July 8, 2015*

Legislative Update

for the

NCI Clinical Trials and Translational Research Advisory Committee

**Content current as of June 30, 2015*

Activities of the 114th Congress-

First Session

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I. Appropriations

Where we Stand –

In June both the House and Senate Appropriations Committee passed their fiscal year (FY) 2016 Labor, HHS, Education, and Related Agencies (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. In 2014, the Senate appropriators introduced a bill, but it never made it to mark up. The remarkable progress made so far with the FY 2016 spending bills may be stymied because the LHHS bill is the largest and often considered the most contentious of all annual spending bills. Plus, 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. As of the end of June, the House has passed 6 out of the 12 spending bills while the Senate has passed none.

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 incudes 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 Appropriations 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), an $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, 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 M may be used for facilities repairs and improvements at NCI-Frederick.

Prior Activity: LHHS Subcommittee Allocations and Hearings –

The passage of the House and Senate LHHS bills out of Committee follows action in both chambers in April and May of 2015 to confirm each Subcommittee's allocation for FY 2016. Total allocations in both the House and Senate adhere to budget caps set by the 2011 Budget Control Act, which imposed budget reductions known as "sequestration" across federal agencies. A December 2013 budget agreement negotiated by Sen. Patty Murray (D-WA) and Rep. Paul Ryan (R-WI), eased those budget caps in FY 2014 and 2015, reducing the scale of sequestration cuts. A similar agreement is not in place for FY 2016.

Allocations for the full Appropriations Committees in the House and Senate - often referred to as 302(a) s –are the same and adhere to the caps at $1.01 trillion. Allocations for each Subcommittee, known as 302(b) s, vary slightly between the House and the Senate, and are generally less than the President's FY 2016 Budget Request, which proposed an additional $71 billion in federal funding above the caps. The Subcommittee allocations for LHHS are set at $153.05 billion in the House and $153.19 billion in the Senate, as compared to the President's Budget Request of $167.67 billion for agencies under the Subcommittee's jurisdiction. The President's Budget proposes a funding level of $31.3 billion for NIH (an increase of $1 billion over FY2015), and proposes a funding level of $5.098 for NCI (an increase of $145 million over FY2015).

Both the House and Senate LHHS Subcommittees held NIH hearings in recent months, as well as a House LHHS Public Witness Hearing. Dr. Collins, accompanied by a number of NIH Institute and Center (IC) Directors, testified before the House LHHS Subcommittee on 3/3/2015. His opening statement noted that cancer death rates have decreased by one percent per year for the last 20 years. He highlighted the President's proposed Precision Medicine Initiative and its initial focus on cancer, and also shared the story of a lung cancer survivor treated with targeted therapy to illustrate the possibilities of precision medicine.

Dr. Doug Lowy, NCI Acting Director, and other IC Directors joined Dr. Collins at the Senate L-HHS hearing on 4/30/2015. Dr. Collins featured the Precision Medicine Initiative in his opening remarks and shared the story of a pediatric cancer survivor. Dr. Lowy responded to a question from Subcommittee Chairman Senator Roy Blunt (R-MO) about the Precision Medicine Initiative and highlighted key elements of the its cancer research focus, commenting, "We really are at an inflection point where it comes to cancer treatment. As a result of the genomic revolution, we now understand in much more detail than ever before that cancer instead of being one disease, even breast cancer for example is many different diseases and the opportunity for targeted treatment that we hope will be better, smarter, and have fewer side effects really is at hand. We already have several clear examples of targeted F.D.A. approved drugs

that are able to do just that. With the new precision medicine initiative, we are able at a much larger scale to be able to conduct clinical trials that involve both adults and children that instead of being focused principally on the origin side where the cancer develops. Instead is focused on the abnormalities in the cancer and the targeted drugs treat those specific abnormalities."

Researchers and advocates were among those who testified at the House LHHS public witness hearing on 4/29/2015, including Ms. Danielle Leach, Director of Government Relations and Advocacy for the St. Baldrick's Foundation and Co-Chair of the Alliance for Childhood Cancer. Ms. Leach gave compelling and thoughtful testimony that included descriptions of her personal experience as a sibling to a childhood cancer survivor, and as a mother to a child with cancer, as she shared the story of her son Mason who died in 2007 from medulloblastoma.

II. Special Topics

Update: House Energy and Commerce *21st Century Cures* Markup and Senate HELP *Innovation for Healthier Americans* Precision Medicine Hearing

The House Energy and Commerce Committee unanimously passed H.R. 6, the 21st Century Cures Act, by a vote of 51-0 on 5/21/2015. The bipartisan vote came after a year of hearings and roundtable discussions focusing on opportunities to streamline the drug and medical device discovery, development, and delivery process, and also after various discussion drafts had been released for stakeholder comment. The full committee markup saw little activity beyond statements from Committee members – aside from the Manager's Amendment from Rep. Fred Upton (R-MI), all other amendments that had been offered were withdrawn, and the session was described by Rep. Bobby Rush (D-IL) as "a love fest."

