

November 12, 2014

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

**Activities of the 113th Congress-
Second Session**

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

Visit the Office of Government and Congressional Affairs website at:
<http://legislative.cancer.gov>

I. Appropriations

Despite early momentum and statements from both House and Senate Appropriations leadership (Chairman Hal Rogers, R-KY, and Chairwoman Barbara Mikulski, D-MD) about intentions to complete all 12 individual appropriations bills before the end of the fiscal year, progress stalled in early summer. Disputes over policy riders and funding levels for some of the individual measures are reported to have caused the delay. Congress left for the August recess without sending even one of the 12 appropriations bills to the President. As Congress returned on September 8, work proceeded on a Continuing Resolution (CR) to provide short-term funding for government operations for a period of time after the end of the fiscal year (September 30). Chairman Rogers introduced the CR on September 9, and the House passed it by a vote of 319-108 on September 17, and the Senate quickly followed the next day, passing the CR by a vote of 78-22. The President signed the bill into law on September 19. The CR extends until December 11, providing funding at FY 2014 levels through the November election and into a lame duck session. The bill included a very limited number of spending and authorization changes known as “anomalies” including measures to provide \$88 million for government efforts to fight the Ebola virus and changes that allow the FDA to collect fees for the inspection of compounded drugs.

To review action thus far on FY 2015 appropriations, the President’s budget was released in March, and includes \$30.4 billion for NIH, an increase of \$211 million over FY2014. However, while the proposed NIH budget is an increase relative to FY2014, it is less than the NIH FY2012 appropriation of \$30.86 billion. The FY2015 proposal includes approximately \$4.93 billion for NCI. Again, this proposed budget is an \$8 million increase relative to FY2014; it is less than the NCI FY2012 appropriation of approximately \$5.07 billion.

Overall FY15 funding allocations for the individual subcommittees were finalized in May, with the Senate Labor-HHS Subcommittee at \$156.8 billion, and the House Labor-HHS Subcommittee at \$155.7. The Senate Labor-HHS-Education Subcommittee marked up a draft Labor-HHS bill on June 10th, proposing approximately \$30.5 billion for NIH, an increase of approximately \$605 million relative to FY14. However, full committee markup set for June 12 was canceled abruptly with a statement that the Committee schedule was “under review.” Although the full Committee has not moved to reschedule a vote on the Labor-HHS bill, the Subcommittee did post its draft bill and report on its website on July 24 – it proposes \$30,459,181,000 in funding for NIH for FY2015, including \$5,003,932,000 for NCI.

In the House, 7 of the 12 appropriations bills were passed by the full House, 4 were passed by the Appropriations Committee - Labor-HHS is the only bill that was not acted on by the full Subcommittee. Unlike the Senate, the House Subcommittee has not made the bill or the report public by posting on the website. Therefore at this point, we do not know the funding levels that the House will provide for NIH or NCI. However, on 9/15/14, Rep. Rosa DeLauro (D-CT) introduced a bill on behalf of the minority members of the House Labor-HHS Subcommittee, H.R. 5464, the “Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of 2015.” The minority’s proposal recommends an FY 2015 Appropriation for NIH of \$30.6 billion, \$500 Million (an increase of 1.6%) more than the FY 2015 President’s budget request. This would fully restore NIH to pre-sequestration level. The bill proposes an increase of 2% for the NCI.

II. Congressional Hearings, Briefings, and Visits

Rep. John Delaney (D-MD) Visits NCI’s Frederick National Lab for Cancer Research (FNLCR, 10/22/14): Rep. Delaney visited FNLCR, which is located in his district (MD-6), on October 22. Dr. Craig Reynolds provided an overview of FNLCR and the type of research supported at the facility, highlighting the unique capabilities and flexibility of the national lab model. Rep. Delaney and his staff had expressed interest in learning about breast cancer research underway at FNLCR. Dr. Shyam Sharan of NCI’s Center for Cancer Research presented his research focusing on mouse embryonic stem cells and other mouse models to distinguish between non-harmful and deleterious mutations, and gave examples of family pedigrees with BRCA1 and BRCA2 mutations and incidence of disease. Rep. Delaney also toured the Small Animal Imaging Facility with Dr. J.D. Kalen.

Rep. Dan Lipinski (D-IL) Attends NIH I-Corps™ Launch (led by NCI SBIR, 10/6/14): Rep. Dan Lipinski (D-IL), Ranking Member of the Research and Technology Subcommittee of the House Committee on Science, Space, and Technology, spoke at the opening session of the NIH I-Corps™ program on October 6. The NIH Innovation Corps Team Training Pilot Program was developed in collaboration with the National Science Foundation (NSF), and is a pilot initiative designed to support training that will help project teams at NIH-funded small businesses overcome key obstacles along the path of innovation and commercialization. Eleven of the 23 NIH teams are supported by NCI, and NCI's SBIR office leads planning and implementation of the NIH pilot. Rep. Lipinski, who has been a vocal supporter of the NSF I-Corps™, praised NIH for launching the pilot program.

NIH Director Speaks at Congressional Childhood Cancer Caucus Summit (9/19/14): Dr. Francis Collins gave the keynote address at the 5th annual Congressional Childhood Cancer Caucus Summit, hosted by caucus co-chairs Reps. Michael McCaul (R-TX) and Chris Van Hollen (D-MD). Dr. Collins provided an overview of childhood cancer research efforts supported by the NCI and other NIH institutes, as well as NIH's critical investments in basic research and in genomics research, including NCI's pediatric TARGET (Therapeutically Applicable Research for Effective Treatments) initiative. Drs. Ronald DePinho, Director, MD Anderson Cancer Center, and Amrit Ray, Chief Medical Officer, Janssen Pharmaceuticals, also spoke at the summit.

Senate Staff Visit NCI (8/18/14): Staff from the offices of Senators Dianne Feinstein (D-CA) and Johnny Isakson (R-GA), co-chairs of the Senate Cancer Coalition, visited the NCI on 8/18/14. The staff toured labs and clinics in NCI's Center for Cancer Research, and discussed NCI's National Clinical Trials Network and precision medicine oncology trials. They met with Dr. Bill Dahut, Clinical Director, Center for Cancer Research (CCR); Dr. Jeff Abrams, Director of Clinical Research, Division of Cancer Treatment and Diagnosis (DCTD); Dr. Shivaani Kummar, Head of Early Clinical Trials Development within NCI's DCTD; Dr. James Doroshow, NCI Deputy Director for Clinical and Translational Research, and Director, DCTD; and Dr. Pete Choyke, Director of the Molecular Imaging Program within NCI's CCR.

NCI Director Testifies at House Science Hearing (7/17/14): Dr. Varmus testified before the House Committee on Science, Space, and Technology, Subcommittee on Research and Technology at a hearing titled "Policies to Spur Innovative Medical Breakthroughs from Laboratories to Patients." Additional witnesses were Dr. Marc Tessier-Lavigne, President and Carson Family Professor, Laboratory of Brain Development and Repair, The Rockefeller University; Dr. Jay Keasling, Hubbard Howe Jr. Distinguished Professor of Biochemical Engineering, University of California, Berkeley and Director, Synthetic Biology Engineering Research Center; and Dr. Craig Venter, Founder, Chairman, and Chief Executive Officer, J. Craig Venter Institute. Dr. Varmus' testimony focused on evaluating the scientific landscape and research enterprise, particularly under current fiscal constraints. He addressed the importance of achieving balance across key elements of the scientific enterprise, the importance of multidisciplinary research and NCI's efforts in this area, and the critical role of basic biological research in driving future scientific discovery. Please see Appendix 1 on page 13 for Dr. Varmus' full written testimony.

Congressional Caucus on the Deadliest Cancers Briefing (6/19/14): Dr. James Doroshow, Deputy Director for Clinical and Translational Research, spoke on behalf of NCI at the inaugural briefings of the Congressional Caucus on the Deadliest Cancers – a caucus convened by co-chairs Reps. Anna Eshoo (D-CA), Leonard Lance (R-NJ), Henry Waxman (D-CA), and Dave Reichert (R-WA) to focus on cancers with five-year relative survival rates below fifty percent. Reps. Eshoo and Lance offered opening remarks, and other panelists included Dr. Anil Rustgi of the University of Pennsylvania and representatives of pancreatic and gastric cancer advocacy organizations.

