SUMMARY OF FISCAL YEAR 2016 HOUSE LABOR, HEALTH AND HUMAN SERVICES APPROPRIATIONS
BILL REPORT LANGUAGE

On June 23, the House Appropriations Committee released the bill text and report language for the fiscal year (FY) 2016 Labor, Health and Human Services (LHHS) spending bill. Report language is available HERE. Bill text is available HERE. The Appropriations Committee passed the bill by a vote of 30-21 on June 24.

There are interesting items in the report language, including a significant expansion of data to be collected in the National Institutes of Health (NIH) existing database on research spending by disease and condition and a provision requiring each Institute and Center (I/C) Director to adopt a policy for reviewing and approving every grant that is funded. The report also features statements on conflict of interest, research prioritization, reproducibility, young researchers, protection of human subjects and non-human primate research, as well as language criticizing NIH for requesting new initiatives each year without asking for proper long term funding to support them. Additional language is included expressing support for the Maximizing Investigators Research Award (MIRA) and Capstone grant proposal. Finally, the Committee requested that the NIH FY 2017 budget justification provide updates on dozens of initiatives and projects currently underway at the agency.

The report language introduction notes that “the Committee recommendation reflects the challenges inherent in achieving deficit reduction solely through reductions in discretionary spending.” It also notes that funding for biomedical research was a priority in the bill, including support for Alzheimer’s research and the precision medicine initiative in the FY 2016 NIH budget request.

SPECIFIC ITEMS THAT MAY BE OF INTEREST TO FASEB SOCIETIES

Evaluation Tap – The Committee did not include the Administration’s request to increase the tap (it will remain at 2.4 percent or $1.010 billion). “Consistent with the fiscal year 2015 appropriations, all the TAP funds received by NIH are allocated to the National Institute of General Medical Sciences (NIGMS). This continues to ensure the TAP transfers are a net benefit to NIH rather than a liability.” (pg. 56 & pg. 180)

Extramural Research/ Young Investigators – “The Committee encourages NIH to restore at least 90 percent of all NIH resources to the extramural community. Further, the Committee expects NIH to continue its focus on emerging investigators and first-time renewals of these young investigators in an effort to significantly reduce the average age of an NIH-supported new investigator. The Committee expects NIH to support a consistent NIH-wide inflationary policy across all Institutes and Centers (ICs).” (pg. 56)

NRSA Awards – “The Committee remains concerned that the number of Ruth L. Kirschstein National Research Service Awards declined in fiscal year 2014 and is only projected to increase by 15 in fiscal year 2015. The Committee notes the NIH budget policy is to increase the number of training grants to 15,735. The Committee expects to adhere to at least this budget policy level for training grants and to provide a stipend level that is at least consistent with any fiscal year 2016 federal employee pay raise.” (pg. 56)

Portfolio Analysis & Strategic Planning – “The Committee appreciates NIH’s recent movement to start an NIH-wide portfolio analysis and strategic planning process. The Committee encourages NIH 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. Further, the Committee
encourages NIH 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.” (pg. 57)

Allocations for Specific Programs (Alzheimer’s; BRAIN; Precision Medicine; Combating Antibiotic Resistance) – “The increase provided to NIH is generally distributed proportionately among NIH Institutes and Centers (ICs). However, additional resources were added to specific ICs to support specific initiatives. The Committee has provided a $300,000,000 increase for Alzheimer’s disease research initiative in the National Institute on Aging and a $95,000,000 increase for the Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative spread across the 10 ICs that participate in BRAIN. The Committee also provides the requested level of $200,000,000 for the Precision Medicine Initiative (PMI) with $130,000,000 within the Common Fund to support the trans-NIH project and $70,000,000 with National Cancer Institute for specific PMI projects. Finally, the Committee also provides the requested $100,000,000 increase to support the antibiotic initiative in the National Institute of Allergy and Infectious Diseases (NIAID).” (pg. 57, pg. 61-63)

Common Fund – “The Common Fund is supported as a set-aside within the Office of the Director at $675,639,000, which includes the $12,600,000 to support pediatric research as described in the recently enacted Gabriella Miller Kids First Research Act.” (pg. 57)