There are a number of provisions in the proposal that would affect NIH and NCI, and those are described in more detail in the bill summary of H.R. 6 in the "Legislation of Interest" section of this update. These provisions include a reauthorization for NIH for FY 2016-2018 and the establishment of an NIH "Innovation Fund" with funding of $2 billion per year for five years which would not be subject to transfer authority or recurring expenses. The bill also calls for the NIH Director to develop a strategic plan for the Innovation 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 proposes a number of requirements specific to NIH ICs. In addition to the strategic plan provision, it would require each IC director to "review and approve" R-series awards, and would also require each IC director to establish "high-risk, high-reward" research and set aside a percentage of funding for these projects, with the percentage to be determined by the NIH Director.

Despite a very public push to get a vote in June, Rep. Upton announced on June 19th that the bill would not go to the floor for a vote until after the 4th of July recess due to continuing negotiations about the offsets to pay for the bill. The Energy and Commerce Committee filed a conference report on the bill in late June, however that document does not include the final offsets. Reports indicate that the Energy and Commerce Committee has reached an agreement with the House Appropriations Committee to make the proposed $10 billion for the five-year NIH Innovation fund, and proposed $550 million for the FDA both mandatory funding. Rep. Upton continues to call for a floor vote immediately after the July 4th recess, and he has indicated he intends to file a Manager's Amendment on Thursday, July 2, to include the final offsets and the revised bill language addressing mandatory funding for NIH and FDA.

In the meantime, the Senate HELP Committee continues with its parallel effort entitled "Innovation for Healthier Americans," and Chairman Lamar Alexander (R-TN) has indicated that he hopes to introduce

legislation in the Senate sometime early next year. He is working closely with Ranking Member Patty Murray (D-WA), and shortly after the House markup he reiterated that the Senate will be introducing a separate bill, and that his 2016 timeline remains unchanged by activities in the House. He has also indicated that the Senate bill will include a stronger focus on electronic health records, and that a bipartisan group of committee staff have been meeting with the HHS Office of the National Coordinator and NIH staff for regular discussions to inform their work on this topic.

Electronic health records were discussed at length during a hearing before the HELP Committee on 5/5/2015 focusing on Precision Medicine. Sens. Alexander and Murray, along with Sen. Bill Cassidy (R-LA) had a number of questions for the HHS National Coordinator for Health IT, who was joined by Dr. Jeffrey Shuren of the FDA, and NIH Director Dr. Francis Collins. In his opening statement, Dr. Collins also spoke about the initial cancer focus of the Precision Medicine Initiative.

III. Congressional Hearings, Briefings, and Visits

Rep. David McKinley (R-WV) Visits NIH: Rep. McKinley, accompanied by his wife Mary, who is a retired critical care nurse, and his legislative director, visited NIH on 5/21/2015. Rep. McKinley is Chair of the Hearing Health Caucus and is hearing impaired, and the majority of his visit focused on meeting with leadership and touring labs and clinics at the National Institute on Deafness and Other Communication Disorders. The Congressman was interested in learning more about NCI and the Office of Cancer Centers, and met with Dr. Bill Dahut, Clinical Director for the Center for Cancer Research, and Dr. Henry Ciolino, Acting Director of the Office of Cancer Centers.

Dr. Lowy Visits House L-HHS Appropriations Chairman Tom Cole: On 4/13/2015, Dr. Doug Lowy met with House Labor-HHS-Education Appropriations Subcommittee Chairman Tom Cole (R-OK) to discuss opportunities and challenges in cancer research. Chairman Cole stressed the need for "a better budget deal" in the future, alluding to the restrictive budget caps put in place by the Budget Control Act of 2011. He stressed the importance of visits to NIH, and noted the enthusiasm and positive responses of several members who visited NIH with him in early 2015. Chairman Cole encouraged NCI to take opportunities to speak to congressional audiences and to continue to host members of congress and their staff for visits to NCI, and indicated that funding for NCI and NIH is a bipartisan priority for the subcommittee.

House L-HHS Appropriations Subcommittee, NIH FY 2016 Budget Hearing: Dr. Collins, accompanied by a number of NIH IC Directors, testified before the House L-HHS Subcommittee on 3/3/2015. Dr. Collins highlighted the President's proposed Precision Medicine Initiative and its initial focus on cancer, and also shared the story of a lung cancer survivor treated with targeted therapy to illustrate the possibilities of precision medicine. He received questions from members of the Subcommittee focusing on liver cancer, pediatric low-grade astrocytoma, and precision medicine in the context of cancer treatment.