SBIR House and Senate Briefings (5/20/14): Michael Weingarten, Director of NCI's Small Business Innovation Research Program, spoke at back-to-back House and Senate briefings entitled "Public Private Partnerships: Advancing Treatments and Cures," organized by an informal consortium of state BIO and trade organizations. The briefings were sponsored by Reps. Susan Davis (D-CA) and Fred Upton (R-MI) in the House, and Sens. Amy Klobuchar (D-MN) and Pat Toomey (R-PA) in the Senate. The Melanoma Research Alliance also spoke at the House briefing, highlighting recent discoveries and advances in treating melanoma that are a direct result of NCI support.

Senate Special Committee on Aging Hearing (5/7/14): Dr. Varmus testified before the Senate Special Committee on Aging at a hearing titled “The Fight Against Cancer: Challenges, Progress, and Promise.” Additional witnesses were Dr. Thomas Sellers, Director of the H. Lee Moffitt Cancer Center; Valerie Harper, Actress and Cancer Survivor; Mary Dempsey, Assistant Director, The Patrick Dempsey Center for Cancer Hope and Healing; and Chip Kennett, Advocate and Cancer Survivor, who is also a former staffer to Sen. Susan Collins (R-ME), ranking member of the committee. Dr. Varmus’ testimony focused on the biological relationship between cancer and aging, cancer control, and expanding knowledge to improve cancer care. He addressed questions from Committee members regarding the NIH budget and sustainable funding for biomedical research, surprising cancer research discoveries, cancer prevention and the cost of cancer care, coordination with Department of Defense cancer research efforts, and pancreatic cancer research. Please see Appendix 2 on page 19 for Dr. Varmus’ written testimony.

Sen. Roy Blunt (R-MO) Visits NIH and Tours Center for Cancer Research Lab (4/15/14): Senator Roy Blunt (R-MO), member of the Senate Appropriations Committee, visited the NIH and met with Dr. Collins. Sen. Blunt is also a prostate and kidney cancer survivor, and during his visit he toured the lab of Dr. Marston Linehan, Chief of the Urologic Oncology Branch in NCI’s Center for Cancer Research.

NIH Senate Labor-HHS Appropriations Subcommittee Hearing (4/2/14): Dr. Collins, accompanied by Dr. Varmus and various IC Directors, testified before the Senate Labor-HHS Appropriations Subcommittee regarding the FY 2015 budget. Dr. Varmus addressed questions from Subcommittee members regarding cancer research broadly, highlighting areas including genomics, immunology, and biochemistry; as well as focusing on clinic trials, including in community settings.

Energy and Commerce Health Subcommittee Staff Briefing on PDAC Framework (3/28/14): Dr. Toby Hecht, Associate Director of the Translational Research Program within NCI’s Division of Cancer Treatment and Diagnosis, and Dr. Sheila Prindiville, Director of NCI’s Coordinating Center for Clinical Trials, provided a briefing for Energy and Commerce Health Subcommittee Staff. The briefing focused on the scientific framework on pancreatic ductal adenocarcinoma (PDAC), which NCI sent to Congress as called for under the Recalcitrant Cancer Research Act. Drs. Hecht and Prindiville provided staff with an overview of the framework, focusing on plans for implementation of four recommended research initiatives (RAS initiative; PDAC/diabetes mellitus relationship; screening and biomarker research; immunotherapy approaches).

Dr. Lou Staudt Presents at American Cancer Society Briefing (3/28/14): Dr. Lou Staudt, Director of NCI’s Center for Cancer Genomics, spoke at a briefing organized by the American Cancer Society Cancer Action Network, entitled “Advancing Patient Care Through More Personalized Cancer Treatment.” His remarks focused on the molecular diagnosis of cancer, and featured his research on diffuse large B-cell lymphoma as well as the NCI MATCH Initiative.

NIH House Labor-HHS Appropriations Subcommittee Hearing (3/26/14): Dr. Collins, accompanied by Dr. Varmus and various IC Directors, testified before the House Labor-HHS Appropriations Subcommittee regarding the FY 2015 budget. Dr. Varmus addressed questions from Subcommittee members focusing on pancreatic and liver cancer research.

Dr. Crystal Mackall Presents at AACR Briefing (3/13/14): Dr. Crystal Mackall, Chief of the Pediatric Oncology Branch in NCI’s Center for Cancer Research, spoke at a briefing organized by the American Association for Cancer Research entitled “Making Research Count for Patients: A Continual Pursuit.” The briefing showcased the AACR Cancer Progress Report, and was sponsored by Reps. Debbie Wasserman Schultz (D-FL) and Mike Fitzpatrick (R-PA), who are featured in the report and also spoke at the briefing to share their personal experiences as cancer survivors. Dr. Mackall spoke about her research efforts focused on immunotherapies to treat children with cancer, and emphasized that recent exciting advances in cancer immunology are the result of years of investment from the NCI.

III. Legislation of Interest

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

Selected Bills With Recent Activity or Interest (113th Congress)

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

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

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of 2015 (H.R.5464; 113th Congress)

- The bill proposes an FY 2015 Appropriations for NIH of \$30.6 billion, \$500 Million (an increase of 1.6%) more than the FY 2015 President's budget request. This would fully restore NIH to pre-sequestration level.
- The bill proposes an increase of 2% for the NCI.
- The bill also includes a provision that would grant the NIH Director authority to require registration and disclosure of Phase I clinical trials outcomes.
- Rep. Rosa DeLauro introduced H.R. 5464 on 9/15/2014, and the bill was referred to the Appropriations Committee. Rep. DeLauro serves as Ranking Member of the House Labor-HHS Appropriations Subcommittee, and this proposal was introduced on behalf of the minority members of the subcommittee, and does not represent the funding recommendations of the full Subcommittee. Rep. Nita Lowey (D-NY), Ranking Member of the House Appropriations Committee, was an original cosponsor. Reps. Barbara Lee (D-CA) and Michael Honda (D-CA), members of the Labor-HHS Subcommittee, also cosponsored the bill.

Early Act Reauthorization of 2014 (H.R. 5185/S. 2655; 113th Congress)

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

Accelerating Biomedical Research Act (S.2658/H.R. 5580; 113th Congress)

- The bill aims to restore funding to NIH and provide a predictable funding plan. It would establish a budget cap adjustment that would allow for additional funds to be appropriated to NIH if Appropriators maintain at least \$29.9 billion in NIH funding.
- The bill would maintain the current funding of \$29.9 billion for NIH for FY2015, and aims to increase appropriations to \$46.5 billion by the end of FY 2021. These provisions would restore NIH funding to the 2003-post doubling level, recognizing that since 2003, budget caps and other funding constraints have resulted in significant erosion of NIH purchasing power.
- The NIH would receive an initial increase of 10% in each of the first two fiscal years, FY 2015 and FY 2016, to mitigate the effects of sequestration; and thereafter an increase of 5% in each of the remaining years.
- Sen. Tom Harkin (D-IA) introduced S. 2658 on 7/24/14. Rep. Rosa DeLauro (D-CT) introduced H.R. 5580 on 9/18/14. The bills were referred to the Senate and House Budget Committees, respectively. Sen. Harkin serves as chair of the Senate Appropriations Labor-HHS Subcommittee, and Rep. DeLauro serves as the Ranking Member of the House Appropriations Labor-HHS Subcommittee.

Sunscreen Innovation Act (H.R. 4250/S. 2141, 113th Congress)

- The bills aim to accelerate FDA review and approval of sunscreens with new active ingredients. FDA's Center for Drug Evaluation and Research would be required to complete its review of eligible applications within 300 days of the request being filed. If the center did not act within that time, the request would be transferred to the FDA Commissioner for review within 60 days.
- Provisions in the bills are specific to FDA, and NCI would not have any responsibility for implementation.
- The House passed H.R. 4250, the Sunscreen Innovation Act on 7/28/14 and the bill was received in the Senate on 7/29/14. H.R. 4250 was originally introduced by Rep. Ed Whitfield (R-KY) on 3/13/14, and Sens. Jack Reed (D-RI) and Johnny Isakson (R-GA) introduced a companion bill, S. 2141 on the same date. The Senate passed S. 2141 on 9/17/14, agreeing to the measure by Unanimous Consent. The House will now need to approve the Senate-passed version of the bill before sending a final bill forward to the President for signature.

