



CONSORTIUM of SOCIAL SCIENCE ASSOCIATIONS

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**COSSA ANALYSIS OF THE
FY 2016 HOUSE & SENATE LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION, and RELATED AGENCIES APPROPRIATIONS BILLS**

June 30, 2015

The House and Senate both passed their respective fiscal year (FY) 2016 appropriations bills for the Departments of Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) through committee last week. The House, which had marked up its bill in subcommittee on June 17 (see COSSA’s preliminary analysis) sent its bill to the floor on June 24. The Senate marked up its bill in subcommittee on June 23 and in full committee on June 25. The House draft bill is available [here](#), and the Committee report can be found [here](#). Click [here](#) for the Senate’s version of the bill and [here](#) for its Committee report.

Below is an analysis of both bills and their accompanying report language (not otherwise covered in our [preliminary analysis of the House bill](#)) and their implications for social and behavioral science.

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NATIONAL INSTITUTES OF HEALTH

For the National Institutes of Health (NIH), the Senate Appropriations Committee would provide \$32.1 billion, an increase of \$2 billion above the FY 2015 funding level and \$900 million more than the House bill. It is the largest increase the NIH has received since the completion of the doubling of the agency’s budget in 2003. This sum includes \$940 million in transfers available under section 241 of the Public Health Service (PHS) Act. The Committee continues its “reform to section 241 allocations such that no NIH funding will be removed from NIH under this authority” designed to “ensure that section 241 transfers are a benefit to NIH rather than a liability,”

The House bill would provide the NIH with \$31.2 billion, a \$1.1 billion increase above the FY 2015 funding level and \$100 million more than the President’s budget request. The total includes \$30.2 in discretionary appropriations and \$1 billion in PHS transfers. The Committee-provided level is \$560,700 above the pre-sequester level of \$30.6 billion that NIH received in FY 2012. An amendment offered during markup by Labor-HHS Subcommittee Ranking Member Rosa DeLauro (D-CT) to increase NIH funding by an additional \$3 billion by adjusting the spending cap was defeated by a vote of 20-30. The House bill, however, did not provide the increase to the PHS transfers

requested by Administration, “which would have allowed the Secretary to divert an estimated [\$850 thousand] away from NIH.” Instead the bill directs that all PHS funds received by NIH are allocated to the National Institute of General Medical Sciences (NIGMS).

The Senate Appropriations Committee also emphasizes the reprioritization of “how funding is allocated and must clearly recognize the essential role biomedical research plays in every American’s life.” The Committee report accompanying the bill notes that its recommendation “places a high priority on funding by the NIH and believes this funding is necessary to address our Nation’s growing health concerns.” The report notes that the NIH has lost approximately 22 percent of its purchasing power for research, and the likelihood that a grant application will receive funding has fallen to the lowest percentage in decades, now less than 20 percent.

The Senate Committee recommendation also would provide \$650 million in new funding from the Department of Health and Human Services’ (HHS) Non-recurring Expenses Fund (NEF). The bill includes language that would repurpose the NEF, created in FY 2008, specifically for biomedical research activities at NIH. The report emphasizes that the NEF provides a new, additional source of funding for biomedical research. The NIH is directed to provide expenditures from the NEF in FY 2016 in the FY 2017 Congressional Justification actual expenditures.

The Senate Committee notes that funding that would be provided to NIH will increase the resource for investigator-initiated research by seven percent and support more than 11,000 new and competing grants in FY 2016, an increase of 2,500 grants and more than 26 percent above the FY 2015 funding level.

The Senate Committee recommendation includes an increase of \$350 million for Alzheimer’s disease (National Institute on Aging); \$100 million for antimicrobial resistance (National Institute of Allergy and Infectious Diseases); a \$70 million increase for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative; \$200 million for the Precision Medicine Initiative; \$300 million, an increase of \$26.7 million, for the Institutional Development Award (IDeA); and \$12 million for the *Gabriella Miller Kids First Act*. The bill also would provide an increase to every Institute and Center (IC).

The increase in funding provided to NIH by the House bill is generally distributed proportionately among NIH ICs. Specific funding levels are continued for the Clinical and Translational Science Awards program (\$480 million), the Institutional Development Awards program (\$311.8 million), Cures Acceleration Network, Common Fund (\$675.6 million, including \$12 million to support pediatric research as described in the *Gabriella Miller Kids First Research Act*), and the National Children’s Study (\$165 million). Additional resources were added to specific ICs’ budgets to support specific initiatives: Alzheimer’s disease (\$866 million, a \$300 million increase), antibiotic resistance (\$461 million, a \$100 million increase), BRAIN initiative (\$150 million, an increase of \$95 million), and the President’s proposed Precision Medicine Initiative (\$200 million, the requested amount).