Senate L-HHS Appropriations Subcommittee, NIH FY 2016 Budget Hearing: Dr. Lowy and other NIH IC Directors joined Dr. Collins at the Senate L-HHS hearing on 4/30/2015. Dr. Collins featured the Precision Medicine Initiative in his opening remarks and shared the story of a pediatric cancer survivor and researcher. Dr. Lowy responded to a question from Subcommittee Chairman Senator Roy Blunt (R-MO) about the Precision Medicine Initiative and highlighted key elements of the its cancer research focus. Members of the subcommittee did not ask additional questions focused specifically on cancer research. (Dr. Lowy's statement for the record is included as Appendix 1 on page 13.)

Senate HELP Committee Hearing on Precision Medicine: Dr. Collins testified with colleagues from the FDA and the HHS ONC at a Senate HELP Committee Precision Medicine hearing on 5/5/2015. Dr. Collins' opening statement noted the cancer component of the proposed initiative, and focused on the future

promise of precision medicine, incorporating a hypothetical example of a lung cancer patient who benefitted from liquid biopsy, targeted therapy, and immunotherapy.

Briefing on Prostate and Breast Cancers: Dr. Bill Dahut, Clinical Director and Head of the Prostate Cancer Clinical Research Section in NCI's Center for Cancer Research spoke at a briefing on 4/16/2015 organized by the Men's Health Network. Dr. Dahut provided a prostate cancer research update, and was joined by patient advocates who shared their experiences. Speakers included a prostate cancer survivor, a breast cancer survivor and representatives of the Men's Health Network and Healthy Women.

IV. Legislation of Interest

The following bills and resolutions were selected for inclusion in this update due to anticipated interest among CTAC 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*

*Please see section *I. Appropriations*, starting on page 1, for a detailed summary of the House and Senate proposals for FY 2016 Appropriations for the Departments of Labor, Health and Human Services, and Related Agencies.

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.

Cancer Treatment Parity Act of 2015 (H.R. 2739/S. 1566)

- The bill would require group and individual health insurance coverage and group health plans to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for anticancer medications administered by a health care provider.

- For the Patient-administered medication, the provider can charge annual deductibles, coinsurance, copayments, as long as they do not exceed payments for anticancer medications administered by a health care provider under the plan or coverage for the same purpose. The provider cannot: increase out-of-pocket costs of anticancer medications; reclassify anticancer medications benefits; or apply more restrictive limitations on prescribed oral, intravenous, or injected anticancer medications.
- H.R. 2739 was introduced by Rep. Leonard Lance (R-NJ) and Brian Higgins (D-NY) on 6/11/2015. The bill was referred to the House Energy and Commerce Committee. S.1566 was introduced by Sens. Mark Kirk (R-IL) and Al Franken (D-MN) on 6/11/2015 and was referred to the Committee on Health, Education, Labor, and Pensions.

<u>National Prostate Cancer Plan Act (H.R. 2730/S. 222/S.216)</u>

- 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.
- S.222 and S.216 would authorize appropriations of $2 million for the five year period of 2016 through 2020.
- Rep. G.K. Butterfield (D-NC) introduced H.R. 2370 on 6/11/15 and the bill was referred to the Committee on Energy and Commerce. Sens. Barbara Boxer (D-CA) and Jim Sessions (R-AL) introduced S. 222 and S. 216, respectively, on 1/21/2015. The bills were 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.

<u>Breast Cancer Awareness Commemorative Coin Act (H.R. 2722)</u>

- 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, half of the surcharge would be paid to the Breast Cancer Research Foundation, and half to Susan G. Komen for the Cure, to further research funded by the organizations.

- H.R. 2722 was introduced on 6/10/15 by Rep. Carolyn Maloney (D-NY) and was referred to the Committees on Financial Services and Budget. Rep. Maloney introduced a similar proposal in the 113th Congress and the bill did not move out of Committee.

Breast Cancer Patient Education Act (S.1192/H.R.2540)

- The bill would amend the Public Health Service Act to direct the HHS to provide for the planning and implementation of an education campaign to inform breast cancer patients anticipating surgery about the availability and coverage of breast reconstruction, prostheses, and other options, with a focus on informing patients who are members of a racial and ethnic minority groups.
- The information would be disseminated through postings on the web sites of relevant federal agencies, including the Office of Women's Health, the Office of Minority Health, and the Office of Rural Health Policy.
- The Secretary is encouraged to consult with appropriate medical societies and patient advocates who represent underserved populations in developing the information.
- Sen. Roy Blunt (R-MO) introduced S. 1192 on 5/5/2015. The bill was referred to the Committee on Health, Education, Labor, and Pensions. Rep. Leonard Lance (R-NJ) introduced H.R. 2540 on 5/21/2015 and the bill was referred to the Committee on Energy and Commerce.

21st Century Cures (H.R. 6)

The bill aims to accelerate the discovery, development, and delivery of cures, treatments, and preventive measures. It includes a number of provisions directed at NIH and FDA, as well as certain provisions directed at other Department of Health and Human Services offices and operating divisions, including the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the Office of Human Research Protections. The bill also aims to increase funding for NIH and FDA and would require the FDA to issue guidance in the development of biomarkers, precision drugs, and biological products.

