Initiative, the NCI Experimental Therapeutics Program (NExT), Pediatric MATCH, and the Cancer Moonshot. Caucus co-chairs, Rep. Michael McCaul (R-TX) and Rep. Chris Van Hollen (D-MD), provided welcoming remarks, and Rep. Jackie Speier (D-CA) shared remarks on survivorship. Dr. Greg Simon, Director of the Cancer Moonshot Task Force; Dr. Gregory Aune, a childhood cancer survivor, pediatric oncologist at UT Medicine Health Science Center San Antonio, and member of the National Council of Research Advocates (NCRA); pediatric cancer patients Luke Gidden and Sydney Jankowski; and patient parent Amy Jensen Cunniffe also participated in the event.

Dr. Lou Staudt spoke at Congressional Biomedical Research Caucus Briefing (September 21): Dr. Lou Staudt, Director, NCI Center for Cancer Genomics, spoke at a briefing on September 21 organized by the Coalition for Life Sciences and the Congressional Biomedical Research Caucus as part of the monthly

CBRC Briefing Series. Dr. Staudt 's talk focused on cancer genomics and his own lymphoma research. Rep. Steve Cohen (D-TN), a chair of the Caucus, attended the briefing and introduced Dr. Staudt.

Dr. Malcolm Smith spoke at ACS/Alliance for Childhood Cancer Briefing (September 8): Dr. Malcolm Smith, Associate Branch Chief for Pediatric Oncology in NCI's Division of Cancer Treatment and Diagnosis, spoke at a congressional briefing on September 8 organized by the Alliance for Childhood Cancer and the American Cancer Society Cancer Action Network. The briefing focused on opportunities and challenges in childhood cancer research and drug development and coincided with the release of the ACS/Alliance *Childhood Cancer Research Landscape Report*. Other speakers included: Katherine Sharpe, American Cancer Society Senior VP for Patient and Caregiver Support; Carlos Sandi, Father of childhood cancer survivor and St. Baldrick's Foundation Ambassador Phineas Sandi; Dr. Tahira Khan, Genentech; Dr. Susan Blaney, Texas Children's Hospital and the Children's Oncology Group; and Dr. Martha Donoghue, Office of Hematology Oncology Products, Food and Drug Administration.

Congressional Staff Visit to NCI at Frederick (August 23): House Labor-HHS Appropriations Subcommittee staff John Bartrum, and Health Legislative Assistant to Chairman Tom Cole (R-OK), Steve Waskiewicz, visited the NCI at Frederick. The visit included a focus on the Precision Medicine Initiative for Oncology, and they toured labs within the Patient Derived Models program with Dr. Melinda Hollingshead; as well as the Molecular Characterization Lab with Dr. Anand Datta. They met with Dr. Doug Lowy, NCI Acting Director; Dr. Jeff Abrams, Acting Director for Clinical Research at NCI; and Dr. Jerry Collins, Associate Director of NCI's Developmental Therapeutics Program; as well as Dr. Craig Reynolds, Associate Director of the NCI at Frederick, and Dr. Dave Heimbrook, Laboratory Director, Frederick National Laboratory for Cancer Research.

Dr. Jennifer Couch spoke at Briefing on Next Generation Biotechnology (June 30): Dr. Jennifer Couch, Chief of the Structural Biology and Molecular Applications Branch in NCI's Division of cancer Biology, spoke on a panel at a congressional briefing on June 30 organized by the American Chemical Society. The briefing focused on new opportunities and tools in the field of biotechnology. Other panelists included: Megan Palmer, Center for International Security and Cooperation, Stanford University; Reshma Shetty, Co-founder, Ginkgo Bioworks, Inc., and Dan Voytas, Center for Genome Engineering, University of Minnesota and also Chief Science Officer, Calyxt, Inc.

Dr. Doug Lowy spoke at Briefing on Cancer Research Opportunities (June 28): Dr. Doug Lowy, Acting Director, NCI, spoke at a briefing organized by the American Association for Cancer Research focusing on opportunities in cancer research, including the Cancer Moonshot and activities of the Moonshot's Blue Ribbon Panel. The standing room only briefing was held in the Dirksen Senate Office Building, and AACR President Dr. Nancy E. Davidson moderated the event. AACR President Dr. Marge Foti also spoke, and the briefing included a panel discussion with early career investigators: Dr. Kara A. Bernstein, University of Pittsburgh; Dr. Major K. Lee, IV, University of Pennsylvania and the Veteran's Administration Medical Center; Dr. Christine M. Lovly, Vanderbilt University; Dr. Paul A. Northcott, St. Jude Children's Research Hospital; and Dr. Jose G. Trevino, II, University of Florida.