Precision Medicine Initiative – “The Committee provides the requested funds to support the five-year NCI PMI plan that will support activities such as the pediatric MATCH trial, clinical trials for five major cancer types based on genomic driven data, liquid biopsies, new models of cancer diagnostics, test targeted agents for clinical trials, and the related informatics infrastructure. The Committee understands the NCI PMI is a one-time increase of $70,000,000 for five years. The Committee requests NCI to provide a breakout in the fiscal year 2017 budget request and future years with the specific science and funding details with these and NCI funds already supporting the PMI activity. The details should include long-term goals, milestones, and annual progress. The Committee encourages NCI, as scientifically feasible, to support existing research networks, especially collaborative efforts among NCI supported cancer centers and institutions serving historically underserved populations as they have certain attributes of cancer genomic data sharing that may be particularly effective.” (pg. 59)

BRAIN Initiative – “The BRAIN initiative, created with a 10-year plan, was expected to require an annual budget of at least $400,000,000 by fiscal year 2019. The Committee accelerates the requested funding for BRAIN to $150,000,000 to ensure the initiative stays on track towards its program goals and objectives. The funds are allocated to NINDS, NICHD, NEI, NIA, NIDCD, NIAAA, NIDA, NIMH, NIBIB, and NCCIH on the same pro-rata bases as provided in the budget request. The Committee recognizes initiatives of this nature must maintain adequate funding to assure achievement of the goals and plan milestones. The Committee expects NIH to ensure the fiscal year 2017 request provides an appropriate level of funding to keep on this path. Further, the Committee encourages the distribution of a reasonable portion of BRAIN research resources through co-funded projects in the IDeA program.” (pg. 61)

Antibiotic Resistance (AbR) – “The Committee provides the requested $100,000,000 increase to spur research and development related to scientific gaps to reduce AbR and develop new antibiotics. The Committee directs NIAID to work with BARDA to develop a joint plan toward addressing this growing and serious threat posed by AbR bacteria. NIAID is encouraged to consider research focused on novel approaches to combat AbR, which may include unique modalities such as antibodies and vaccines, new
mechanisms, new rapid diagnostics, and a genomic database of reported human infections. The Committee encourages consideration of research on novel approaches to antimicrobial resistance like unique modalities, new mechanisms, or new antimicrobials. The Committee requests NIAID to provide a multi-year AbR research and funding plan, developed in conjunction with BARDA, which includes specific goals and annual milestones to support this initiative within 180 days of enactment.” (pg. 62-63)

Institutional Development Award (IDeA) – “The Committee provides a significant increase to the IDeA program in recognition of the success of this program. The Committee expects NIH to ensure the program is supported at a level of at least 1 percent of total NIH funding in future budget requests. Further, the Committee notes the NIH Centers of Biomedical Research Excellence (COBRE) is proven to successfully increase the number of new scientists at institutions in states eligible for IDeA. The NIH policy has limited the number of COBRE institutions in IDeA states. The Committee expects NIH and NIGMS Directors 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. The Committee requests a summary of the outcome of the review and plan forward in the fiscal year 2017 budget request. The Committee expects the NIH Director to ensure all Clinical Translations Science Research awardees actively solicit interaction with IDeA designated states.” (pg. 63-64)

Clinical and Translational Science Awards (CTSA) – “The Committee is pleased that NCATS is implementing recommendations from the recent IOM report on the CTSA program. NCATS is encouraged to continue to work closely with the CTSA community and related stakeholders moving forward to continue to identify emerging opportunities and areas for programmatic improvement.” (PG. 70)

Therapeutics for Rare and Neglected Diseases (TRND) Program – “The Committee encourages NCATS to focus on additional neglected diseases through the TRND program. The Committee expects NCATS’ contributions to neglected disease research be included in the joint CDC, FDA and NIH global health strategy describing coordination and prioritization of global health research activities within the three agencies.” (pg. 70)

Office of the Director – “The Committee expects 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 Committee expects the NIH Director to ensure all ICs continue to support the pathways to independence program, which provides new investigators with mentored grants that convert into independent research project grants. In addition, the Committee continues to support an increase in new innovator awards, director’s pioneer awards, and the transformative R01 program through the Common Fund.” (pg. 71)