Specific provisions directed toward NIH include the following:

- Reauthorizes NIH at funding levels of $31.81 billion for FY 2016, $33.33 billion for FY 2017, and $34.85 billion in FY 2018. In addition, proposes the NIH Innovation Fund, which would provide $2 billion in funding for NIH for each of the FYs 2016-2020 would be provided. However, funds would not be available except to the extent and in such amounts as are provided in advance in appropriation Acts. The funds would be used to supplement, not supplant funds otherwise allocated to the NIH.
- Proposes the Accelerating Advancement Program (AAP), whereby the NIH Director would partner with the NIH Institutes and Centers (ICs) to accomplish important research objectives. ICs would be required to match funding received from the Innovation Fund, the amount to be determined by the NIH Director. A minimum of $500,000 would be allocated from the Innovation Fund for the AAP each fiscal year.
- Would require NIH to establish a 5-year biomedical research strategic plan with strategic focus areas, to be reviewed every five years and updated accordingly. The ICs would be required to develop individual plans and identify research opportunities based on the NIH plan. The IC plans would be required to have a common template and also identify strategic focus areas.
- Would establish 5-year renewable terms for IC Directors (an exception is noted for the presidential appointment of the NCI Director). Would also require each IC Director to review and approve R-series awards and would require an Institute of Medicine study regarding possible duplication in Federal biomedical research.

- Authorizes the NIH Director to require recipients of an award or other financial support, provided that the research is fully funded through such grant or other support, to share scientific data generated from research conducted through such support, for research purposes.
- The bill includes a number of other proposals that would affect NIH, including provisions addressing standardization of data reported in ClinicalTrials.gov, development of a data sharing system for clinical trials, revisions of HIPAA rules and other provisions addressing human subject regulations, implementation of measures to reduce administrative burdens of NIH funded researchers, authorization of a Capstone award, expansion of the NIH loan repayment program, expanded authorities for National Center for Advancing Translational Sciences, a provision to make the National Pediatric Research Networks permanent (first authorized in the PREEMIE Act of 2013), encouragement of global pediatric clinical trials and of minority inclusion in clinical trials, and a provision requiring NIH to develop guidelines regarding age as an inclusion variable in human subjects research.

As noted above, the bill proposes $10 billion in funding for NIH, as well as $550 million in funding for FDA. The bill also proposes a number of measures to off-set these costs. As currently proposed, funds would be obtained from the following sources, however final proposed offsets are still being negotiated:

- Drawing down the strategic petroleum reserve to generate $5.2 billion savings; adjusting the timing of Medicare pre-payments to Medicare Advantage Part D prescription drug sponsors so that the government would keep the interest revenue instead of the insurers, resulting in an anticipated saving of $5-7 billion; limiting the durable medical equipment reimbursement rates in Medicaid to those of Medicare for a saving of $2.8 billion; and limiting federal payments for x-ray imaging services by incentivizing the use of digital imaging instead of film for an anticipated savings of $200 million.

Committee Activity and Current Status: H.R. 6 was introduced by Rep. Fred Upton (R-MI) on 5/19/2015 and referred to the Committees on Energy and Commerce (E&C), and Ways and Means. The E&C Subcommittee held a markup on 5/14/15 and the bill was approved by voice vote. The full E&C Committee held a markup on 5/21/2015, and the bill, including a Manager's Amendment from Rep. Upton, was approved unanimously by a 51-0 vote. The bipartisan vote came after a year of hearings and roundtable discussions and also after various discussion drafts had been released for stakeholder comment. The full committee markup saw little activity beyond statements from Committee members – aside from the Manager's Amendment, all other amendments that had been offered were withdrawn. The Energy and Commerce Committee filed a conference report on the bill in late June, and Rep. Upton continues to call for a floor vote immediately after the July 4th recess. He has indicated he intends to file a Manager's Amendment on Thursday, July 2, which is expected to include revised bill language addressing proposed funding for NIH and FDA.

Additional information: Many sections of H.R. 6 have also been introduced in the House as stand-alone bills. More information is available on https://www.congress.gov/. To date individual proposals include: H.R. 2419 (reauthorize NIH funding for FY2016-2018), H.R. 2420 (reduce administrative burden), H.R. 2421 (IC Director terms, IC Director review of R-series awards, GAO report on duplication), H.R. 2436 (age groupings in clinical research), H.R. 2439 (Senior Biomedical Research Service), H.R. 2440 (loan repayment program), H.R. 2447 (NIH strategic plan), H.R. 2448 ("high-risk, high-reward" research), H.R.2456 (data sharing), H.R. 2548 (National Pediatric Research Network), H.R. 2468 (minority inclusion in clinical trials).

SCREEN Act of 2015 (S.1079/H.R. 2035)

- The bill would amend the Social Security Act to maintain calendar year 2015 Medicare reimbursement rates for colonoscopy procedures for providers participating in the colorectal cancer screening quality improvement registry.