| <i>(in millions)</i> | Enacted FY 2015 | Proposed FY 2016 | FY 2016 House | FY 2016 Senate | Senate vs. FY 2015 | Senate vs. Request | House vs. Senate |
|---|--------------------|---------------------|------------------|-------------------|-----------------------|-----------------------|---------------------|
| National Institutes of Health Total | 30311.3 | 31311.3 | 31184.0 | 32084.0 | 5.8% | 2.5% | -2.8% |
| John E. Fogarty International Center for Advanced Study in the Health Sciences | 67.6 | 69.5 | 68.6 | 70.9 | 4.9% | 2.1% | -3.3% |
| National Cancer Institute | 4953.0 | 5098.5 | 5081.8 | 5204.1 | 5.1% | 2.1% | -2.3% |
| National Center for Advancing Translational Sciences | 632.7 | 660.1 | 643.1 | 699.3 | 10.5% | 5.9% | -8.0% |
| National Center for Complementary and Integrative Health | 124.1 | 127.5 | 127.6 | 130.2 | 4.9% | 2.1% | -2.0% |
| National Eye Institute | 676.7 | 695.2 | 698.1 | 709.5 | 4.9% | 2.1% | -1.6% |
| National Heart, Lung, and Blood Institute | 2995.9 | 3071.9 | 3035.1 | 3135.5 | 4.7% | 2.1% | -3.2% |
| National Human Genome Research Institute | 498.7 | 515.5 | 505.6 | 526.2 | 5.5% | 2.1% | -3.9% |
| National Institute on Aging | 1197.5 | 1267.1 | 1518.4 | 1548.5 | 29.3% | 22.2% | -1.9% |
| National Institute on Alcohol Abuse and Alcoholism | 447.2 | 459.8 | 456.0 | 469.4 | 5.0% | 2.1% | -2.8% |
| National Institute of Allergy and Infectious Diseases | 4417.6 | 4614.8 | 4512.9 | 4710.3 | 6.6% | 2.1% | -4.2% |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases | 521.5 | 533.2 | 528.1 | 544.3 | 4.4% | 2.1% | -3.0% |
| National Institute of Biomedical Imaging and Bioengineering | 327.2 | 337.3 | 338.4 | 344.3 | 5.2% | 2.1% | -1.7% |
| Eunice Kennedy Shriver National Institute of Child Health and Human Development | 1286.9 | 1318.1 | 1305.6 | 1345.4 | 4.5% | 2.1% | -3.0% |
| National Institute on Deafness and Other Communication Disorders | 405.2 | 416.2 | 412.4 | 424.9 | 4.9% | 2.1% | -2.9% |
| National Institute of Dental and Craniofacial Research | 397.7 | 406.7 | 404.8 | 415.2 | 4.4% | 2.1% | -2.5% |
| National Institute of Diabetes and Digestive and Kidney Diseases | 1749.1 | 1788.1 | 1771.4 | 1825.2 | 4.3% | 2.1% | -2.9% |
| National Institute on Drug Abuse | 1015.7 | 1047.4 | 1050.9 | 1069.1 | 5.3% | 2.1% | -1.7% |
| National Institute of Environmental Health Sciences | 667.3 | 681.8 | 675.8 | 695.9 | 4.3% | 2.1% | -2.9% |
| National Institute of General Medical Sciences | 2372.3 | 2433.8 | 2439.4 | 2511.4 | 5.9% | 3.2% | -2.9% |
| National Institute of Mental Health | 1433.7 | 1489.4 | 1512.9 | 1520.3 | 6.0% | 2.1% | -0.5% |
| National Institute on Minority Health and Health Disparities | 270.9 | 281.5 | 272.5 | 287.4 | 6.1% | 2.1% | -5.2% |
| National Institute of Neurological Disorders and Stroke | 1604.6 | 1660.4 | 1656.3 | 1694.7 | 5.6% | 2.1% | -2.3% |
| National Institute of Nursing Research | 140.9 | 144.5 | 142.7 | 147.5 | 4.7% | 2.1% | -3.3% |
| National Library of Medicine | 337.3 | 394.1 | 341.1 | 402.3 | 19.3% | 2.1% | -15.2% |

House Committee Report Language

Recognizing the value of extramural research, the Committee encourages NIH to restore at least 90 percent of all NIH resources to the extramural community. NIH is expected to continue its focus on emerging investigators and first-time renewals of young investigators in an effort to significantly reduce the average age of an NIH-supported new investigator. NIH is also expected to support a consistent NIH-wide inflationary policy across all institutes and centers (ICs).

NIH is commended for its recent movement to start an NIH-wide portfolio analysis and strategic planning process. The agency is encouraged to engage with outside strategic planning experts and the community on this effort to promote the advancement of biomedical science “in a manner that builds public trust and accountability.” NIH is further encouraged to “use this tool in a manner that allows for more rigorous oversight prior to the awarding of funds to ensure that NIH grants are connected to the core mission and priorities of NIH.”

Prioritization of Funding

The Committee report includes an emphasis on the “prioritization of funding.” The NIH is expected to “prioritize federal funds for medical research on discovery over outreach and education.” It is also expected to “distribute funding based on the merit of researchers [sic] ideas and productivity, without applying discriminatory review requirements to extramural investigations, or creating barriers to funding for research institutes or team-based research. The report emphasizes the Committee expectation that the NIH will complete and “actively use” a five-year “scientific plan” directed in the FY 2016 Appropriations Act to prioritize funding. The Committee “expects NIH to allocate resources through a meritoriously based competitive peer review process to best target resources to diseases with the significant opportunity to improve the current or future health of the American population.”

National Children's Study Alternative

In the report, the Committee expresses disappointment that the NIH determined it was not feasible to implement the National Children's Study (NCS) as originally conceived. The report notes that the June 2014 Institute of Medicine (IOM) report found that the “NCS’ goals and mission had the potential to add to the scientific knowledge of children’s health and development.” Accordingly, the Committee “directs and provides funding for continuation of the NCS in an alternative form called the National Children's Study Alternative (NCS-A).” The NIH is further directed to work with pediatric groups to “develop a series of alternative research activities that build on NCS data and the overarching goals of the NCS to address the developmental origins of health and disease through a series of studies (including longitudinal) that incorporate expertise in biology and epidemiology, integrate basic science, and leverage maternal/infant cohorts, either de novo or from extant networks.” The agency is expected to focus on “at least prematurity, obesity, autism, asthma, and pediatric, rare diseases like cancer.” It is further expected to obtain data, biological samples, and specimens that can ultimately improve child health and well-being.