Next Generation Research Act (S.1552/H.R. 5451; 113th Congress)

- The main goal of this bill is to increase opportunities for the development of our next generation of researchers through the establishment of the Next Generation of Research Initiative within the National Institutes of Health (NIH). The proposed initiative would promote efforts aimed at improving opportunities for new researchers including efforts to strengthen mentorship programs pairing new and veteran researchers, to enhance workforce diversity efforts, and to help improve new researchers' success in obtaining renewal funding.
- The bill would require the National Academy of Sciences (NAS) to conduct a comprehensive study of legislative, administrative, educational, and cultural barriers to providing for a successful next generation of biomedical researchers.
- In addition, a report to Congress would be required within five years of the date of enactment concerning the results of the NAS study including an evaluation of the impact of sequestration on the next generation of researchers and recommendations for the implementation of policies to incentivize, improve entry to, and sustain careers in research.
- S. 1552 was originally introduced by Sen. Tammy Baldwin (D-WI) on 9/26/13 and was referred to the Senate HELP Committee. Rep. Mark Pocan (D-WI) introduced a companion bill, H.R. 5451, on 9/11/2014. The bill was referred to the House Committee on Energy and Commerce.

Breast Density and Mammography Reporting Act (S. 2622/H.R. 5145, 113th Congress)

- The bill would amend the Mammography Quality Standards Act (MSQA) of 1992 to require mammography results to include information about a patient's breast density, and for that information to be reported to patients in their mammography results summary.
- The bill directs the Health and Human Services (HHS) Secretary to establish reporting requirements based on current scientific knowledge, and also requires that the summary communicate the effect of dense breast tissue in masking breast cancer on mammography. For women with results indicating they have dense breast

tissue, the summary must also include language encouraging them to consult with their physician regarding whether additional screening would be beneficial.

- The bill also directs the HHS to “expand and intensify” HHS programs related to (1) applied research on breast density; (2) research on the cost-effectiveness, effectiveness, and feasibility of reimbursement models for supplemental imaging related to breast density; (3) research supporting clinical guidelines and best practices for mammography screening for women with dense breasts.
- Rep. Rosa DeLauro (D-NY) and Rep. Steve Israel (D-NY) introduced H.R. 5154 in the House on 7/17/2014, and the bill was referred to the Committee on Energy and Commerce. Sens. Dianne Feinstein (D-CA) and Kelly Ayotte (R-NH) introduced S. 2622, companion bill to H.R. 5154, on 7/17/2014. The bill was referred to the Committee on Health, Education, Labor and Pensions.

Additional Information: Rep. DeLauro introduced similar legislation in the 111th and 112th Congresses, as well as a similar bill earlier in the 113th Congress. The section directing HHS to expand and intensify relevant research efforts was not included in previous proposals.

Gabriella Miller Kids First Research Act (H.R.2019/Signed into law as P.L. 113-94)

- This law amends the Internal Revenue Code to eliminate taxpayer financing of political party conventions and to reprogram savings to provide for a 10-year pediatric research initiative administered through the National Institutes of Health Common Fund.
 - The bill calls for funds for political conventions currently in accounts maintained by national committees of political parties to be transferred to a fund in the Treasury to be known as the “10-Year Pediatric Research Initiative Fund” in the amount of \$12.6 million per year for fiscal years 2014-2023.
 - The funds are to be made available to NIH Common Fund “in such amounts as are provided in advance in appropriation Acts.”
 - Effect of the law is limited to identifying a specific source of funds and authorizing an appropriation to the NIH Common Fund. By itself, the law does not actually provide any funds to NIH.
 - As pointed out by Reps. Nita Lowey (D-NY) and Rosa DeLauro (D-CT) (Ranking Members of the House Appropriations Committee and Labor-HHS Appropriations Subcommittee, respectively), in order for NIH to receive such funds, Congressional Appropriators must include a specific appropriation of funds in the Labor-HHS Appropriations Act, which has yet to be finalized for FY 2015. If this does not happen, the funds remain in the Treasury “10-Year Pediatric Research Initiative Fund” indefinitely. Reps. Lowey and DeLauro also noted that the appropriations needed to make these funds available would be fully subject to the spending caps in place under the Budget Control Act, and to the budget resolution spending allocations to the Appropriations Committee and Labor-HHS Subcommittee. This means that an increase in appropriations to NIH by the “10-Year Pediatric Research Initiative Fund” would need to be offset by a reduction elsewhere in the Labor-HHS-Education bill.
- H.R. 2019 was introduced by Rep. Gregg Harper on 5/16/13, as the Kids First Research Act, and was renamed in honor of Gabriella Miller, a 10-year-old girl from Virginia who passed away in October 2013 due to a pediatric brain tumor, Diffuse Intrinsic Pontine Glioma.
- H.R. 2019 was referred to the House Energy and Commerce Committee, Subcommittee on Health, as well as the House Committees on Administration, and Ways and Means. The bill did not proceed through mark up and was not passed out of committee. On 12/11/13, the House passed the bill under suspension of the rules, in a vote of 295-103. On 3/11/13, the Senate passed the bill by unanimous consent. **The President signed the bill into law on 4/4/14.**

Selected New Bills (113th Congress)

Reducing Disparities Using Care Models and Education Act of 2014 (S. 2841/H.R. 5507; 113th Congress)

- The bill would direct the HHS Secretary to have the Institute of Medicine (IoM) conduct a study on health disparities in the U.S., including factors that may contribute to disparities; existing programs and policies; best practices and successful strategies in such programs; priorities for successful intervention and potential opportunities for expansion and replication.

- The bill would direct the Secretary to develop guidelines for development and implementation of programs and activities to reduce health disparities no later than 90 days after the submission of the IoM report.
- The bill would authorize HHS to award grants for disparities reduction activities.
- The bill did not direct any specific action to be undertaken by NIH or NCI.
- The findings sections of the bill highlighted disparities in cancer mortality among African Americans as compared to Whites, mentioning prostate and breast cancer mortality disparities in particular.
- Sen. Cory Booker (D-NJ) introduced S. 2841 on 9/17/10. The bill was referred to the Committee on Health, Education, Labor and Pensions. Rep. Bill Pascrell (D-NJ) introduced H.R. 5507 on 9/17/1. It was referred to the Committee on Energy and Commerce and the Committee on Ways and Means.

National Prostate Cancer Council Act (S. 2813; 113th Congress)

- The bill would establish the National Prostate Cancer Council on Screening, Early Detection, Assessment, and Monitoring of Prostate Cancer (Council) within the HHS.
- The bill directs the Council to develop a national 5-year strategic plan to guide research and development, and to play a role in coordinating research efforts across federal agencies.
- Additional responsibilities of the Council would include evaluating all federal prostate cancer programs; submitting an annual report to Congress regarding implementation of the 5-year plan; and ensuring that men at high-risk for the disease be included in clinical research.
- The bill would require that the first annual report include recommendations to expand, eliminate, coordinate, or condense federal programs, subsequent reports would identify specific roles for NCI, NIMHD, and the DHHS Office of Minority Health.
- Federal members of the Council would include a representative of the NCI, NIBIB, CDC, CMS, FDA, AHRQ and one member each designated by the Director of the DoD Congressionally Directed Medical Research Program and by the Director of the Office of Minority Health.
- Sen. Barbara Boxer (D-CA) introduced S. 2813 on 9/16/2014. The bill was referred to the Committee on Health, Education, Labor, and Pensions.