- The bill would eliminate Medicare beneficiary cost-sharing for colorectal cancer screening tests, for the removal of tissue or other mater during the screening test, or for a follow-up procedure.
- The bill would also direct Center for Medicare and Medicaid Innovation to test a payment and service delivery model that is a demonstration project to evaluate the effectiveness of a pre-operative visit before screening colonoscopy and hepatitis C screening.
- Sen. Ben Cardin (D-MD) introduced S. 1079 on 4/23/2015. The bill was referred to the Committee on Finance. Rep. Richard Neal (D-MA) introduced H.R. 2035 on 4/27/2015. The bill was referred to the Committees on Energy and Commerce and on Ways and Means.

<u>Breast Cancer Research Stamp Reauthorization Act of 2015 (H.R. 2191/S. 1170)</u>

- 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 five years, through 2019.
- The bill would ensure that the agencies receiving funds (NCI and the Department of Defense), 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.

<u>Cancer Care Payment Reform Act of 2015 (H.R. 1934)</u>

- The bill would direct the HHS Secretary to establish a national Oncology Medical Home Demonstration Project under the Medicare program, Part B, for the purpose of changing the Medicare payment for cancer care to enhance the quality of care and to improve cost efficiency.
- Applicants would be limited to 1,500 practicing oncologists in small, medium, and large-sized practices in different geographic areas, and could be either physician-owned, or affiliated with or owned by a hospital.
- Measures would include patient care, resource utilization, survivorship, and end-of-life care, and the Secretary would have discretion to modify or add to these measures, working with relevant stakeholders. Stakeholders noted in the bill include appropriate oncology societies; oncologists accepting Part B payment; allied health professionals; health insurance companies that had implemented alternative payment models for oncologists, patients, and organizations representing patients; and biopharmaceutical and other medical technology manufacturers.
- Assessments would be made annually of participants' performances and the extent to which breakthrough or other best-in-class therapies were used. Payments would be made in six-month increments for the first two years of the project. Payments would be aggregated and should not be more than the expenditures of previous years, before the initiation of the pilot project.
- The bill also calls for a Government Accountability Office report no later than June 1, 2019, to be submitted to Congress evaluating the success of the demonstration project, and making recommendations regarding the possible expansion of the project and any possible reforms that could be made to the program with respect to payment for cancer care.
- Rep. Cathy McMorris Rodgers (R-WA) introduced H.R. 1934 on 4/22/2015. The bill was referred to the Committees on Energy and Commerce and on Ways and Means.

<u>21st Century Investment Act of 2015 (H.R.1852)</u>

- The bill would amend the Internal Revenue Code to increase and make permanent the tax credit for increasing research activities, allowing a 25% tax credit rate for research expenses incurred in the U.S.

- The bill would increase to 15%, through 2024, the tax deduction for income attributable to domestic manufacturing production activities for which substantially all of the research and development occurred in the U.S.
- Rep. Donna Edwards (D-MD) introduced H.R. 1852 on 4/16/2015. The bill was referred to the Committee on Ways and Means.

American Cures Act (H.R. 2104)

- The bill would prioritize funding for an expanded and sustained national investment in biomedical research. It would amend the Balanced Budget and Emergency Deficit Control Act of 1985 to require certain adjustments to discretionary spending limits in FY2016 - FY2021 to accommodate increases in appropriations for agencies that perform biomedical research, including the NIH, the CDC, the DOD and Department of Veterans' Affairs' medical and prosthetics research program.
- The NIH would receive additional new budget authority for $1.7 billion in FY 2016, $3.4 billion in FY 2017, $5.2 billion in FY 2018, $7 billion in FY 2019, $9.1 billion in FY 2020, and $11.4 billion in FY 2021; and the proposal would exempt appropriations provided for this bill from sequestration.
- The bill would require annual appropriations for each of the programs and agencies referenced to be at least the amount appropriated in FY 2015.
- Rep. Anna Eshoo (D-CA) introduced H.R. 2104 on 4/29/2015. The bill was referred to the Committees on Armed Services; Budget; Energy and Commerce; and Veterans; Affairs. This is a companion bill to S. 289, introduced by Sen. Dick Durbin (D-IL) on 1/28/2015.

Lymphedema Treatment Act (H.R.1608)

- The bill would require Medicare to cover certain lymphedema compression treatment items as "durable medical equipment."
- H.R. 1608 was introduced by Rep. David Reichert (R-GA) on 3/25/15 and was referred to the Committees on Energy and Commerce and Ways and Means.

Advancing Hope Act (H.R. 1537)

- The bill proposes to reauthorize and make permanent the FDA's Rare Pediatric Disease Priority Review Voucher Program, which was first proposed in the Creating Hope Act and signed into law as Section 529 of the FDA Safety and Innovation Act (FDASIA) in July 2012. It also proposes changes to the definition of rare pediatric disease to include any pediatric cancer and any form of sickle cell disease.
- H.R. 1537 was introduced by Rep. G.K. Butterfield (D-NC) and colleagues on 3/23/15 and was referred to the House Energy and Commerce Committee Subcommittee on Health.