The bill language directs the NIH to submit a spending plan on NCS-A’s next phase to both the House and Senate Appropriations Committees within 90 days of enactment. The Committee directs the NIH to establish an advisory panel with outside pediatric experts and submit and make public an NCS-A 10-year plan that includes milestones, goals, objectives, and projected funding estimates. The plan is due within 180 days of enactment of the bill. The NIH is urged to review the plan at least every five years in a manner that includes public input and “allows for flexibility to expand or adjust the focus areas based on the state of the science and the best impact on children’s health.” The agency is to establish and maintain a tracking system to ensure funds for NCS “do not supplant but supplement other children’s research.” NIH is to further report on the NCS-A in the annual budget request.

Human Subjects Data

The report reiterates the Committee’s concern related to the protection of privacy of individuals who are subjects of research. It highlights language included in the FY 2015 Appropriations Act directing the agency to include requirements related to privacy protections in every grant that includes human subjects, including suggesting that the NIH issue a “certificate of confidentiality.” Bill language also would require investigators receiving NIH funding for research designed “to generate and analyze large volumes of data derived from human research participants” to obtain such a certificate. Highlighting the fact that the success of genomic research, including the Precision Medicine Initiative, will require privacy protections, the report requests that no later than 90 days after enactment of the bill that NIH provide a report on the specific steps NIH can and will take to further to protect the privacy of human subjects including specific legislative actions that could further protect research participants in future NIH-supported research.

Young Investigators

The House Committee report directs NIH to report within 120 days of enactment actions it has taken to lower the median age at which investigators receive their first investigator-initiated awards. The agency is also required to submit an accompanying plan outlining "concrete steps to lower the median age." NIH is encouraged to convene a working group of stakeholders from academia, young researchers, industry leaders, and government officials to address the issue.

Office of the Director

The report notes that the Committee expects the NIH Office of the Director (OD) to establish a systematic process with the ICs and HHS agencies to coordinate the dissemination of research results in a manner that uses existing HHS outreach programs and prevents duplication from NIH organizations to allow better focus of NIH IC funds to support research efforts.

The NIH director is expected to ensure that all ICs continue to support the pathways to independence program, which provides new investigators with mentored grants that convert into independent research project grants. The Committee continues to support an increase in the New Innovator awards, Director's Pioneer awards, and the Transformative R01 program through the Common Fund. At the same time, the Committee also expresses concern that resources in the Common Fund are being moved away from the Pioneer, New Innovator, and the Transformative RO1 awards. "These high-risk, high-impact awards have shown great success and the Committee expects NIH to use more of these types of awards throughout NIH, not less."

Citing the NIGMS Maximizing Investigators Research Award (MIRA) as an example, NIH is encourage to continue to support new grant models that would provide a single award in support of all of the projects in an investigator's lab. The Committee encourages NIH to "facilitate similar programs in all ICs."

Common Fund

The Committee expects NIH to continue the longstanding policy for Common Fund projects to be short-term, high-impact awards, with no projects receiving funding for more than ten years. The report notes that the "Committee appreciates NIH's efforts to support only bio-medical research within the Common Fund."

Capstone Award

NIH is expected to pursue the establishment of new grants, called Capstone Awards. The report notes that the award "could be made to promote partnership between a senior and junior investigator, to provide opportunities for acquiring skills needed for transitioning to a new role, or other reasons as determined by the NIH director in consultation with the IC directors, patient advocacy groups, and industry leaders." The agency is expected to develop a time period and amount for each Capstone Award by the NIH Director in consultation with the IC directors, researchers, patient advocacy groups, and industry leaders.

Grant Review

Echoing provisions within the *21st Century Cures Act* (H.R. 6), the "Committee encourages NIH to establish policies for the directors of each IC to review and approve every grant awarded by his or her IC." The Committee requests an update in the FY 2017 budget request.

Marijuana Research

The Committee is concerned that as more states choose to enact laws that allow access to and use of marijuana for medical purposes there is no significant body of medical and scientific research validated by NIH or NIDA on the actual medical efficacy of marijuana. Accordingly, the Committee directs NIH to report back to the Committee in 120 days after enactment with a plan by which the NIH could engage the appropriate institutes and other agencies (e.g., FDA) to construct long- and short-term studies on the potential benefits and detriments of the use of the marijuana for medical purposes.

Review of Maternal Deprivation Studies

Citing concerns raised by "prominent experts and animal advocacy organizations" about the scientific and ethical justifications for maternal deprivation studies involving baby monkeys being conducted in both the intramural and extramural NIH-funded laboratories, and despite an investigation and recommendations by the NIH Office of Laboratory Animal Welfare in response, the Committee requests NIH conduct a review of its policies and processes with respect to nonhuman primate research subjects in consultation with outside experts. NIH is to provide an update on these efforts in its FY 2017 budget request.

Requests for Programs Updates in FY 2017 Budget Request

The Committee requests general updates in the FY 2017 budget request for a number of diseases, conditions, and topics describing the latest efforts, both ongoing and planned, including behavioral science research in the National Institute of Mental Health (NIMH), aging demographic research, alcohol dependence, the administrative burden workgroup, diabetes, environmental exposures, global infectious disease health research, kidney disease, and the NIH workforce study.

Cancer Disparities

The Committee requests that the National Cancer Institute (NCI) and the National Institute on Minority Health and Health Disparities (NIMHD) prepare a joint update in the FY 2017 budget request of the efforts underway and planned to end cancer disparity, including activities to focus on research, prevention, and treatment of cancer in minority communities. An update on how NCI supports or plans to support Institutional Development Awards (IDeA) programs in states to broaden the NCI designated cancer center representation within these states is also requested in the FY 2017 budget request.

BRAIN Initiative

The report notes that the BRAIN initiative, created with a 10-year plan, is expected to require an annual budget of at least \$400 million by FY 2019. The Committee would accelerate the requested funding to \$150 million to ensure the initiative "stays on track toward its program, goals, and objectives." The funds would be allocated to the National Institute of Neurological Disorders and Stroke (NINDS), Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD), National Eye Institute (NEI), National Institute on Aging (NIA), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Biomedical Imaging and Bioengineering (NBIB), and the National Center for Complementary and Integrative Health (NCCIH) on the same pro-rata bases as provided in the budget request. The NIH is expected to ensure the FY 2017 request provides an appropriate level of funding to keep on this path. The Committee further encourages the NIH to distribute "a reasonable portion of the BRAIN research resources through co-funded projects in the IDeA program."