Patient Centered Quality Care for Life Act (S. 2800; 113th Congress)

- The bill would direct the HHS Secretary to hold a strategic summit to analyze key health system barriers to providing patient-centered health care and identify strategic solutions for collectively addressing quality of life concerns.
- The bill would direct the Secretary, through the CDC, to establish a quality of life education and awareness grants program for seriously ill patients, their families and their health professionals.
- The bill would direct the Secretary to create grants to develop information, resources, and communication materials on illness management.
- The bill was introduced by Sen. Mark Begich (D-AK) on 9/11/2014. The bill was referred to the Committee on Health, Education, Labor, and Pensions.

Sugar Sweetened Beverages Tax (SWEET) Act of 2014 (H.R. 5279; 113th Congress)

- The bill proposes to tax sugar-sweetened beverage products and to appropriate an amount equal to the revenues directly to the Prevention and Public Health fund.
- The bill directs that those appropriated funds would be allocated to the HHS for programs and research designed to reduce the human and economic costs of diabetes, obesity, dental caries, and other diet-related health conditions. The bill findings also recognize that obesity increases the risk for certain cancers, including postmenopausal breast, colorectal, and pancreatic cancers.
- Rep. Rosa DeLauro introduced H.R. 5279 on 7/30/2014, and the bill was referred to the Committees on Energy and Commerce, and Ways and Means.

Health Equity and Accountability Act (H.R. 5294; 113th Congress)

- The bill seeks to improve the health of minority individuals and includes a multi-part focus on cancers and minority populations.

- The bill would direct NCI to conduct a strategic review and prioritization of grants to reduce lung cancer mortality.
- The bill calls for the creation of a prostate cancer task force, to include the NCI, to develop a comprehensive interagency strategy.
- The bill directs the NCI, along with NIH and the CDC, to conduct research in areas including the prevention, history, pathophysiology, screening, diagnostics, management and treatment of hepatitis b, hepatitis c, and liver cancer.
- The bill calls for the creation of an advisory committee, to include NCI, on acquired bone marrow failure diseases. The bill would also direct NCI to conduct research on the causes and treatments for these bone marrow failure diseases.
- Rep. Lucille Royal-Allard (D-CA) introduced H.R. 5294 on 7/30/2014. The bill was referred to the Committees on Energy and Commerce; Ways and Means; Agriculture, Education and the Workforce; the Budget, Veterans' Affairs, Armed Services; the Judiciary; and Natural Resources.

Additional information: Similar legislation was introduced by Rep. Barbara Lee (D-CA) and former Sen. Daniel Akaka (D-HI) in the 112th Congress, and Rep. Donna Christensen (D-VI) in the 111th Congress. These proposals did not move out of committee.

Research and Development Efficiency Act (H.R. 5056; 113th Congress)

- The bill directs the Office of Science and Technology Policy (OSTP) to establish a working group under the National Science and Technology Council, to include the Office of Management and Budget, to review Federal regulations affecting research and research universities and make recommendations to eliminate duplicative regulations and reporting requirements in an effort to reduce the administrative burden on research universities.
- The bill findings emphasize a need to streamline the administrative costs of federally funded research and reference a goal of ensuring that a larger proportion of federal R&D funding goes to support direct research costs.
- The bill calls for input from a variety of non-Federal research and development stakeholders, including federally or non-federally funded researchers, universities, and industry.
- The bill requires the OSTP Director to issue a report to Congress within a year and then annually for the next 3 years on actions taken to implement the working group's recommendations.
- Reps. Larry Bucshon (R-IN) and Scott Peters (D-CA) introduced H.R. 5056 on 7/10/2014. The bill was referred to the Committee on Science, Space, and Technology. **The bill was considered under suspension of the rules in the House on 7/14/14, and passed by a voice vote.**

International Science and Technology Cooperation Act (H.R. 5029; 113th Congress)

- The bill directs the Office of Science and Technology Policy (OSTP) to establish an entity under the authority of the National Science and Technology Council to identify, coordinate, and advance international science and technology programs conducted or funded by the U.S. government. OSTP and Department of State senior level officials will co-chair the entity.
- The bill requires the entity to establish priorities for such research in alignment with U.S. foreign policy goals. The bill also aims to identify broad issues, including barriers, to enhance the collaboration and training of U.S. scientists and engineers with their foreign counterparts.
- The bill calls for input from a variety of non-Federal science and technology stakeholders, including academia, scientific and professional societies and industry, to identify opportunities for research.
- The bill requires the OSTP Director to issue an annual report to the House Committee on Science, Space and Technology and the House Committee on Foreign Affairs and its counterparts on the Senate side.
- Rep. Daniel Lipinski (D-IL) introduced H.R. 5029 on 7/8/14. The bill was referred to the Committee on Science, Space and Technology. **The House passed the bill by roll call vote, 346-41, under suspension of the rules on 7/14/14.**

Stop Selling and Marketing to our Kids E-Cigarettes (SMOKE) Act (H.R. 5010; 113th Congress)

- The bill proposes to amend the Federal Food, Drug, and Cosmetic Act to give the Food and Drug Administration (FDA) direct regulatory authority over electronic nicotine delivery systems and e-liquids (ultimately bypassing the deeming process currently underway for e-cigarettes and other tobacco products).
- The bill also proposes to amend the Federal Cigarette Labeling and Advertising Act to include e-cigarettes and other electronic nicotine delivery systems in addition to cigarettes and other tobacco products currently covered by the Act. This would effectively require that electronic nicotine delivery device packaging include health-related warning labels approved by HHS, and would also prohibit television and radio advertising for these products. Additionally, the bill would direct the Federal Trade Commission, through existing authorities to prohibit deceptive practices, to prohibit the marketing of electronic nicotine delivery systems to children.
- The bill would direct the FDA to conduct within a year a study on whether the use of flavorings in e-liquids appeals to adults and children. Upon completion of the study, the FDA will determine whether to prohibit or restrict the use of flavorings.
- The bill would require child-proofing packaging and limitations on nicotine dosage and concentration for e-liquids.
- The bill does not preempt state law except for specific provisions inconsistent with this Act.
- Rep. Jackie Speier (D-CA) introduced H.R. 5010 on 6/26/2014. The bill was referred to the Committee on Energy and Commerce.

Research for All Act of 2014 (HR 4879. 113th Congress)

- The bill, among other provisions, encourages additional research on the study of female animals, tissues, and cells, directing the NIH to make a determination within one year regarding when to include both male and female cells, tissues or animals in basic research projects. The bill would require the NIH Director to consult with the NIH Office of Research on Women's Health, the NIH Office of Laboratory Animal Welfare, the Institute of Medicine and other members of the scientific community in making the determination.
- The bill would also require, that within one year of enactment, that the results of NIH-supported basic research are disaggregated according to whether animal subjects are male or female, and whether cells or tissues are derived from male or female organisms.
- The bill indicates that the HHS Secretary may award grants or other support for the continued operation and expansion of "Special Centers of Research on Sex Differences," and also directs the GAO to update its 2000 report on NIH efforts to increase women's participation in research.
- Rep. Jim Cooper (D-TN) introduced H.R. 4879 on 6/17/2014. The bill was referred to the Committee on Energy and Commerce.

Women and Minorities in STEM Booster Act (H.R. 4833)

- The bill directs the National Science Foundation to establish a grant program to support increasing the participation of women and underrepresented minorities in the fields of science, technology, engineering, and mathematics.
- Rep. Carolyn Maloney (D-NY) introduced H.R. 4833 on 6/10/14. The bill was referred to the Committee on Science, Space and Technology.

Robin Danielson Act of 2014 (H.R. 4746)

- The bill would direct the NIH to support research to study the risks posed by the presence of dioxin, a known human carcinogen, and other components of feminine hygiene products.
- The bill identifies specific areas of study, including risks relating to cervical, ovarian, and breast cancers and requires that the NIH submit reports on research results to Congress, the Food and Drug Administration, and the Environmental Protection Agency.
- Re. Carolyn Maloney (D-NY) introduced H.R. 4746 on 5/28/14. The bill was referred to the Committee on Energy and Commerce.