Cancer Patient Protection Act of 2015 (H.R. 1416)

- The bill proposes to reverse cuts to Medicare under sequestration that have resulted in reduced reimbursements for some cancer treatments.
- The bill would require the Government Accountability Office to conduct a study that examines the shift of cancer care from physician-run community cancer clinics to hospitals and the attendant costs to the Federal Government and to Medicare beneficiaries; and to submit the report by 2/1/2017.
- H.R. 1416 was introduced by Rep. Renee Ellmers (R-NC) on 3/18/2015 and was referred to the Committees on the Budget; Ways and Means; and Energy and Commerce.

Removing Barriers to Colorectal Cancer Screening (H.R. 1220/S.624)

- The bill would require a waiver of coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening.

- H.R. 1220 was introduced by Rep. Charlie Dent (R-PA) on 3/3/2015 and was referred to the Committees on Energy and Commerce; and Ways and Means. S. 624 was introduced by Senator Sherrod Brown (D-OH) on 3/3/2015 and was referred to the Committee on Finance.

Accelerate the End of Breast Cancer Act (S. 746/H.R. 1197)

- The bill would establish the Commission to accelerate and help end breast cancer by January 1, 2020.
- H.R. 1197 would direct the Commission to identify opportunities and ideas within the government and the private sector that are key components in achieving the end of breast cancer yet have been overlooked or would be unlikely to be achieved by the private sector due to technical and financial uncertainty. It would direct the Commission to identify, recommend, and promote initiatives, partnerships, and research that can be turned into strategies to prevent breast cancer and its metastasis.
- The bill would ensure that the Commission's activities are coordinated with, and do not duplicate the efforts of programs and laboratories of other government agencies.
- The Commission would be required to submit within six months to the President and to the relevant congressional committees a description of the Commission's strategic plan; and submit an annual report to the President, Congress, and the public.
- The bill would direct the President to enter into an agreement with the Institute of Medicine for an evaluation of the Commission's progress, including whether the Commission should be continued or terminated on its due date of June 1, 2020.
- S. 746 would authorize to be appropriated for the Commission's activities $8 million for FY2016; $12 million for each of FY2017 and FY2018; and such sums as necessary for other years until the Commission terminated.
- H.R. 1197 was introduced by Rep. Kathy Castor (D-FL) on 3/2/2015 and was referred to the Committee on Energy and Commerce. S. 746 was introduced by Sen. Chuck Grassley (R-IA) on 3/16/2015 and was referred to the HELP 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

Designation of May as National Bladder Cancer Awareness Month (S.Res. 187)

- The resolution expresses support for the designation of May 2015 as Bladder Cancer Awareness Month.
- Sen. Robert Menendez (D-NJ) introduced S. Res. 187 on 5/21/2015. The resolution was considered and unanimously agreed to in the Senate.

Designation of March 2015 as National Colorectal Cancer Awareness Month (S.Res. 128)

- The resolution supports the goals and ideals of the National Colorectal Cancer Awareness Month and encourages appropriate awareness and educational activities during the month of March.
- The resolution was introduced by Sen. Michael Enzi (R-WY) on 3/27/2015 and was agreed to by Unanimous Consent.

Introduced

Supporting National Men's Health Week (H. Con Res. 57)

- The resolution requests that Congress support the annual National Men's Health Week, to be observed during the week of June 15th, 2015; and requests the President to issue a proclamation calling upon individuals and groups to observe the week with appropriate ceremonies and activities.
- The resolution recognizes a number of diseases and conditions common among men, including testicular cancer, prostate cancer, and colon cancer.
- Rep. Donald Payne (D-NJ) introduced H. Con Res. 57 on 6/18/2015. The resolution was referred to the Committee on Oversight and Government Reform.

Designation of May as National Bladder Cancer Awareness Month (H.Res. 282)

- The resolution expresses support for the designation of May 2015 as Bladder Cancer Awareness Month.
- Rep. Matthew Cartwright (D-PA) introduced H. Res. 282 on 5/21/2015. The resolution was referred to the Committee on Energy and Commerce.

Designation of June 2015 as National Men's Cancer Awareness Month (H.Res. 203)

- The resolution expresses support for the designation of June 2015 as National Men's Cancer Awareness Month.
- H.Res. 203 was introduced by Rep. Alcee Hastings (D-FL) on 4/15/15 and was referred to the Committee on Energy and Commerce Subcommittee on Health.

Designation of March National Multiple Myeloma Awareness Month (H. Res. 174)

- The resolution expresses support for the designation of March as National Multiple Myeloma Awareness Month.
- H. Res. 174 was introduced by Rep. Brian Higgins (D-NY) on 3/25/2015 and referred to the Committee on Oversight and Government Reform.