Institutional Development Award

The report notes the Committee's "significant increase to the IDeA program in recognition of the success of this program." The Committee expects the NIH to ensure that the program is supported at a level of at least one percent of total NIH funding in future budget requests. It notes that the Centers of Biomedical Research Excellence (COBRE) "is proven to successfully increase the number of new scientists at institutions in states eligible for IDeA. The report states that the NIH policy has limited the number of COBRE institutions in IDeA states. The Committee expects NIH and NIGMS to "jointly review this policy and develop a plan to expand the number of competitively awarded COBREs per institution that include shared funding from outside NIGMS resources." It requests a summary of the outcome of the review and plan forward in the FY 2017 budget request. Further, the Committee expects the NIH Director to ensure all CTSA awardees actively solicit interaction with IDeA designated states.

Alzheimer's Disease

The Committee accelerates the funding for Alzheimer's disease (AD) research to \$886 million, an increase of \$300 million above the FY 2015 budget "as an important next step to ensure success of this critical initiative to develop preventative treatment and cures." NIH is expected to ensure that the FY 2017 budget request provides the appropriate level of funding to keep this path. The reports notes that the Committee encourages the distribution of a reasonable portion of Alzheimer's research support to meritorious IDeA program researchers. NIA is requested to convene a working group of stakeholders, including patient advocacy organizations and nonprofit funders of AD and dementia research within 180 days of enactment of the bill to develop possible frameworks and strategies for a direct public-private partnership to fund meritorious research proposals on AD that are not supported directly by NIH. Further, NIH is directed to provide an annual report, beginning in FY 2017, identifying the total level of NIH peer-reviewed research supported by qualified third-party AD researchers through such partnership.

Drug Abuse

The report applauds the Collaborative Research on Addictions at NIH initiative and the launch of the Adolescent Behavioral and Cognitive Development (ABCD) study. It notes that the study is "unique in its scope and duration" and will recruit 10,000 youth before they begin using alcohol, marijuana, nicotine, and other drugs, and follow them over ten years into early adulthood to assess how substance use affects the trajectory of the developing brain. The Committee further commends the study design "which will use advanced brain imaging as well as psychological and behavioral research tools to evaluate brain structure and function and track substance use, academic achievement, IQ, cognitive skills, and mental health over time."

The report highlights NIDAMED, an initiative designed to reach out to physicians, physicians in training, and other health care professionals to help those treating young people to better recognize the signs that lead to drug abuse and addiction. The Committee notes that it remains concerned about prescription drug abuse, specifically the misuse of orally administered opioid drugs. NIDA is expected to continue to fund research to better prevent and treat prescription drug abuse and to coordinate with the Centers for Disease Control and Prevention to help identify scientific research gaps. The Committee requests an update in the FY 2017 budget request regarding the activities related to addressing the opioid drug abuse problem.

Mental Health

The report notes that Community Based Participatory Research (CBPR) is an applied collaborative approach that enables community residents to more actively participate in the full spectrum of research. The Committee requests NIMHD to provide an update in the FY 2017 budget request on any CBPR activities it supports and "the most appropriate role for CBPR within the NIMH portfolio."

NIMH is applauded for its support of early detection and intervention of efforts involving psychosis in young people and is encouraged to coordinate with other ICs to expand these efforts.

Basic Biomedical Research

The Committee urges the NIH director to continue "the traditional focus on basic biomedical research and requests that NIH take actions to ensure the percentage of funding in the extramural research program on basic research does not fall below 55 percent of NIH resources.

Coordination with CDC

The report notes the Committee's concern regarding the duplication of efforts and overlapping of responsibilities and funding priorities between the NIH and CDC. It encourages the agencies to coordinate further on cross-cutting initiatives, ensuring that each funds programs within its respective core mission. The Committee requests an update in the FY 2017 budget request how each NIH program coordinates with the CDC Centers.

Enhanced Reporting on Research Spending by Disease and Affected Population

The Committee reiterates its directive in the FY 2015 Explanatory Statement for NIH to make public, on an annual basis, enhanced RCDC spending data with the number of American affected by each category of diseases according to the CDC or other federally-sourced data. NIH is further requested to include the number of Americans who die from each disease annually. NIH is expected to upload all available data immediately and to have the full data set on-line no later than May 1, 2016. The Committee requests an update of the process in the FY 2017 budget request.

The Committee notes its concern that every year NIH announces new initiatives and although the initiatives start at the planned level, over time these projects are not supported by the budget requests "at levels that will result in the achievement of initial expectations." NIH is requested to provide a table in the FY 2017 and future budget requests with the current-year plus five-year planned funding levels for each initiative started over the past five years or ongoing and proposed in the current budget. The table should identify the planned budget level provided, a list of participating ICs, the linkage to the NIH-wide strategic plan, and percentage of the funds focused on basic science for each initiative.

Reproducibility of Scientific Methods

Noting that the gold standard of good science is the ability of a lab to reproduce a method and finding, the Committee expresses its continued concern with reports that some published biomedical research cannot be easily reproduced. The Committee requests an update in the FY 2017 budget request on how NIH is measuring the effectiveness of each step the agency has taken to develop and implement best practice guidelines.

Senate Committee Report Language

Burden of Disease

In its report, the Senate Appropriations Committee states that it "expects NIH to consider the burden of Disease when setting priorities and developing strategic plans across the Institutes and Centers." According to the report, diseases such as "Alzheimer's, diabetes, heart disease, and cancer affect a large portion of the population, especially the aging population...Targeting biomedical research funding toward these diseases is an important strategy to finding better treatment and cures."