Congressional Staff Visit to NCI (May 31): Staff to Congressmen Michael McCaul (R-TX) and Chris Van Hollen (D-MD), cochairs of the Congressional Childhood Cancer Caucus, visited NCI to meet with investigators in the Pediatric Oncology Branch in NCI's Center for Cancer Research (CCR), as well as extramural program leaders for NCI-supported pediatric oncology research, including childhood cancer survivorship research. Staff to Reps. Jackie Speier (D-CA) and Rodney Davis (R-IL), Sens. Jack reed (D-RI), Shelley Moore Capito (R-WV), and Brian Schatz (D-HI), also attended, as well as Majority staff for the House Energy and Commerce Committee, Subcommittee on Health.

Congressional Staff Visit to NCI (May 6): Staff to Rep. Steve Cohen (D-TN) visited NCI to meet with leadership of the Office of Cancer Nanotechnology Research, tour the radiation Oncology Branch in NCI's Center for Cancer Research (CCR), and visit with investigators at a cryo electron microscopy (cryo-EM) facility within CCR's High Resolution Electron Microscopy program.

Congressional Visit to NIH (April 12): Reps. Bob Dold (R-IL), Katherine Clark (D-MA), David Valadao (R-CA), Joe Kennedy (D-MA), and Susan Brooks (R-IN) visited NIH on April 12. They met with NIH Director Dr. Francis Collins and other NIH Institute and Center (IC) Directors, and toured Dr. Christian Hinrichs' lab in the NCI Center for Cancer Research's (CCR) Experimental Transplantation and Immunology Branch. They also met with one of Dr. Hinrichs' patients. Dr. Bill Dahut, CCR Clinical Director, welcomed the group and joined them for the NCI portion of their visit. The members of Congress also toured facilities of other NIH ICs.

IV. Legislation of Interest

The following bills and resolutions, introduced since the last CTAC meeting in July, 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: <http://cancer.gov/about-nci/legislative/current-congress>

Recent Legislative Activity and Public Laws

DoD Medical Research Provisions in FY 2017 National Defense Authorization Act (NDAA, S. 2943)

- The FY2017 NDAA authorizes appropriations and provides policy directives for the Department of Defense (DoD), military construction, and defense activities carried out by the Department of Energy. The bill was introduced by Chairman of the Senate Armed Services Committee, Sen. John McCain (R-AZ).
- Sen. McCain included provisions within the FY 2017 bill that aimed to restrict the scope of research supported through Department of Defense medical research programs, including cancer research efforts within the Congressionally Directed Medical Research Program (CDMRP). The provisions would have directed DoD to limit medical research efforts to those that aim to provide direct benefit to members of the Armed Services, and not veterans and military families; and would have imposed additional review and audit requirements for each award, contract, or cooperative agreement supported by the CDMRP.
- Senators Richard Durbin (D-IL) and Lisa Murkowski (R-AK) offered an amendment to the bill on June 7 to strike these provisions. The Senate voted 66-32 in favor of the Durbin/Murkowski amendment, removing these provisions from the NDAA bill.

Cancer Clusters Provisions - Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576; P.L. 114-182)

- H.R. 2576 aims to update and reauthorize the Toxic Substances Control Act of 1976. Provisions within the bill direct the Department of Health and Human Services to develop criteria for designating potential "cancer clusters," develop guidelines for investigating such clusters, and investigate such clusters.
- Currently, the Centers for Disease Control and Prevention, in partnership with the Council of State and Territorial Epidemiologists, provides guidelines for investigating suspected cancer clusters. Local or state health departments, along with cancer registries, currently respond to cancer cluster

questions and have the most current local data. If needed, states request technical advice from CDC, its Agency for Toxic Substances and Disease Registry, and the Environmental Protection Agency.