Designation of March 2015 as National Colorectal Cancer Awareness Month (H.Res. 131)

- The resolution supports the goals and ideals of the National Colorectal Cancer Awareness Month and encourages appropriate awareness and educational activities during the month of March.
- The resolution was introduced by Rep. Donald Payne (D-NJ) on 2/27/2015 and referred to the Committee on Oversight and Government Reform.

Appendix 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2016 Budget Request

Statement for the Record
Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Douglas R. Lowy M.D.
Acting Director, National Cancer Institute

Mr. Chairman and Members of the Committee:

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the National Cancer Institute (NCI) of the National Institutes of Health (NIH). The fiscal year (FY) 2016 NCI budget of $5,098,479,000 includes an increase of $145,451,000, or 2.9 percent, compared to NCI's FY 2015 budget.

NCI FY 2016 OVERVIEW

Precision Medicine is a promising, marquee initiative for NCI for FY 2016. With the additional resources in our FY 2016 budget, NCI can broadly advance and successfully integrate the many disciplines – including genomics, informatics, pharmacology, and cancer biology – required to launch a new era of Precision Medicine, with a long-term goal of improving outcomes for patients with all types of cancer.

However, the FY 2016 NCI budget supports a wide range of research priorities in other areas as well. The NCI research portfolio encompasses three broad areas –

- basic research, including genetics, cell biology, immunology, cancer pathogenesis, and other fields
- translational and clinical sciences to prevent, screen, and diagnose cancer, and to develop and test drugs, biomarkers, imaging technologies, diagnostics, and radiotherapies
- population sciences, including epidemiological, environmental, and behavioral studies.

While many of these disciplines will experience profound changes based on the new understanding of cancer that is driving Precision Medicine, others will continue to depend on more traditional approaches to research. Thanks to the support of this subcommittee, your funding for these traditional approaches has yielded important results during the past decade and has helped to decrease cancer mortality rates, to improve our ability to manage the symptoms of cancer, and to monitor the prevalence of cancers and the factors that confer the risks of cancers.

Continued research funding across all these disciplines is essential to achieve further progress into understanding the causes and mechanisms of cancer, preventing cancer, and strengthening cancer screening. Likewise, funding all these disciplines is essential to produce tangible clinical benefits for the many Americans suffering from cancer, those at risk of cancer, and the growing population of cancer survivors.

The NCI research portfolio is very broad with many important priorities, and I would like to highlight a few of these areas – prevention, screening, basic science, and environmental factors – in addition to the Precision Medicine Initiative.

Prevention and Screening: Preventing cancer and screening for cancer have long been central priorities within NCI's mission. Prevention takes many forms, such as controlling tobacco use, vaccinating against cancer-causing viruses such as human hepatitis B virus and human papillomaviruses, limiting exposure to sunlight, and regulating exposure to carcinogenic substances such as asbestos. These priorities have contributed to reducing the incidence and the mortality rates of many cancers. Population-wide screening for certain cancers can have a substantial impact on mortality, and NCI continues to support research to advance this important area.

The experience with lung cancer – the most common cause of death due to cancer in the United States – serves as a good example of progress in prevention and the benefits of cancer screening. Between 2001 and 2010, there was a 25 percent decrease in male death rates and an eight percent decrease in female death rates due to lung cancer. Most of these reductions are related to decreased tobacco consumption in the United States. In the area of screening, the National Lung Screening Trial (NLST), which studied more than 50,000 patients who were current heavy smokers or former heavy smokers, found that helical computed tomography (CT) screening could reduce lung cancer mortality for these patients. The NLST results have led the U.S. Prevention Services Task Force and the Centers for Medicare and Medicaid Services to endorse helical CT screening for patients with smoking histories similar to those who participated in NLST.

We know there are other promising opportunities in the areas of screening and prevention, as the 2014 report of the President's Cancer Panel points out. In particular, the 2014 report emphasized that increased use of HPV vaccines could dramatically reduce the incidence and mortality of several types of cancer, including cervical, anal, and oropharyngeal cancers. NCI continues to invest heavily in cancer screening and prevention because substantial additional progress is possible. For example, NCI-supported research has identified the ability of HPV-based screening to reduce the risk of developing cervical cancer to a greater degree than traditional Pap smear screening.

However, despite progress in these and other areas, too many Americans face a cancer diagnosis, and far too many are dying from the disease. It is estimated that more than 600,000 people in the United States will die from cancer in 2015 and that there will be more than 1.6 million new cases. In addition, our progress in preventing, diagnosing, and treating cancers is not universal for all forms of the disease. Although mortality rates for many cancers have decreased, mortality rates for certain cancers have actually increased. For example, death rates from liver cancer increased by about 20 percent between 2001 and 2010. Thus, much work remains.