Minority Research

The Committee applauds the NIH Director's efforts to reverse the trend of underrepresentation of researchers from ethnically diverse backgrounds. NIH is encouraged "to continue newly established programs to enhance NIH-funded workforce diversity."

National Children's Study

The Committee finds the decision by the NIH Director in December 2014 to discontinue the National Children's Study (NCS) per the recommendations of an NIH Advisory Committee's conclusions and after \$1.3 billion in federal investment "deeply troubling." It calls the discontinuation of the NCS is "a significant setback as the NCS had the potential to add substantially to scientific knowledge about the impact of environmental exposures on children's health and development in the United States."

NIH is urged "to recalibrate and realign the investment already made in the NCS to initiate new and focus existing longitudinal studies to address the objectives identified for the NCS. The NIH should rely upon a formal scientific advisory mechanism to coordinate efforts across studies. The research efforts should incorporate expertise in population health and environmental epidemiology, integrate basic science, and leverage maternal/infant cohorts." For example, the report states, "it is important to thoroughly examine pathways linking chronic and intermittent exposures to the physical and social environments to adverse health and developmental outcomes in children. It is also important to study the intertwined biological, behavioral, and social transmission of obesity and obesity-related risk factors across generations and to test intergenerational, exposure-disease associations by linking maternal and infant/child data."

Next Generation Research Initiative

The report states that the National Academy of Sciences (NAS) will conduct an evaluation of the legislative, administrative, educational, and cultural barriers to providing for a successful next generation of researchers to be completed no later than one year after the date of enactment of the act. The bill would provide \$1.2 million for the study. Additionally, the Committee directs the NAS to submit to the Director of NIH and the Committees on Appropriations of the House and Senate the results of the study which shall include: (a) an evaluation of the legislative, administrative, educational, and cultural barriers faced by the next generation of researchers; (b) an evaluation of the impact of Federal budget constraints on the next generation of researchers; and (c) recommendations for the implementation of policies to incentivize, improve entry into, and sustain careers in research for the next generation of researchers, including proposed policies for agencies and academic institutions.

Science Education

The NIH is directed to continue funding the Science Education Partnership Awards (SEPA) program at no less than last year's level.

Precision Medicine

The Committee expresses strong support for the new Precision Medicine Initiative and provides \$70 million for National Cancer Institute's (NCI) portion of the program. The Committee notes that the NCI's Community Oncology Research Program is an important element of NCI's ongoing efforts in precision medicine, and will allow NCI to incorporate underserved populations into cancer clinical trials under the FY 2016 Precision Medicine Initiative.

Minority Cancer Rates

The Committee expresses its concern that for some preventable and detectable cancers, minority communities still suffer at disproportionate rates, despite falling rates in the general population. The Committee requests that NCI and the National Institute of Minority Health and Health Disparities (NIMHD) continue to coordinate and support research focused on treatment, prevention, communication, and outreach to minority communities for early intervention to reduce and eliminate these disparities.

National Clinical Trials Network

The Committee highlights the fact that NCI's National Clinical Trials Network (NCTN) is "critical to the development of improved, personalized treatments for cancer" and specifically pointed out that "the burden of cancer mortality is felt disproportionately among racial and ethnic minorities." The report stresses that "continued research is needed regarding the biological, socioeconomic, environmental, and behavioral factors that cause these disparities." NCI is urged to continue research in these areas through the NCI Community Oncology Research Program, NCI's Center to Reduce Cancer Health Disparities, minority participation in the NCTN clinical trials, and additional NCI-supported research focused on health disparities.

Institutional Development Award (IDeA) program

As noted above, the Senate bill includes \$940 million in transfers available under section 241 of the PHS Act. The transfer in funds would be available to the National Institute of General Medical Sciences (NIGMS). The bill would provide \$300 million for the Institutional Development Award (IDeA) program, an increase of \$26.7 million. The Committee expresses its belief that the IDeA program “has made significant contributions to biomedical research and has led to the creation of a skilled workforce and made the IDeA program an essential component of NIH’s research portfolio.”

The Committee also articulates concern that many of the institutions eligible for funding under the National Science Foundation Experimental Program to Stimulate Competitive Research (EPSCoR) program are ineligible for funding under the IDeA program. It conveys further concern that “after several years of specific direction..., the administration continues to refuse to submit legislative information to update the eligibility criteria of the IDeA program to bring it in line with EPSCoR eligibility.” As a consequence, the bill contains language “to allow entities eligible for participation in the EPSCoR program for the past two consecutive years to apply for inclusion in the IDeA Network for Biomedical Research Excellence award.”

The Committee, however, is supportive of the President’s proposed initiative in the FY 2016 budget request for directed small business research funding to IDeA states to “foster the development of products to advance public health.” NIGMS is asked to consider allocating funding for one shared innovation incubator in each of the four IDeA regions that would be competitively bid among IDeA states to serve IDeA states. The Committee specifies that NIH “should not use funding from the IDeA program to fund these grants.”

Demographic Research

The Committee notes that “Demographic or population research is essential for understanding the short- and long-term consequences” of the dramatic growth of the world’s population on individuals and communities. It further notes that longitudinal studies funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), “including the *National Longitudinal Survey of Adolescent to Adult Health* and the *Fragile Families and Child Well Being Study*, are yielding important data about the linkages between health, socioeconomic status, family dynamics, genetics, and environment.” The Committee encourages NICHD to “continue to support these and other similar studies such as the *Human Placenta Project*, affecting population health and well-being.”

Mother-Infant Relationship

NICHD is applauded for “its multi-disciplinary, cutting-edge research” on child and maternal health and development. The Committee encourages a continued focus on basic and applied research to advance understanding of attachment in mother-infant relationships and its impact on development. The Committee urges NICHD “to continue support for a robust intramural and extramural research portfolio identifying and describing the complex interaction of behavioral, social, environmental, and genetic factors on health outcomes with the ultimate goal of improved understanding of and interventions for disorders such as depression, addiction, and autism.”