- The House passed the bill in June 2015, and the Senate passed the bill in December 2015. The House approved an amended bill in May 2016, and worked to resolve differences with the Senate in early June. The Senate passed an amended version of the bill on 6/7/2016. **The President signed the bill into law on 6/22/2016 (P.L. 114-182).**

Breast Cancer Commemorative Coin Act (H.R. 2722/S.2185; P.L. 114-148)

- 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.
- Rep. Carolyn Maloney (D-NY) introduced H.R. 2722 on 6/10/2015. The bill was referred to the Committees on Financial Services; and the Budget. S.2722 was introduced by Sen. Heidi Heitkamp (D-ND) and referred to the Committee on Banking, Housing, and Urban Affairs on 10/20/15.
- The House passed H.R. 2722 on 7/15/2015 after it was amended 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. The Senate passed the bill on 4/19/2016. **The President signed the bill into law on 4/29/2016 (P.L. 114-148).**

Selected New Bills in the 114th Congress

The Research to Accelerate Cures and Equity (RACE) for Children Act (S. 3239/H.R. 5858)

- This bill would amend the Federal Food, Drug, and Cosmetics Act to establish a program to provide additional incentives for the development of new drugs to treat pediatric cancers.
- More specifically, this bill would modify the Pediatric Research Equity Act (PREA) to allow children with cancer to have access to clinical trials of cancer drugs or biologics that have potential therapeutic benefits for pediatric cancer patients based on molecular targets rather than type of cancer by organ.
- In addition, this bill would remove the orphan waiver under PREA for drugs directed at a specific molecular target present in pediatric cancer populations.
- The bill would also require the submission of a report to Congress on the implementation of the amendments resulting from this bill by July 12, 2021, if enacted.
- S. 3239 was introduced on 7/14/2016 by Sens. Michael Bennet (D-CO) and Marco Rubio (R-FL) and was referred to the HELP Committee. H.R. 5858 was introduced by Reps. Michael McCaul (R-TX), G.K. Butterfield (D-NC), Sean Duffy (R-WI), and Chris Van Hollen (D-MD) on 7/14/2016 and was referred to the Energy and Commerce Committee.

Women and Lung Cancer Research Preventive Services Act of 2016 (H.R. 5263/S. 2941)

- The bill would require the Secretary of HHS, along with the Secretary of Defense and the Secretary of Veterans Affairs, to conduct an interagency study to evaluate the status of and make recommendations for increased research on women and lung cancer, access to lung cancer preventive services, and strategic public awareness and education campaigns on lung cancer.
- The bill also calls for a report to Congress, including a review of current and previous research related to women and lung cancer across the Federal Government, recommendations for a

collaborative research program, and recommendations for the development of a national public education and awareness campaign.

- H.R. 5263 was introduced by Rep. Richard Nolan (D-MN) on 5/17/2016 and was referred to the Energy and Commerce Committee. S. 2941 was introduced by Sen. Kelly Ayotte (R-NH) on 5/17/2016 and was referred to the HELP Committee.

Breast Cancer Patient Protection Act of 2016 (H.R. 5195)

- This bill would require health plans to provide coverage for a minimum hospital stay for mastectomies, lumpectomies, and lymph node dissection for the treatment of breast cancer, as well as coverage for secondary consultations.
- H.R. 5195 was introduced by Rep. Rosa DeLauro (D-CT) on 5/11/2016 and was referred to the Energy and Commerce, Ways and Means, and Education and the Workforce Committees.

Reports Reduction Act of 2016 (S. 2875)

- This bill would remove the requirements for each of the following reports currently required to be submitted by the NIH: Annual Report on Pediatric Research Initiative, Biennial Report on Organ Donation, Biennial Report on Organ Transplantation, Report on Breast and Cervical Cancer Program, Report of Trans-NIH Research, Annual Report on Living Organ Donation, and Report on Centers of Excellence.
- S. 2875 was introduced by Sen. Mark Warner (D-VA) on 4/28/2016 and was referred to the Committee on Homeland Security and Governmental Affairs.