Basic Research: In the area of basic research, NCI hopes to discover clues that will lead to new approaches to preventing, screening, diagnosing, and treating cancer. We know that cancers are disorders of cell growth, cell survival, and other cell behaviors, fueled largely by changes in genes. Therefore, NCI continues to make substantial investments in many fundamental aspects of cell biology and genetics, recognizing that basic biological science is essential to understand cancers.

For example, we have known for several decades that much of a cell's RNA contains the messengers that instruct the cell to make its proteins. Through more recent research, we have discovered that cells contain other forms of RNA that are not translated to make proteins. Instead, they directly regulate the expression of many genes that do encode proteins. Many of these regulatory "non-coding" RNAs can influence the behavior of cancer cells. We are intensely studying the roles that these and other regulators may have and their relationship to cancer. Such research may yield a more profound understanding of how a normal cell becomes a cancer cell, as well as new ways to classify and treat cancers.

Understanding the Role of Environmental and Microenvironmental Factors: A wealth of research supported by NCI and others has determined that cancer develops through a complex interplay of genetic and environmental factors. In some cases, the risk of developing cancer is strongly influenced by inheriting a mutation in a single gene, such as BRCA1 or BRCA2. Mutations in these genes confer a high risk of breast and ovarian cancer. More commonly, however, the genetic background of individuals plays a more subtle role in cancer risk. Although genes can make important contributions to cancer susceptibility, the sum of an individual's exposure to various environmental and lifestyle factors likely accounts for most cancers. Environmental factors such as tobacco use, certain infections, and exposure to ultraviolet light can contribute to cancer risk, as can lifestyle factors, such as obesity, lack of exercise, and an unhealthy diet. Once we identify and understand these risks and exposures, we can often develop effective prevention strategies.

Our understanding of the importance of the tumor microenvironment, which is composed of the noncancerous cells and materials that surround cancer cells in a tumor mass, is also rapidly increasing. For example, we now recognize the importance of immune cells, blood vessels that support tumor growth, and

other factors, such as hormonal mediators of cell growth and extracellular matrix proteins that influence tumor cell migration and tumor architecture. Further research on the components of the microenvironment and their interactions with the tumor will improve our understanding of the interplay between tumors and their hosts. These interactions are likely to be complex but profound, and may hold clues to future prevention, screening, and treatment.

NCI'S PRECISION MEDICINE INITIATIVE

This is a transformational moment for cancer patients and for cancer research. Thanks to the investments by Congress in NCI and NIH research, we now recognize that cancers are fundamentally diseases of the genome and that understanding cancer begins by identifying the abnormal genes and proteins that confer the risk of developing cancer, the mechanisms that drive these changes, and the underlying causes of cancer.

After decades of research, we are poised to enter a new era of medical practice where detailed genetic and other molecular information about a patient's cancer is routinely used to deploy effective, patient-specific remedies to treat it. We are entering the era of Precision Medicine.

The increased FY 2016 resources that we request for the Precision Medicine Initiative will allow NCI to make strategically important research advances. Under the Initiative, NCI will assemble and analyze additional genomic data sets to increase our understanding of cancer genomes and their relationship to gene variants that a patient may have inherited. Based on the genomic information we uncover, NCI will test new therapies against childhood cancers and several common adult cancers. NCI will also develop better animal and cell-based models of cancer, study mechanisms of drug resistance, and identify new therapies and therapeutic combinations to overcome drug resistance. NCI will build on what it has already learned in ways that will accelerate the pace of discovery and will deliver important benefits to patients through clinical practice.

The FY 2016 initiative rests on a solid foundation of programs that support and advance Precision Medicine. This foundation includes NCI research related to the causes of cancer, genomics and cancer biology, and molecular pathology, immunology and immunotherapy research, cancer imaging research, and translational and therapeutic studies. NCI will continue this ongoing work as it also supports new and expanded Precision Medicine research with the additional funds proposed in our FY 2016 budget.

Under the Precision Medicine Initiative, NCI will increase funding to four broad areas: 1) clinical trials, 2) drug resistance, 3) preclinical models, and 4) a knowledge system to support Precision Medicine. NCI will conduct the priority activities of the initiative through competitive grants, cooperative clinical research, and research and development contracts. The results of Precision Medicine will apply to all facets

of oncology: in diagnostics and therapeutics, in cancer prevention and screening, in how we monitor tumors using molecular analysis and imaging, and how we assess the causes of cancer.

CONCLUSION

The FY 2016 NCI budget supports core, ongoing biomedical research that will advance scientific discovery and continue to reduce the burden of cancer in America. It will also foster a promising new era of Precision Medicine, in which the medical community routinely uses detailed molecular information to identify the most effective patient- and tumor-specific approaches to treating cancer. With these resources, NCI can alter the landscape for the practice of cancer medicine, foster standards for molecular medicine in other domains, stimulate development of important new therapies within our nation's biomedical industries, and enlarge U.S. prestige for its public health leadership and for improving outcomes for cancer patients across the globe.