Reading Disability and Genetic Screening

Citing the failure to identify learning disabilities early, as well as the failure to optimally match a specific intervention program to an individual child and the significant detrimental impact on the lives of individuals, cost of education, and the economy, the Committee encourages NICHD to support research to increase the ability to identify the risk, including the role of genetic analyses, early detection, and optimal educational interventions, for reading disabilities. The Committee further urges NICHD to explore additional ways to encourage and sustain research to achieve meaningful interventions and therapies to help those with reading disabilities.

Alzheimer’s disease

The Committee notes that in keeping with “long-standing tradition,” it has not earmarked funding for research on specific diseases. “However, the Committee has included \$350.9 million increase for the National Institute on Aging (NIA) and expects that a significant portion will be dedicated to high quality research on Alzheimer’s disease, subject to the scientific opportunity presented in the peer review process.” The Institute is encouraged to continue addressing the research goals in the *National Plan to Address Alzheimer’s Disease*, as well as the recommendations from the 2015 Alzheimer’s Disease Research Summit.

The Committee expects to receive a report in the FY 2017 congressional justification that outlines research conducted on Alzheimer’s disease relative to the milestones established in the National Plan, as well as the

professional judgement budget for Alzheimer’s disease for FY 2017. Further, the Committee directs NIA to continue support for existing “well-characterized, longitudinal, population-based cohort studies aimed at providing new insights into disease prevention, particularly among minority populations where disease burden is greatest.” The Committee conveyed that it is “particularly interested in NIH’s plan to place additional emphasis on high-risk, high-reward projects using a DARPA-like approach to goal-oriented and milestone-driven research.” It believes that such an approach “can be particularly valuable in addressing major scientific gaps and encourages NIH to establish clear priorities, including Alzheimer’s disease and dementia and other high cost diseases of aging.”

Population Research

The Committee highlights NIA-supported research that confirms that by 2030 there will be 72 million Americans aged 65 and older. The report notes that NIA’s current investment in population aging research and surveys, including the Demography and Economics of Aging, Roybal Centers for Translational Research, and the Health and Retirement Study, is essential to understanding the implications of an increasing older population. To accelerate current understanding, NIA is urged to “continue investing in large-scale longitudinal studies that explore how genetic, behavioral, and psychosocial factors, including socioeconomic status, interpersonal relationships, and social environments, affect health and well-being.” The Committee is “pleased NIA is developing an initiative to explore why other industrialized countries surpass the United States in health at older ages and longevity—especially in light of new NIA-supported research findings that more than half of premature deaths are due to social and behavioral issues.”

Pain Research

The Committee is encouraged by the National Center for Complementary and Integrative Health (NCCIH) and NIDA’s collaboration with the Department of Veteran’s Affairs (VA) on a new initiative funding 13 studies examining non-pharmacological management of pain and other symptoms experienced by military personnel and veterans. The Committee believes it is critical to support research on complementary and integrative health approaches to ensure the best quality of care for veterans, as opioid prescribing rates have increased at the VA in recent years, and opioid abuse has risen among young veterans. The Committee urges NIH and VA “to continue this vital research.”

Minority Enrollment in Cohort Studies

The report notes that the Committee is “aware of novel efforts underway in racially and ethnically diverse urban, low-income neighborhoods to enroll households for participation in future neighborhood cohort studies. Under these approaches, families are interviewed, consented, and then provided information on a range of medical and socioeconomic issues for inclusion in a growing database of such household information. These families can then be re-contacted for participation, as appropriate, in future clinical trials and other research.” NIMHD should support the development of this type of research infrastructure through its community-based participatory research program, the Committee notes.

Research Centers in Minority Institutions

The Committee highlights that it continues to recognize the critical role played by minority institutions, especially at the graduate level, in addressing the health research and training needs of minority populations. Accordingly, it requests that NIH maintains the Research Centers in Minority Institutions (RCMI) program in its current form and funds it at no less than last year’s level.

Clinical and Translational Science Awards

The Committee supports the goals of the Clinical and Translational Science Awards (CTSA) program and believes the principles that serve as the foundation of NCATS—public-private partnerships, community outreach, faster access to clinical trials, and distributed patient cohorts—have tremendous potential for addressing the long-standing scientific and operational problems associated with getting treatments to patients, including those with health disparities. NCATS is encouraged to work closely with the CTSA community and related stakeholders moving forward to continue to identify emerging opportunities and areas for programmatic improvement. NCATS is also encouraged to fund CTSA’s with a history of serving health disparity populations, as well as CTSA’s that address the unmet needs associated with rare diseases, so that research funding provided through the various Institutes can be leveraged to address the clinical and translational research challenges associated with those populations.

The Senate bill would provide \$499.7 million for the CTSA program, an increase of \$25 million above the FY 2015 funding level for NCATS to implement the recommendations from the 2013 Institute of Medicine report on the CTSA program. The Committee specifically supports the goal of the CTSA program to build networking capacity and innovative collaborative projects. The Committee included the additional funding to allow the program to

retain its merit-based CTSA funding to institutions while expanding the network capacity to conduct multi-site clinical studies and collaborative projects.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The Senate bill would provide the CDC with \$5.7 billion in discretionary funding, in addition to \$893 million in transfers from the Prevention and Public Health Fund. This amount is \$348.5 million less than the amounts proposed in both the House bill and the President’s request and \$220.8 million less than FY 2015.