Promoting Inclusion of Minorities in Clinical Research (S. 2745)

- This bill will require the NIH Director to develop, submit, and post on the website an NIH Strategic Plan to provide direction on biomedical research investments and facilitate coordination between ICs. ICs will also be required to prepare regular strategic plans, but specific requirements are not provided.
- The NIH Director would be required to collect, and make available on its website, data from each IC on study populations which specify the inclusion of women, minority groups, relevant age categories, as well as other demographic variables. In addition, the NIH director is directed to foster collaboration between ICs to allow for increased subjects to be studied and the utilization of diverse study populations. This bill also directs the NIH Director to encourage efforts to improve research related to the health of sexual and gender minority populations.
- The bill redesignates “interagency coordination” as “Intra-NIH Coordination” to facilitate partnerships between ICs to achieve the goals of the NIH that are related to minority health and health disparities.
- The NIH Director would be required to convene a working group, within one year of the date of enactment, to develop and issue recommendations for a formal policy to enhance rigor and reproducibility of scientific research funded by NIH, and would require a report to Congress regarding implementation of the recommendations.
- Among other provisions, the bill also directs the NIH Director to develop policies for projects of basic research to assess relevant biological variables includes sex and how differences between male and female cells, tissues, or animals may be examined and analyzed.
- This bill was introduced by Sen. Susan Collins (R-ME) on 4/5/2016 and was referred to the HELP Committee. S. 2745 was reported out of committee on 4/18/2016.

Genetic Research Privacy Protection Act (S. 2744)

- This bill will require the Secretary to issue a Certificate of Confidentiality to researchers who apply for federal funding (regardless of whether the research receives funding) to conduct research in which identifiable, sensitive information is collected.
- Researchers that receive a Certificate of Confidentiality will be required to protect the privacy of those individuals who participate in their research.
- Exceptions to the disclosure of this information include instances when it may be necessary for medical treatment of the individual to whom the information pertains, when an individual provides consent to disclose of the information about himself or herself, and for use in other scientific research that is compliant with Federal human subjects protection regulations.
- This bill does not limit the access of research participants to information collected about them during their research participation. The bill also exempts from disclosure under FOIA biomedical information about an individual that is gathered or used during research.
- This bill was introduced by Sens. Elizabeth Warren (D-MA) and Mike Enzi (R-WY) on 4/5/2016 and was referred to the HELP Committee. The bill was included as an amendment to S. 2713, the Advancing Precision Medicine Act, on 4/6/2016.

Promoting Biomedical Research and Public Health for Patients Act (S. 2742)

- This bill directs NIH to prepare a triennial rather than a biennial report and includes provisions that would roll Trans-NIH Research Reporting into the Triennial report. The report must include a description of intra-NIH activities, including the percentage of funds made available by each IC for collaborative research and recommendations for promoting coordination of information among ICs. In addition, the bill specifies that relevant age categories must be included as part of the demographic variables for study participants.
- This bill requires the Secretary to review and revise policies related to the disclosure of financial conflicts of interest to harmonize and reduce the administrative burden on researchers. In addition, the NIH Director will be required to implement measures to reduce the administrative burdens related to monitoring subrecipients of grants by primary awardees; and to review and revise applicable policies for the care and use of laboratory animals to reduce administrative burden on investigators.
- The bill requires the OMB Director to establish a Research Advisory Board to provide information on the effects of regulations related to Federal Research requirements and make recommendations to harmonize these regulations across research agencies.
- This bill would allow NIH contractors to collect and retain payments from the sale of research substances, and to forward those payments to the Secretary by crediting the appropriations accounts that incurred the costs to make available the research products involved.
- This bill would allow the NIH Director to provide the option of clinical trial information for an applicable device clinical trial to be publicly posted prior to the date of clearance or approval.
- The NIH Director, in collaboration with the FDA Commissioner, would be required to submit reports regarding compliance under the Expanded Clinical Trial Registry Data Bank.
- The bill also recognizes that the NCI Director is appointed by the President and establishes 5-year terms for all other IC Directors, which are appointed by the HHS Secretary, through the NIH Director. For these IC Directors, there would be no limit to the number of terms they can serve.
- This bill was introduced by Sen. Lamar Alexander (R-TN) on 4/4/2016 and was referred to the HELP Committee. S. 2742 was reported out of committee on 4/18/2016.