Use of Director’s Discretionary Fund for Pediatric Research – “Further, to ensure enhanced support for pediatric research, the Committee urges the NIH Director to use a portion of the $10,000,000 made available to the Director’s Discretionary Fund (DDF) to support additional pediatric research, such the development of cutting edge bioinformatics programs for pediatric cancers; tools, methods, and other regulatory science to directly support the data that accelerate drug approval for pediatric patients; or projects that integrate cutting-edge technology like bio-microelectromechanical systems (MEMS), biomaterials or portable advanced imaging technologies related to pediatric diseases. The Committee requests, within 30 days after the end of each quarter, a quarterly report on DDF obligations for each activity supported. The report should include a description of the program, the ICs that will provide the
continuation costs and how this research serves a high priority. Further, the quarterly reports shall be posted on-line via the NIH web-site within 30 days after being released to the Committee.” (pg. 71)

**Capstone Awards** – “The Committee expects NIH to pursue the establishment of new grants, called Capstone Awards. Capstone Awards 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 NIH is expected to develop a duration and amount for each Capstone Award by the NIH Director in consultation with the IC Directors, researchers, patient advocacy groups, and industry leaders.” (pg. 71-72)

**Grant Review** – “The Committee encourages NIH to establish policies for the Director of each IC to review and approve every grant awarded by his or her IC. The Committee requests an update in the fiscal year 2017 budget request on this endeavor.” (pg. 72)

**New Innovative Awards** – “The Committee encourages NIH to continue to support new grant models similar to the Maximizing Investigators Research Award (MIRA) program at NIGMS that would provide a single award in support of all of the projects in an investigator’s lab. The Committee encourages the NIH Director to facilitate similar programs in all ICs.” (pg. 72)

**Quarterly Updates of NIH Operating Plans** – “The Committee continues the understanding that the IC mechanism tables serve as the NIH operating plans for available resources and requests NIH continue to provide quarterly updates of these plans to the Appropriations Committee of the House.” (pg. 72)

**Review of Maternal Deprivation Studies/Non-Human Primate Research** – “The Committee is aware that prominent experts and animal advocacy organizations have raised concerns about the scientific and ethical justifications for maternal deprivation studies involving baby monkeys being conducted in both intramural and extramural NIH funded laboratories. The Committee is further aware that the NIH Office of Laboratory Animal Welfare opened an investigation in response to these allegations on September 9, 2014. The investigations consulted with research investigators, the USDA, nonhuman primate center scientists, veterinarians, animal care staff and other relevant experts. As a result of the investigation, several modifications were made to the protocol and several procedures removed. Accordingly, the Committee requests NIH to conduct a review of its ethical policies and processes with respect to nonhuman primate research subjects, in consultation with outside experts, to ensure it has appropriate justification for animal research protocols and to provide an update on these efforts in the fiscal year 2017 budget request.” (pg. 72)

**Trans-NIH Research** – “The Committee directs the Director of DPCPSI to develop a trans-NIH strategic approach to improve coordination and facilitation of trans-NIH research with measurable objectives. The Director should also take specific steps with the ICs to strengthen to reduce duplication and increase effectiveness and efficiency of research.” (pg. 73)

**Common Fund** – “The Committee is concerned that resources in the Common Fund are being moved away from the Pioneer, New Innovator, and the Transformative R01 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.” (pg. 73, pg. 57, & pg. 181)
Basic Research – “The Committee urges the NIH Director to continue the traditional focus on basic biomedical research. The purpose of basic research is to discover the nature and mechanics of disease and identify potential therapeutic avenues likely to lead to the prevention and treatment of human disease. Without this early scientific investigation, future development of treatments and cures would be impossible. Basic biomedical research must remain a key component of both the intramural and extramural research portfolio at the NIH. The Committee also requests 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.” (pg. 75)

Children in NIH Research – “The inclusion of children in clinical research is essential to ensure that children benefit from important scientific advances. The Committee understands NIH has a formal policy mandating the inclusion of children in research relevant to child health, but it does not systematically track enrollment data to determine if children are actually being enrolled appropriately in clinical research. The Committee recognizes that without better data collection, the Committee is unable to fully exercise its oversight role and researchers are unable to determine whether children as a whole, or particular pediatric subpopulations, are underrepresented in federally funded biomedical research. The Committee directs NIH to collect data and report publicly on the actual numbers of children in the various pediatric age groups that are enrolled in its clinical studies.” (pg. 75)