Generally, the House bill’s funding allocations are higher than the Senate’s for CDC activities relevant to social and behavioral science. The National Center for Health Statistics (NCHS), for example, would receive a \$5 million increase from FY 2015 in discretionary funding under the House bill, consistent with the President’s request (although it would not receive a requested allocation from the Prevention and Public Health Fund), but would see a \$10 million cut from FY 2015 in the Senate’s version.

| <i>(in millions)</i> | Enacted FY 2015 | Proposed FY 2016 | FY 2016 House | FY 2016 Senate | Senate vs. FY 2015 | Senate vs. Request | House vs. Senate |
|---|--------------------|---------------------|------------------|-------------------|-----------------------|-----------------------|---------------------|
| Centers for Disease Control and Prevention | 5968.1 | 6095.8 | 6095.8 | 5747.3 | -3.7% | -5.7% | 6.1% |
| HIV, Viral Hepatitis, STI, and TB Prevention | 1117.6 | 1161.7 | 1117.6 | 1090.6 | -2.42% | -6.1% | 2.5% |
| Chronic Disease Prevention, Health Promotion | 1199.2 | 1058.1 | 1097.5 | 1052.9 | -12.2% | -0.5% | 4.2% |
| Environmental Health | 179.4 | 178.5 | 160.6 | 145.3 | -19.0% | -18.6% | 10.5% |
| Health Statistics | 155.4 | 160.4 | 160.4 | 145.4 | -6.4% | -9.4% | 10.3% |
| Injury Prevention and Control | 170.4 | 257.0 | 211.3 | 187.9 | 10.3% | -26.7% | 12.4% |
| Occupational Safety and Health | 334.9 | 283.4 | 341.1 | 305.9 | -8.7% | 7.9% | 11.5% |
| Global Health | 416.5 | 448.1 | 426.9 | 411.8 | -1.1% | -8.1% | 3.7% |
| Public Health | 1352.6 | 1381.8 | 1460.8 | 1340.1 | -0.9% | -3.0% | 9.0% |
| Preparedness and Response | 160.0 | 0.0 | 170.0 | 160.0 | 0.0% | +\$160.0m | 6.3% |
| Preventive Health & Health Services Block Grant | | | | | | | |

House Committee Report Language

Language in the House’s Committee Report expresses concern that CDC and NIH may be duplicating efforts. The agencies are instructed to “more actively coordinate on cross-cutting initiatives, ensuring that each agencies focuses on its respective core mission.” The report also requests an update in next year’s budget request on how the CDC and NIH requests coordinate to “share scientific gaps related to activities supported in NIH research portfolios.” CDC is also instructed to review its research portfolios to reduce potential duplication.

The report also suggests that there may be duplication of data collection between the National Center for Health Statistics’ (NCHS) National Health and Nutrition Examination Survey (NHANES) and the American Heart Association and instructs CDC to submit a report on this with the FY 2017 budget request.

According to the report, the Committee believes CDC’s environmental health research is duplicative of the research conducted by the NIH’s National Institute of Environmental Health Science (NIEHS), and thus fails to provide funding for these activities.

The bill refrains from funding climate-related environmental health programs under the CDC's Environmental Health activities, including Building Resilience Against Climate Effects, Climate and Health, and the Built Environment and Health Initiative.

A lengthy rider in the section on Injury Prevention and Control continues to prohibit the CDC from using any funding to support research or data collection related to gun violence prevention:

The Committee continues the general provision to prevent any funds provided from being spent on gun research, to include collecting data for potential future research, such as was proposed in the budget request for the National Violent Death Reporting System. The Committee notes the budget request for Gun Violence Prevention Research is not funded and would be contrary to the prohibition. The Committee reminds CDC that the longstanding general provision's intent is to protect rights granted by the Second Amendment. The restriction is to prevent activity that would undertake activities (to include data collection) for current or future research, including under the title "gun violence prevention", that could be used in any manner to result in a future policy, guidelines, or recommendations to limit access to guns, ammunition, or to create a list of gun owners.

Senate Committee Report Language

The Senate Committee Report instructs the CDC to develop ways to obtain better measurements of Alzheimer's and dementia death rates and to submit a report to Congress that estimates these diseases' mortality burden.

NCHS is asked to submit a plan to address states that have not yet implemented electronic death registration systems with next year's budget request.

The Senate bill would eliminate funding for Climate Change under the CDC's Environmental Health program (for which the Administration had proposed a \$10 million increase).

The Senate bill would provide some increases to the National Center for Injury Prevention and Control for combatting opioid abuse (although not as much as requested by the President). The additional funds would include \$5.6 billion to strengthen surveillance for heroin-related deaths.

Within the CDC's Global Health activities, the bill would not fund the Administration's proposed Global Health Security Agenda or the existing National Public Health Institutes program. Language in the Committee Report expresses support for both of these programs, but argues that because they received substantial emergency supplemental funding during the Ebola outbreak, funding in FY 2016 is not needed.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Unlike the House bill, which would eliminate the Agency for Healthcare Research and Quality (see COSSA's preliminary [analysis](#)), the Senate bill maintains funding for AHRQ. However, the agency would still face a \$127.7 million cut that would be distributed across all of AHRQ's research portfolios.

The Senate bill does include \$4 million for research on safe health information technology (IT) practices, which the Committee expects to generate evidence that will inform policies across HHS.

The Committee also provides \$10 million within AHRQ's healthcare-associated infection activities for the Combatting Antibiotic Resistant Bacteria (CARB) initiative. The funds will be used to promote improved antibiotic stewardship in ambulatory and long-term care settings.