Fit for Life Act of 2014 (H.R. 4765)

- The bill would address childhood obesity in underserved American communities through a variety of measures including expansion of fresh fruit and vegetable programs and establishing programs aimed at improving healthy eating and physical activity among children
- The bill directs HHS to award competitive grants to establish a 3-year pilot program to 5 state health departments to help reduce and prevent obesity in childcare settings. It would also require HHS to award competitive grants to prevention research centers or universities to evaluate the pilot program.
- Rep. Marcia Fudge (D-TX) introduced H.R. 4765 on 5/29/14. The bill was referred to the Committees on Energy and Commerce, the Agriculture, Education and the Workforce, the Judiciary, Financial Services and Natural Resources.

Removing Barriers to Colorectal Cancer Screening Act of 2014 (S.2348)

- The bill aims to amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening. This would provide for full coverage of colorectal cancer screening tests under Medicare part B.
- S.2348 was introduced by Sen. Sherrod Brown (D-OH) on 5/15/14 and was referred to the Committee on Finance.

Additional Information: Rep. Charles Dent (R-PA) had introduced an identical bill in the House, H.R. 1070, on 3/12/13. The House bill, which has 71 co-sponsors, was referred to the House Energy and Commerce Committee, Subcommittee on Health, as well as the House Ways and Means Committee, and has not moved out of either committee.

American Cures Act/ America HEALS Act (S. 2115/H.R. 4384)

- The bill proposes to establish a Biomedical Research Fund, to be administered by the Secretary of Treasury, and authorizes funding to be appropriated to support an expanded and sustained national investment in biomedical research by increasing funding for eligible programs within the NIH, the Centers for Disease Control and Prevention, the Department of Defense and the Department of Veterans Affairs.
- The bill proposes \$150 billion in mandatory funding over 10 years, starting with \$1.8 billion in the first year. Each year, the bill would increase funding for each agency and program at a rate of GDP-indexed inflation plus 5 percent.
- S. 2115 was introduced by Sen. Richard Durbin (D-IL) on 3/12/14 and was referred to the Health, Education, Labor, and Pensions (HELP) Committee.
- Rep. Anna Eshoo (D-CA) introduced the America HEALS (Helping Encourage Advancements in Lifesaving Science) Act, H.R. 4384 on 4/3/14. Other than their titles, S. 2115 and H.R. 4384 are identical. H.R. 4384 was referred to the House Energy and Commerce Committee, Subcommittee on Health.

Selected Recent Resolutions (113th 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.

Introduced

Expressing Support for Designating September 2014 as “National Prostate Cancer Awareness Month” (H.Res. 740; 113th Congress)

- The resolution emphasizes support for research to improve screening and treatment of prostate cancer, and designates September 2014 as National Prostate Cancer Awareness Month.
- Rep. Randy Neugebauer (R-TX) introduced the resolution on 9/18/2014. The resolution was referred to the Committee on Energy and Commerce.

Expressing Support for Designating September as “Clinical Research Innovation Month” (H. Res. 733; 113th Congress)

- The resolution recognizes the many contributions of clinical research organizations to the U.S., including research to combat diseases such as breast cancer, hepatitis and diabetes.
- Rep. Scott Peters (D-CA) introduced H.Res. 733 on 9/17/2014. The resolution was referred to the Committee on Energy and Commerce.

National Ovarian Cancer Awareness Month (H. Res. 697)

- This resolution designates September 2014 as National Ovarian Awareness Month to increase public awareness of ovarian cancer.
- H. Res. 697 was introduced by Rep. Rosa DeLauro (D-NY) on 7/30/14. The resolution was referred to the Committee on House Oversight and Government Reform.

National Public health Week (H.Res. 527)

- A resolution supporting the goals and ideals of National Public Health Week, April 7-13, 2014. The resolution includes languages recognizing the contributions of local public health efforts to cancer prevention.
- H.Res. 527 was introduced by Rep. Lucille Roybal-Allard (D-CA) on 3/27/14 and was referred to the Energy and Commerce Committee.

National Multiple Myeloma Awareness Month H.Res. 528

- A resolution expressing support for designation of March 2014 as National Multiple Myeloma Awareness Month.
- H.Res. 528 was introduced by Rep. Spencer Baucus (R-AL) on 3/27/14 and was referred to the Oversight and Government Reform Committee.

National Minority Health Month (H.Res. 560)

- This resolution recognizes April as National Minority Health Awareness Month.
- H. Res. 560 was introduced by Rep. Al Green (D-TX) on 4/30/14 and was referred to the Committee on Oversight and Government Reform.

Recognizing the Mortality Rate of African American Women with Breast Cancer (H.Res. 554)

- The resolution recognizes the disparity in treatment rates of African-American breast cancer patients and calls for immediate action to raise awareness of breast cancer screening and to expand access to treatment for all breast cancer patients regardless of race.
- H.Res.554 was introduced by Rep. Janice Hahn (D-CA) on 4/10/14 and was referred to the Energy and Commerce Committee.

National Bladder Cancer Awareness Month (H.Res. 538)

- A resolution expressing support for designation of May as National Bladder Cancer Awareness Month.
- H.Res.538 was introduced by Rep. Matt Cartwright (D-PA) on 4/3/14 and was referred to the Energy and Commerce Committee.

Expressing the sense of the House of Representatives that the National Institutes of Health should develop a pilot program to improve medical trial participation, retention, efficiency, effectiveness, and diversity. (H.Res. 510)

- The resolution would demonstrate the sense of the House that the National Institutes of Health (NIH) should, within existing budget and authority, establish a pilot partnership with non-profit organizations to increase the efficiency and effectiveness of clinical trials of the National Institutes of Health, increase patient enrollment and retention, and address the lack of diversity in NIH trials.
- The resolution indicates that the goals of the partnership should include providing navigation services to help patients find, enroll, and manage the logistical issues related enrollment and retention in federally supported clinical trials, and to improve participation levels among “underrepresented and uninsured individuals.”

- H.Res. 510 was introduced by Rep. Jack Kingston (R-GA) on 3/11/14 and was referred to the House Committee on Energy and Commerce.

Passed

Expressing Support for Designating September 2014 as “National Prostate Cancer Awareness Month” (S.Res. 575; 113th Congress)

- The resolution emphasizes support for research to improve screening and treatment of prostate cancer, and designates September 2014 as National Prostate Cancer Awareness Month.
- Sen. Jeff Sessions (R-AL) introduced the resolution on 9/18/2014, and the Senate passed the resolution by unanimous consent.

National Ovarian Cancer Awareness Month (S. Res. 536)

- This resolution designates September 2014 as National Ovarian Awareness Month to increase public awareness of ovarian cancer.
- S. Res. 536 was introduced by Sen. Debbie Stabenow (D-WI) and was agreed to in the Senate by unanimous consent on 8/1/14.

National Men’s Health Week (S.Res. 473)

- This resolution celebrates the 20th Anniversary of Men’s Health Week (June 9-15, 2014), and mentions a number of health conditions that affect men, including testicular, prostate, and colon cancers.
- S. Res. 473 was introduced by Sen. Mike Crapo (R-ID) on 6/12/14 and was passed by unanimous consent.

National Cancer Research Month (S.Res. 445)

- This resolution recognizes May as National Cancer Research Month as well as the importance of cancer research and the contributions of scientists, clinicians, and patient advocates who are dedicated to finding a cure for cancer.
- S. Res. 445 was introduced by Sen. Dianne Feinstein (D-CA), along with Sen. Johnny Isakson (R-GA) – co-chairs on the Senate Cancer Coalition, on 5/14/14 and was adopted by unanimous consent on 5/21/14.

National Minority Health Month (S.Res. 428)

- This resolution recognizes April as National Minority Health Awareness Month.
- S. Res. 428 was introduced by Sen. Benjamin Cardin (D-MD) on 4/29/14 and was passed by unanimous consent.

Appendix 1.

Testimony Before the Subcommittee on Research and Technology Committee on Science, Space, and Technology United States House of Representatives

**Statement of
Harold Varmus, M.D.
Director
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services**

Thursday July 17, 2014

Chairman Bucshon, Mr. Lipinski, and other Committee members:

Thank you for conducting this important hearing that addresses critical issues about the state of the American scientific enterprise.