Coordination with CDC – “The Committee remains concerned regarding the duplication of efforts and overlapping of responsibilities and funding priorities between the NIH and CDC. The Committee encourages NIH and CDC to coordinate further on cross-cutting initiatives, ensuring that each funds programs within its respective core mission. The Committee requests an update in the fiscal year 2017 budget request how each NIH program coordinates with the CDC Centers.” (pg. 75)

Clinical Trial Participation – The Committee encourages NIH to further the discussion with organizations that participated in the July 2014 NIH Clinical Trial Improvement Workshop as it explores methods to improve participation, enrollment, retention, in NIH supported clinical trials, especially among underrepresented populations. The Committee requests an update on the steps NIH has taken and planned in the fiscal year 2017 budget request.” (pg. 75-76)

Conflict of Interest – “The Committee encourages NIH to review and clarify conflict of interest policies to ensure more effective and transparent industry/institutional research collaborations.” (pg. 76)

Enhanced NIH Reporting on Research Spending by Disease and Affected Populations – “The Committee reiterates its direction identified in the fiscal year 2015 Explanatory Statement for NIH to make public, on an annual basis, enhanced RCDC spending data with the number of Americans affected by each category of disease according to CDC or other federally-sourced data. Further, the Committee requests NIH to include the number of Americans living with each disease, annual number of newly diagnosed Americans for each disease, and number of Americans who die from each disease annually. The Committee appreciates that NIH may not have all available category data during fiscal year 2016 but expects NIH 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 on the process in the fiscal year 2017 budget request. In addition, the Committee encourages NIH to add pediatric cardiomyopathy to the RCDC and spending on the disease for at least the last five year and projected forward.” (pg. 76)

New Initiatives – “The Committee is concerned that every year new NIH initiatives are announced and that, although new initiatives start at the planned level, over time these projects are not supported in
the budget requests at levels that will result in achievement of initial expectations. The Committee requests NIH to provide a table in the fiscal year 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 on-going and proposed in the current budget. The table should identify the planned budget level provided; a list of participating Institutes and Centers (ICs); the linkage to the NIH-wide strategic plan; and percentage of the funds focused on basic science, as a minimum for each initiative.” (pg. 76-77)

**Reproducibility of Scientific Methods** — “The Committee notes that the gold standard of good science is the ability of a lab to reproduce a method and finding and is therefore continues to be concerned with reports that some published biomedical research cannot be easily reproduced. The Committee expects NIH to continue to stress the importance of experimental rigor and transparency of reporting of research findings in order to enhance the ability of others to replicate them. The Committee requests an update in the fiscal year 2017 budget request on how NIH is measuring the effectiveness of each step NIH has taken to develop and implement best practice guidelines to better facilitate the conduct of replicable research and research transparency in the reporting of methods and findings.” (pg. 77)

**Pediatric Research Network** — “The Committee notes the enactment of the National Pediatric Research Network Act that authorizes a collaborative and multi-institution pediatric research network to accelerate the pace of pediatric disease discovery. The Committee requests the NIH Director to provide an update in the fiscal year 2017 budget request on the specific steps on-going and planned towards the aims of the Act and describe how the network can participate in the alternative approach to support the goal of increasing biomedical knowledge on children’s diseases to accelerate cures, treatment, and prevention activities as anticipated in the National Children’s Study.” (pg. 78)