Although AHRQ's Health Services Research, Data, and Dissemination activities would see a 48.3 percent cut under the Senate bill, the Committee maintains FY 2015 funding levels for investigator-initiated research (\$45.9 million).

| <i>(in millions)</i> | Enacted FY 2015 | Proposed FY 2016 | FY 2016 House | FY 2016 Senate | Senate vs. FY 2015 | Senate vs. Request | House vs. Senate |
|---|--------------------|---------------------|------------------|-------------------|-----------------------|-----------------------|---------------------|
| Agency for Healthcare Research and Quality | 363.7 | 363.7 | 0.0 | 236.0 | -35.1% | -35.1% | -100.0% |
| Patient Safety | 76.6 | 76.0 | 0.0 | 65.1 | -15.0% | -14.3% | -100.0% |
| Health Services Research, Data, and Dissemination | 112.2 | 112.3 | 0.0 | 58.0 | -48.3% | -48.3% | -100.0% |
| Health Information Technology | 28.2 | 22.9 | 0.0 | 19.7 | -30.1% | -13.8% | -100.0% |
| Prevention/Care Management | 11.6 | 11.6 | 0.0 | 8.1 | -30.1% | -30.4% | -100.0% |

DEPARTMENT OF EDUCATION

In FY 2016, the House bill would provide \$64.2 million in funding for the Department of Education, while the Senate bill would provide \$65.5 billion.

The House bill would provide \$410 million in funding for the **Institute of Education Sciences (IES)**, a reduction of \$164 million below the FY 2015 funding level and \$265.9 below the budget request. The Senate bill would provide IES an additional \$153 million over the House mark for a total of \$563 million.

The House bill amends a provision allowing the Department to set aside up to 0.5 percent of Elementary and Secondary Education Act (ESEA) funds for evaluation of ESEA programs to clarify that IES is the primary entity to conduct research and evaluation of these programs.

The House bill would zero out funding for IES' Regional Educational Laboratories, which received \$54.4 million in FY 2015. The Senate bill maintains funding for the network of ten laboratories; language in its committee report expresses appreciation of IES's efforts to strengthen the connections between practitioners and the research community.

The Senate committee report praises the National Assessment Governing Board (NAGB) for reinstating assessments for 8th and 12th grade students in U.S. History, Civics, and Geography. Pointing to budget constraints, the Committee notes that its recommendation includes the same level of funding as in FY 2015. However, it encourages the NAGB to continue administering the assessments in those three areas at least every four years in accordance with the current NAEP schedule. Further, the Committee supports NAEP's proposal to move the math and reading assessments into a digital-based platform and expand the Trial Urban District Assessments to ten more urban school districts.

The House bill would maintain flat funding for **International Education and Foreign Language Studies** (\$65.1 million for domestic and \$7.1 million for international), \$5 million below the President's request. The Senate proposes steeper cuts to these programs, allocating a total of \$46.9 million for domestic and international programs combined.

Both the House and Senate bill propose to eliminate the **Fund for the Improvement of Postsecondary Education (FIPSE)**, funded at \$67.8 million in FY 2015. Language in the House report suggests that the fund has been used by the Administration as a "pot of flexible funding for new and often unauthorized initiatives." Neither bill allocates funding to the First in the World program (requested at \$200 million), a competitive grant program aimed at finding solutions to challenges faced by students in completing postsecondary education.

| <i>(in millions)</i> | Enacted FY 2015 | Proposed FY 2016 | FY 2016 House | FY 2016 Senate | Senate vs. FY 2015 | Senate vs. Request | House vs. Senate |
|---|--------------------|---------------------|------------------|-------------------|-----------------------|-----------------------|---------------------|
| Institute of Education Sciences Total | 573.9 | 675.9 | 410.0 | 563.0 | -1.9% | -16.7% | -27.2% |
| Research, Development, and Dissemination | 179.9 | 202.3 | 93.1 | 177.9 | -1.1% | -12.1% | -47.7% |
| Regional Education Laboratories | 54.4 | 54.4 | 0.0 | 53.8 | -1.1% | -1.1% | -100.0% |
| Statistics (National Center for Education Statistics) | 103.1 | 124.7 | 103.1 | 102.1 | -0.9% | -18.1% | 1.0% |
| Assessment | 137.2 | 157.4 | 137.2 | 137.2 | 0.0% | -12.8% | 0.0% |
| StateWide Data Systems | 34.5 | 70.0 | 34.5 | 33.5 | -3.0% | -52.1% | 3.0% |
| Special Education Studies and Evaluations | 10.8 | 13.0 | 6.0 | 10.5 | -2.9% | -19.2% | -42.9% |
| Research in Special Education | 54.0 | 54.0 | 36.0 | 48.0 | -11.1% | -11.1% | -25.0% |
| International Education and Foreign Language Studies | 72.2 | 76.2 | 72.2 | 46.9 | -35.0% | -38.5% | 53.9% |
| Domestic Programs | 65.1 | 67.1 | 65.1 | 43.4 | -33.3% | -35.3% | 50.0% |
| Overseas | 7.1 | 9.1 | 7.1 | 3.5 | -50.4% | -61.5% | 102.9% |
| Fund for the Improvement of Postsecondary Education | 67.8 | 200.0 | 0.0 | 0.0 | -100.0% | -100.0% | 0.0% |
| Graduate Assistance in Areas of National Need | 29.3 | 29.3 | 25.1 | 20.0 | -31.7% | -31.7% | 25.5% |

BUREAU OF LABOR STATISTICS

Under the Senate bill, the Bureau of Labor Statistics would receive \$579.2 million, including \$63.7 million from the Unemployment Trust Fund. This amount is \$29.8 million below the amount provided in the House bill and is \$53.5 million below the President's Request. Neither bill keeps up with inflation, likely placing a strain on BLS' programs.

| <i>(in millions)</i> | Enacted FY 2015 | Proposed FY 2016 | FY 2016 House | FY 2016 Senate | Senate vs. FY 2015 | Senate vs. Request | House vs. Senate |
|----------------------------|--------------------|---------------------|------------------|-------------------|-----------------------|-----------------------|---------------------|
| Bureau of Labor Statistics | 592.2 | 632.7 | 609.0 | 579.2 | -2.20% | -8.46% | 5.15% |