This is a pivotal moment for our enterprise. On the one hand, the United States continues to lead the world in its investments, both public and private, in most fields of science and technology; and its discoveries and applications of scientific knowledge have enriched the country, improved the world, and expanded opportunities for further discovery and application. But, in recent years the United States has been challenged by fiscal constraints, while other countries have quickened the pace of their investments (1).

Under these circumstances, it is important for the Nation to evaluate its scientific enterprise—and not just to determine how much we are prepared to invest. We must also understand the operation of our enterprise well enough to know how the basic and applied sciences can most effectively work together to create knowledge and to use that knowledge for the benefit of society through the applied sciences. I take that to be the ultimate goal of this hearing.

Such an evaluation of the scientific landscape is difficult because the terrain is complex and can be viewed in at least four dimensions. First, many approaches to science exist as defined disciplines, and a confluence of disciplines is often required for important discoveries (2); second, within many fields of inquiry, there is a spectrum of activities, ranging from basic studies of the fundamental principles of nature to more pragmatic efforts to use basic knowledge to solve a wide range of societal problems, as originally described by Vannevar Bush (3); third, these many activities are supported by a variety of sources, including many governmental agencies, small and large companies, academic institutions, and private philanthropies; and, finally, financial

support, especially from Federal science agencies, is provided through several kinds of mechanisms, including small and large grants to individuals, teams, and institutions for open-ended or targeted research or for training.

Balancing the elements in the landscape of science

Achieving an appropriate balance among these elements of the scientific enterprise is of obvious interest to this Subcommittee and to those, like today's panel members, who direct or have directed research on behalf of U.S. Government agencies, academic institutions, or private companies. Based on my own experience and observations as a leader of biomedical research in both the governmental and academic sectors, I would like to make four main points to help guide our discussion of the current dilemma:

- 1) For most major advances in medicine, several scientific disciplines have been essential (I will provide old, recent, and prospective examples below). Thus, the likelihood of more progress in the decades ahead requires diversified support and the encouragement of multi-disciplinary work.
- 2) When financial support is highly competitive, the choice of research projects veers towards the development of deliverable applications of existing knowledge and away from basic science, posing a serious risk to future productivity. This demands informed guidance from leaders in Government and industry to ensure the maintenance of a healthy environment for fundamental research.
- 3) Coordinated efforts among funding sources are desirable and possible but require the cooperation and attention of institutional leaders.
- 4) In my own domain of cancer research—and generally in medical research—several promising efforts are being made by the NCI and rest of the NIH to encourage inter-disciplinary “team” science, protect investigators pursuing fundamental studies, and work with funding partners (again, some specific examples will be mentioned below).

The importance of multiple disciplines to solve problems in medicine

From its earliest days, medical science has been dependent on the disciplines of physics and chemistry. The truth of this assertion is evident from any list of major developments in medicine (4): microscopes (to identify infectious agents and cellular structures), X-ray machines (to reveal the living skeleton and deliver cancer therapy), radioisotopes (to track biological molecules and treat certain cancers), pharmacology (to determine the composition and fate of therapeutic drugs) and the EKG and EEG (to monitor the functional status of the heart and the brain through electrical activity).

More recently, major advances in the study of genes, proteins, and cells—from human beings and many other organisms—have revolutionized the study of normal and diseased human beings. This has been possible only because of crucial discoveries (e.g., crystallography, mass

spectroscopy, nuclear magnetic resonance, DNA sequencing methods and machines) that require physics, mathematics, engineering, and chemistry. Furthermore, the massive data sets now available from the use of these methods would neither exist nor be useful without the powerful tools provided by computational science. New devices for characterizing at one time many genes, many proteins or even many individual cells are the products of advances in physics and engineering—such as microfluidics, cryolithography, materials sciences, and nanotechnology.

Similarly, the ambitions of newly launched initiatives, such as the President’s BRAIN project or therapeutics based on genetic signatures (“precision medicine”), will depend on principles of electrical circuitry, optogenetics, computation, mathematical modeling, and chemi-luminescence. In other words, the future of medicine, just like the past and present, will depend on the vibrancy of allied fields of science and technology and on the alertness of leaders of those fields to the possibilities for productive interaction.

Basic biological research is essential for future discoveries that will be applied to medicine

Most facets of medical research have been transformed over the past decade or two by the unveiling of genetic blueprints and the identification of the specific genetic and biochemical lesions that cause most human diseases. This means that even basic biomedical scientists without direct medical experience can now study human diseases and the means to prevent and treat them more effectively.

However, despite enormous increases in knowledge about mammalian biology, it is also clear that fundamental features of biological systems have yet to be discovered—sometimes because we have yet to develop the necessary experimental tools, sometimes because the right questions have yet to be asked and the right experiments have yet to be done.

This has been demonstrated dramatically over the past few years by the discovery of several unanticipated forms of RNA molecules that perform functions other than their well-known roles in the synthesis of proteins. Some very small RNA’s interfere with the expression of one or more genes—functions that are biologically critical and experimentally transforming—and other longer RNA’s have yet to be assigned a clear function. The need to study unusual organisms to probe the depth of biological complexity has also been illustrated by recent findings of enzymes that can permit rapid and efficient re-engineering of genes (*e.g.*, the TALEN and CRISPR systems) and of proteins that allow monitoring of gene expression and function with light of defined wavelengths (fluorescent proteins).

Furthermore, our understanding of the circuitry of biochemical signals that govern cell functions (such as cell growth, death, aging, metabolism, migration, information processing, and immune responses) are still in a primitive state. Unanticipated results and methods that can come only from unfettered basic research—involving biology, chemistry, physics, math, computational sciences and other disciplines—will be required to solve these problems and

generate a new and completely unanticipated set of ideas from which practical applications can be developed.

Funders of research should aim for a balanced and synergistic portfolio

Many kinds of organizations support a wide array of research and development, so it is unrealistic to expect all components to attend to the needs of all disciplines or to the full spectrum of basic to applied research. For example, the financial demands placed on commercial entities prevent any extensive commitment to unfettered basic research, but those demands do intensify their interest in using new discoveries for development of useful products. Conversely, governmental science agencies, academic institutions, and some charities that support research have a mandate to invest in fundamental science with a long view—a long view that some unanticipated discoveries will be revolutionary in concept, establish positions of national and institutional leadership, and provide new foundations for product development by industry. Indeed, these are the ideas, articulated by Vannevar Bush nearly seventy years ago (3) that have been the basis for the past successes of American science.

Because the boundaries of research are more difficult to define than the extremes, there will inevitably be overlap in the ambitions of the entities that fund research, just as there are in the ambitions of those who perform it. But, the U.S. Government has a unique role in supporting basic research. At the same time, Government agencies, along with universities, private funders, and commercial entities, should be seeking ways to collaborate for at least three purposes: to learn where and how scarce resources are being committed; to seek opportunities to engage in collaborative work; and to exchange information that may accelerate progress along the full spectrum of research and development.

NCI uses a variety of mechanisms to promote effective, multi-disciplinary research

Especially in fiscally challenging times, it is essential that the Government's science agencies maintain the public's trust by deploying their funds in accord with practices that have been productive in the past. The NCI, a component of the NIH, has benefited historically from a portfolio of funding mechanisms. These include the award of various kinds of grants and contracts to individuals, groups, and institutions to perform studies that range from investigator-initiated to agency-determined; the development of an intramural research program conducted by Government scientists in NCI laboratories; and the use of a Government-owned, contractor-operated cancer research laboratory in Frederick, Maryland.