Advancing Precision Medicine Act of 2016 (S. 2713)

- This bill encourages the Secretary to establish and carry out the Precision Medicine Initiative to augment efforts to address disease prevention, diagnosis, and treatment.
- In addition, the bill authorizes the Secretary to coordinate with the Secretary of Energy, private industry, and others; to develop and utilize public-private partnerships; and to leverage existing data sources.
- The Secretary would also be required to ensure the collaboration of the NIH, the FDA, and the Office of the National Coordinator for Health Information Technology; to comply with existing human subjects protection laws and regulations; to implement policies for appropriate secure data sharing; and to ensure diversity of participants.
- This bill allows the Secretary to exempt from disclosure under FOIA biomedical information about an individual that is gathered or used during biomedical research if it could be used to identify the individual.
- This bill authorizes the NIH Director to require recipients of NIH grants or cooperative agreements to share scientific data generated from the awards in a manner that is consistent with all applicable laws and regulations.
- In addition, this bill would allow the NIH Director to approve requests from ICs to use Other Transactions Authority to conduct or support high-impact, cutting-edge research. For each year the authority is used, ICs would be required to submit a report regarding the research activities supported by Other Transactions Authority.
- S. 2713 was introduced by Sen. Lamar Alexander (R-TN) on 3/17/2016 and was referred to the HELP Committee. The bill was reported out of committee on 4/18/2016.

FDA and NIH Workforce Authorities Modernization Act (S. 2700)

- The goal of this bill is to update the authorizing provisions relating to the FDA and NIH workforces.
- For NIH, this bill expands the Senior Biomedical Research Service appointment authority by increasing the maximum number of appointments from 500 to 2,000 and raising the salary cap to \$400,000 (equal to the President's salary).
- The bill also exempts scientific meetings from conference reporting requirements and restrictions and exempts NIH research from the Paperwork Reduction Act.
- The bill was introduced on 3/17/2016 by Sens. Lamar Alexander (R-TN) and Patty Murray (D-WA) and was referred to the HELP Committee. S. 2700 was reported out of committee on 4/18/2016.

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.

Passed

Designating September 2016 as “National Prostate Cancer Awareness Month” (S. Res. 517)

- This resolution designates September 2016 as National Prostate Cancer Awareness Month and calls for steps to raise awareness about prostate cancer screening and treatment; to support research to improve screening and treatment; and to improve access and the quality of health care services for detecting and treating prostate cancer.
- The bill was introduced by Sen. Jeff Sessions (R-AL) on 6/29/2016 and was agreed to by Unanimous Consent.

Designation of May 2016 as National Cancer Research Month (S. Res. 459)

- A resolution supporting the designation May 2016 as “National Cancer Research Month”.
- The resolution recognizes the importance of cancer research and supports efforts to establish cancer research as a priority.
- S. Res. 459 was introduced by Sen. Dianne Feinstein (D-CA) on 5/9/2016, and the resolution was agreed to by Unanimous Consent on 5/25/2016.

Introduced

Designating September 2016 as “National Ovarian Cancer Awareness Month” (H. Res. 811)

- This resolution designates September 2016 as National Ovarian Cancer Awareness Month to increase public awareness for the disease.
- The bill was introduced by Rep. Rosa DeLauro (D-CT) on 7/7/2016 and was referred to the Committee on Oversight and Government Reform.

Designating September 2016 as “National Ovarian Cancer Awareness Month” (S. Res. 521)

- This resolution designates September 2016 as National Ovarian Cancer Awareness Month to increase public awareness for the disease.
- The bill was introduced by Sen. Kelly Ayotte (R-NH) on 7/7/2016 and was referred to the Judiciary Committee.

Designation of May 2016 as National Cancer Research Month (H. Res. 717)

- A resolution supporting the designation May 2016 as “National Cancer Research Month”.
- The resolution recognizes the importance of cancer research and supports efforts to establish cancer research as a priority.
- H. Res. 717 was introduced by Rep. Kevin Yoder (R-KS) on 4/29/2016 and was referred to the Energy and Commerce Committee.

Designation of June 2016 as National Men’s Cancer Awareness Month (H. Res. 705)

- The resolution expressed support for the designation of June 2016 as National Men’s Cancer Awareness Month.
- H. Res. 705 was introduced by Rep. Alcee Hastings (D-FL) on 4/26/2016 and was referred to the Committee on Energy and Commerce.