**Precision Medicine Initiative** — “The Committee provides the requested funds to support the trans-NIH PMI within the Common Fund. The Committee expects to receive a comprehensive plan that outlines the way in which NIH plans to execute the PMI, initiative length and how data on human subjects will be protected. The NIH shall, as part of the planning for this project, examine similar activities being performed by industry, nonprofits, or academia to ensure federal funds are used to fill gaps and not duplicate effort. The PMI plan should consider and evaluate how public private partnership opportunities can be leveraged. Further, the plan should include an examination of drug regulatory processes to ensure the FDA is positioned to support therapies that may result from private or public sector PMI research. The plan should also describe the practical application of genetic discoveries, including how to support the development of appropriate data analytic tools using genetic data and the consideration of pathways involved in chronic diseases. The Committee requests NIH to submit the plan within 90 days of enactment. Future funding requests for the PMI are expected to identify how much existing NIH personalized and precision medicine portfolio funds are being re-competed annually. The Committee notes that further proposed NIH initiatives and programs of this nature should be more fully developed prior to requesting funds and the funds should be specifically identified by IC.” (pg. 79)

**Prioritization of Funding** — “The Committee expects NIH to prioritize federal funds for medical research on discovery over outreach and education. The Committee expects NIH to distribute funding based on the merit of researchers ideas and productivity, without applying discriminatory review requirements to extramural investigations, or creating barriers to funding for research institutes or team-based research. The Committee reiterates its desire for NIH to subject intramural resources to the same policies and review as extramural researchers. Further, NIH is expected to complete and actively use the NIH 5-year scientific strategic plan, directed in the fiscal year 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.” (pg. 79)

Protecting Human Subject Data – “The Committee reiterates its concerns related to the protection of privacy of individuals who are the subject of research. The fiscal year 2015 Appropriations Act included statement language directing NIH to include requirements related to privacy protections in every grant that involves human research, such as the issuance of certificates of confidentiality. The Committee provides bill language to require investigators receiving NIH funding for new and competing research projects designed to generate and analyze large volumes of data derived from human research participants to obtain a certificate of confidentiality. Further, the Committee is aware that NIH recognizes that privacy protections will be critical for the success of the PMI and other similar genomic research. The Committee requests that no later than 90 days after enactment, NIH provide a report on specific steps NIH can and will take to further protect the privacy of human subjects and specific legislative actions that could further protect these individuals who may participate in future NIH supported research.” (pgs. 79-80 & pg. 179)

Translational Research – “The Committee understands NIH has undertaken an expansion of translational research and sciences over the past several years. The Committee requests an update on the specific results of these efforts, current activities, a plan for future activities, and the fiscal year 2013 through 2016 annual NIH expenditures on translational sciences in the fiscal year 2017 budget request. Further, the updates should provide the definition for Translational Research and how it applies the definition as it makes awards to various institutions.” (pg. 80)

Young Investigators – “The Committee directs NIH to report on actions it has taken to lower the median age at which investigators receive their first R01 awards within 120 days of enactment. In addition, the NIH shall submit an accompanying plan outlining concrete steps to lower the median age at which individuals receive their first R01 award. The Committee urges NIH to convene a working group of stakeholders from academia, young researchers, industry leaders, and government officials to move forward on this goal.” (pg. 80-81)

Updates – The Committee requests general updates (latest efforts ongoing and planned) in the fiscal year 2017 budget request on a variety of issues and topics specifically mentioning the Administrative Burden Workgroup and the NIH Workforce Study (pg. 81)

General Provisions – Includes the following:

- **Sec. 203** – limits the salaries on grants to Executive Level III ($168,700 in 2015). This represents a decrease of $14,600 (8 percent) according to an analysis by AAMC (pg. 114 & pg. 180)
- **Sec. 215** – transfers one percent of the funds made available for NRSA to HRSA (pg. 115, pg. 156 & pg. 181)
- **Sec. 232** – new provision requiring the Secretaries of HHS and the Department of Agriculture to develop dietary guidelines based on scientific evidence and to provide for additional public comment (pg. 116)
- **Sec. 516** – requires each department and agency funded in the bill to submit an operating plan to the House Appropriations Committee within 45 days of enactment of the bill (pg. 153)
- **Sec. 522** – requires all departments funded in the bill to continue submitting quarterly reports to the House Appropriations Committee on the status of unspent balances of appropriations, including amounts that are unobligated and uncommitted, committed to contracts, grants, or other planned obligations, and obligated but unexpended, and the source year of balances (pg.
153). There’s additional language expressing concern about agencies not providing timely information on the status of unobligated appropriations balances, including lack of information about the age of balances that extend over several years. (pg. 6 under “Oversight”)