We use these mechanisms to support basic, translational, and clinical work on a wide variety of cancer-related problems and to train scientists in several disciplines. Over the past few years, we have taken advantage of the flexible nature of the mechanisms to establish new programs that we believe are suited to the opportunities and stresses of our times. Some of these efforts are especially noteworthy in the context of today's discussion because of their inter-disciplinary or collaborative nature:

- The Cancer Genome Atlas (TCGA) project, now drawing to a close, has supported many hundreds of DNA sequencers, geneticists, bioinformatics experts, oncologists, and others to identify and compile an extensive set of characteristics about over twenty of the most common forms of human cancer. Now this information is being reviewed for general patterns, used for the pursuit of new diagnostics and therapeutics, and employed as a basis for more detailed studies of certain cancers.
- The Frederick National Laboratory for Cancer Research (FNLCR), itself modeled in part on the Department of Energy's national laboratories, has developed important core laboratories that serve the Nation's efforts in nanotechnology (the Nanotechnology Characterization Laboratory [NCL]), imaging, and other complex multi-disciplinary fields (the NCL is also part of the National Nanotechnology Initiative, a coordinated Federal activity spanning other NIH Institutes and 19 other Federal agencies).
- The FNLCR recently initiated a nationwide project to identify new strategies for attacking cancers driven by one of the three major genes in the RAS family (such cancers constitute about a third of all human tumors). The RAS project has engaged a wide range of scientific expertise—in structural biology, protein chemistry, DOE-derived cell imaging methods, and computation—and investigators at many institutions.
- Both the intramural and the grant-making programs at the NCI have promoted the engagement of engineers, mathematicians, and physicists in cancer research. The intramural program has developed a partnership with physicists at the University of Maryland for collaborative projects. The extramural program has issued a request for applications to continue or create centers for the use of physical sciences in cancer research, and it issues grants and contracts for mathematicians to model cancerous cell behavior and for computational scientists to build cloud-based systems to store and analyze large data sets.
- To provide greater stability for NCI-funded investigators who have a record of high achievement and wish to engage in ambitious, long-term studies, the NCI has recently announced an Outstanding Investigator Award. We believe that these awards will encourage our best investigators to undertake risky work, particularly in the vulnerable fundamental sciences.
- To make “precision medicine” a reality in cancer treatment, the NCI is reorganizing the conduct of its clinical trials to include genetic characterization of each patient's tumor and reference to large databases of clinical information to guide the choice of drugs to be tested. This requires extensive interaction with the Food and Drug Administration, the pharmaceutical industry, and patient advocacy groups, as well as collaboration among scientists and clinicians from several disciplines.
- The NCI's Provocative Questions initiative was created a few years ago to bring imaginative scientists from several disciplines together to identify important questions about cancer that have yet to be adequately addressed. The most interesting questions are advertised by the NCI as topics for individual research projects and many grants have been awarded.

Reprise

Our complex and traditionally successful scientific enterprise now confronts expanded opportunities at a time of fiscal constraints and foreign challenges. Nurturing the health of many disciplines, preserving the Nation's commitment to fundamental research, and coordinating the support of research from many funding sources will be essential to realize the potential of the Nation's enterprise. The NCI is committed to those goals and has taken several steps to honor those commitments.

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Appendix 2.

Testimony Before the Special Committee on Aging United States Senate

**Statement of
Harold Varmus, M.D.
Director
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services**

Wednesday May 7, 2014

Mr. Chairman, Senator Collins, and others:

I am pleased to appear today on behalf of the National Cancer Institute to discuss the relationship of cancer to aging.

It is an opportune moment for this discussion. Thanks in large part to improvements in health care, life expectancy has been extended at unprecedented rates, both in our country and around the world. The number of people over age 65 is growing especially rapidly in countries like the United States that experienced sharp increases in birth rates shortly after World War II, nearly 70 years ago. Furthermore, significant progress is being made in cancer research, with a much deeper understanding of the nature of this complex set of diseases and with improvements in the way we prevent, diagnose, and treat many kinds of cancers. Hence, there is both a need and an opportunity to address more effectively the problems presented by cancers in the elderly.

Because most types of cancer—but not all—are commonly diagnosed in older age groups, the number of people with cancer is rising, and will continue to rise, here and globally. This chart (the only one I will show) displays both the current and anticipated future distribution of new cases of cancer, grouped by age range, in the United States. As you can see, the absolute number of cases will rise from about 1.7 million today to about 2.5 million by 2040. The majority of new cases already occurs in three age groups—65 to 74, 75 to 84, and 85 or greater. The proportions will increase in all three groups over the next thirty years, assuming that current patterns are maintained, with little change in the younger groups. Of course, we aspire to change those patterns with more effective means to prevent cancers. But the pace of such change is inherently slow, in part because cancers develop over many years, not days or months.

As the elderly population grows and our ability to treat cancer improves, we are also observing greater numbers of people, especially among the older age groups, who are survivors of cancer. Cancer survivors are people who have had a cancer diagnosed at anytime in the past, whether or not they remain under treatment or have evidence of cancer currently. At present, there are over 13 million cancer survivors in the United States, up from about three million in the early 1970s, and the number is expected to rise to about 18 million by 2020. More than half of these people are over 65 years of age, and that older group will experience the major increase in numbers.

During the next several minutes, I will summarize what we know about the biological basis of the relationship of cancer to aging; what can now be done to prevent, detect, and treat cancer more effectively, especially among the elderly; and how the NCI and its research community plan to expand our knowledge of the relationship of cancer to aging, in hopes of reducing the burden of cancer among those at advanced ages.

In considering all of these topics, it is important to keep in mind the special vulnerabilities of older individuals—including, in particular, co-existing medical conditions (referred to as “co-morbidities”) that can shorten life independently of the effects of cancer and can complicate delivery of cancer therapies.

The relationship of cancer and aging

Overall, cancers are diseases caused by accumulated changes, mostly mutations, in a cell’s genome. Since those changes accumulate with age, the incidence of cancers also increases as people age. Further, the number of cases in each country rises as life expectancy increases, even without any increase in the incidence (or rate of occurrence). This is a large part of the reason why cancers, as well as other non-communicable diseases, have recently become major causes of morbidity and mortality in the developing world, where overall life expectancy is rising rapidly.

To distinguish between changes in the age distribution of a population and changes in our ability to prevent and treat cancers, it is important to monitor progress against cancer by reporting rates of incidence and mortality, adjusted for changes in length of life, not simply by counting the numbers of cases. Furthermore, the relationship of cancer to age is not simple: not all cancer types show an increased incidence with increased age.

Recall that there are many types of cancer, and these types arise in different kinds of cells and in different organs. Moreover, we now know that these different cancers generally carry different constellations of changes in DNA. This means that the incidence of each cancer type is influenced by the numbers of cells at risk of becoming cancerous in each organ at different ages. The risk of developing cancers of different types is also affected by the degree of exposure to environmental agents that cause mutations; by gene variations inherited from one’s parents; by the function of the immune system, which itself appears to weaken as we age; and by the

availability of methods that prevent cancers or detect abnormal cells before they become fully malignant.

In view of these varied factors, it is not surprising that types of cancer vary with regard to the time of onset. Most dramatically, some cancers—like retinoblastomas, some leukemias and lymphomas, and some brain and bone cancers—are largely confined to children, adolescents, and young adults. In contrast, the median age of onset of most of the common cancers is between the ages of 61 and 72, consistent with the more general conclusion (reflected in the chart) that over half of all cancers are diagnosed in older age groups. There is one further complication: while most findings argue for increasing rates of cancer with increasing age, the age-adjusted rate (or incidence) of many cancers appears to fall at highly advanced ages.¹

I will say more in a few minutes about some of these perplexing—and potentially informative—relationships between age and cancer incidence. But I want to conclude this segment of my testimony by reminding you of the dominant facts and their implications. First, the U.S. population is rapidly aging. The numbers of people over the ages of 65, 75, and 85 will all increase markedly over the next three decades, with nearly a doubling of the number over 65 and nearly a tripling of those over 85. Second, even now over half of all cancers are diagnosed in people over the age of 65, so age must be viewed as a major risk factor for cancer, along with use of tobacco, excessive exposure to other carcinogenic agents, and inheritance of certain genetic variations. Thus the number of cancer cases is likely to rise significantly over the next few decades in this country and around the world.

Preventing cancer as people age: risk assessment, screening, early diagnosis

For people of any age, the first line of defense against cancers and their damaging consequences is prevention. Prevention encompasses at least four strategies: the methods (behavioral change or vaccines) that avoid cancer-causing agents or conditions, like tobacco use, obesity, or infection with certain viruses; an assessment of inherited genetic risk; the screening procedures that detect abnormal cells before they develop into life-threatening cancers; and the long-term use of drugs, as proposed for aspirin, that reduce the incidence of certain cancers.

Some of these have attributes that are particularly relevant to today's discussion of cancer in older populations. I want to mention three of these: tobacco cessation, screening methods, and aspirin use.

(1) It is widely known that use of tobacco, especially cigarette smoking, is the major avoidable risk factor for several types of cancer, especially lung cancers. Nevertheless, the health benefits of stopping tobacco use in middle age are underappreciated, and the benefits of stopping at more advanced ages have been inadequately studied. A recent review by Jha and Peto (New England

¹ <http://wonder.cdc.gov/cancer.html>

Journal of Medicine 370:60, 2014) points out that even long-term smokers can relatively quickly regain several years of life-expectancy lost by active smoking when they stop at age 50. However, not enough information is available about elderly people who have recently stopped smoking to know how significant the benefits would be at higher ages.

(2) Screening tests have been developed for several common types of cancer—such as breast, skin, cervical, prostate, and colorectal cancers—but the use of those tests has often been controversial because of uncertainties about cost-benefit ratios and about the ages at which screening should commence or be concluded. Some common tests—such as the Pap smear for cervical cancer and colonoscopy for colorectal cancer—are not routinely recommended for people over certain ages (65 and 75 in the two instances mentioned), because there are harms (direct effects, such as colon perforation during colonoscopy, or over-diagnosis and over-treatment), as well as the obvious advantages, associated with most screening tests; because overall life expectancy (and hence benefit) declines at increasing age; and because certain cancers (such as cervical cancer) are less frequently diagnosed at advanced ages.

For some tests, there is simply inadequate information to make an evidence-based recommendation. For example, use of helical CT scanning for lung cancer is now being adopted in the United States, with guidelines based mostly on the findings from the NCI's Lung Cancer Screening Trial (New Engl. J. Med 365: 395-409, 2011). In that trial, subjects were smokers or former smokers in good general health between the ages of 55 and 74 at the start of the study. Hence, it is difficult to make recommendations for individuals over the age of 74 or for those with co-morbid conditions, a common situation among tobacco smokers. Current guidance, based upon statistical modeling rather than direct evidence, suggests lung screening until the age of 80, but additional studies will be required to make secure recommendations for still older populations.

(3) Extensive pooled analysis of several studies of people who have taken low-dose aspirin for many years shows a highly significant reduction in incidence and mortality of several types of cancer, including gastro-intestinal and lung cancers (Lancet 377:31-41, 2011; 379:1602-1612, 2012). However, adoption of long-term chemoprevention of cancer with aspirin has been limited by concerns about the major side effect—gastrointestinal bleeding—especially in older individuals. NCI is collaborating with the National Institute on Aging (NIA) on a five-year study of aspirin's preventive attributes and side-effects in 19,000 individuals over age 65 in the United States and Australia, in hopes of providing information that will better guide the use of aspirin for chemoprevention.

Treating cancer appropriately in older patients

Historically, there has been a tendency to use less aggressive therapies in older patients with cancer, but that approach has been changing in response to several observations. First, many have noted the importance of distinguishing between chronological age (one's age in years) and physiological or functional age, especially in the oldest population groups, when making decisions

about a therapeutic strategy. Patients who have a high chronological age are often resilient physiologically and able to withstand the rigors of most aggressive forms of cancer therapy.

In current practice, elderly cancer patients who are otherwise in good health—unlike those with severe co-morbidities or advanced neurological deficits—are now likely to receive surgery, radiotherapy, and/or drug therapy indistinguishable from that provided to relatively young patients.

This is being done because ample evidence suggests that healthy but chronologically old patients are capable of withstanding such therapies; because improved methods exist for controlling the symptoms (such as pain, nausea, and bone marrow suppression) that often accompany cancers or cancer treatment; and because benefits from rigorous therapies have been well documented in patients of advanced age. Moreover, it is anticipated that fewer side-effects of cancer therapy will occur as improved surgical methods are developed, radiotherapy is delivered with greater precision and better division of doses, and drug therapy shifts from traditional chemotherapy to the more targeted approaches of “precision medicine”. In addition, the several new immunotherapies—from the use of therapeutic antibodies to methods to strengthen the activity of immune cells—may be quite well tolerated by patients at advanced ages.

To obtain the evidence that supports the use of these therapies in elderly patients, it will be essential to insure that such patients are included in clinical trials. However, about two-thirds of patients in clinical trials are 65 or younger, even though over half of cancers are diagnosed in patients over 65. Despite some increases in the numbers of patients aged 65 to 75 who now participate in trials, the numbers of patients over age 75 who are enrolled in trials remain low, in the range of 10 percent or less. These numbers reflect the prevalence of co-morbidities that may disqualify such patients from enrollment; the difficulty of travelling to the sites of trials; and a persistent prejudice against inclusion of very old patients in trials. These factors require further examination, and the newly reorganized National Community Oncology Research Program (NCORP) is committed to studying patients at older ages and with the common co-morbidities.

Social and psychological aspects of the care of older patients, including the heavy burden often placed on familial caregivers, also deserve increased attention. It is often no easier to make decisions about when to abandon aggressive, curative measures in favor of symptomatic care and referral to hospice for aged patients than for younger ones. These decisions have important effects on quality of life and on economic costs of care.

Learning More About Cancer and Aging

Because NCI studies cancers of all types and because most cancers occur predominantly in older people, NCI is inherently heavily invested in research on this major cause of morbidity and mortality in aging populations. I have already mentioned a number of ways in which our research specifically addresses the relationship between cancers and aging: through studies of the

epidemiology of many kinds of cancer; through efforts to address the utility of preventive measures, like daily aspirin, in older patients; and through attention to the numbers of elderly patients in our clinical trials. Furthermore, we use CISNET (NCI's Cancer Intervention and Surveillance Modeling Network) to analyze existing data and make predictions about optimal use of screening tests, such as helical CT scanning for lung cancers. And other commonly used agents, like metformin for diabetes and statins for lowering blood lipids, as well as aspirin, are being studied for their possible chemo-prevention activity.

NCI is also supporting work on more fundamental aspects of aging and its relationship to cancer. For example, NCI's Provocative Questions initiative has called for applications to study how life span relates to cancer incidence in animals, starting from the observation that certain short-lived animals, like mice, have relatively high rates of cancer, whereas some much longer lived animals, like naked mole rats or reptiles, have very low rates. Other Provocative Questions ask how biological mechanisms might influence susceptibility to cancer risk factors at different stages of life or what aspects of aging, other than mutations, might promote or protect against cancers.

Other features of the biology of aging are also under investigation. The lengths of telomeres, the specialized DNA sequences at the ends of chromosomes, have been implicated in aging and carcinogenesis by many investigators, and both NCI and NIA have significant investments in telomere biology. The immune system is known to undergo functional changes with aging, and (as mentioned earlier) there is renewed interest in immunotherapies for cancer, so NCI is interested in effects of waning immune potency on cancer incidence and on opportunities for therapeutic intervention in older populations. New technologies allow a detailed description of an individual's microbial population, and numerous ideas about the contribution to diseases like cancers made by the microbes we carry during life, including late life, are being tested. Genetic diseases associated with premature aging ("progerias") have recently been examined for cancer incidence; some do not show increased rates of cancer, while those (like Werner Syndrome), characterized by high mutation rates, do. Studies of the effects of aging of mutation rates in different cell types and of the consequences of exposures to known carcinogens are among some of the other aspects of NCI's research program on aging and cancer.

One especially intriguing observation is the inverse relationship between cancer incidence and a diagnosis of degenerative neurological diseases (such as Alzheimer's and Parkinson's Diseases) that are common at advanced ages. In other words, compared to the general population, people with those neurological diseases are less likely to develop cancer, and vice versa. This observation forms the basis of yet another Provocative Question and has attracted the attention of other NIH institutes as well.

Finally, NCI has assembled or joined standing groups of investigators dedicated to the problems posed by aging and cancer, such as TRAC-I (Translational Research at the Aging and Cancer Interface), the Gerosciences Interest Group, and the Chronic Inflammation and Age-Related Disease group.

I would be pleased to respond to any questions you might have.