Division of Adolescent and School Health (DASH) to evaluate and improve school HIV prevention activities and increase outreach strategies;
Epilepsy;
Hydrocephalus;
Interstitial Cystitis;
National Mesothelioma Patient Registry;
Neonatal Abstinence Syndrome;
Nutrients;
Perinatal Collaboratives; and
Vision Health Initiative.

NATIONAL INSTITUTES OF HEALTH

The Committee recommends an appropriation of $31,184,000,000 for the National Institutes of Health (NIH), which is $1,100,000,000 above the fiscal year 2015 level, and $100,000,000 above the request. The level includes $30,174,000,000 in discretionary appropriations and $1,010,000,000 in PHS Act section 241 evaluation set-aside (TAP) transfers. The Committee did not include the Administration's requested bill language to increase the TAP, which would have allowed the Secretary to divert an estimated $850,000,000 away from NIH. 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. The Committee provided level is $560,741,000 above the pre-sequester level of $30,623,259,000 that NIH received in fiscal year 2012.

The core mission of NIH is to invest in basic biomedical research to uncover new knowledge that can lead to better health and disease cures for everyone. NIH has historically enjoyed a great deal of flexibility from Congress as the Committee has not directed spending for particular diseases or research out of respect for the scientific process.

The Committee understands the value of the extramural research community that is composed of scientists, clinicians, and other research personnel affiliated with more than 2,600 organizations, including universities, medical schools, hospitals, and other research facilities in all 50 states. 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).

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.

The Committee appreciates NIH's commitment to ensure NIH is not supporting research aligned to the "Strengthen Health Care" goal of the HHS Strategic Plan and to other research related to data or policy support of Health Reform as these activities do not directly relate to NIH's mission. The Committee directs NIH to continue this policy and commitment.

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.

The bill continues to provide specific funding levels for the Clinical and Translational Science Awards program, the Institutional Development Awards program, Cures Acceleration Network, Common Fund, and the National Children's Study (NCS) in bill language.

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).

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.

NATIONAL CANCER INSTITUTE (NCI)

Mission.—NCI conducts and supports basic and applied cancer research in early detection, diagnosis, prevention, treatment, and rehabilitation. NCI provides training support for research scientists, clinicians and educators, and maintains a national network of cancer centers, clinical cooperative groups, and community clinical oncology programs, along with cancer prevention and control initiatives and outreach programs to rapidly translate basic research findings into clinical practice. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs. The Committee modifies the bill language, as requested by the Administration, to allow NCI to use up to $16,000,000 for repairs and improvements at the NCI Frederick Federally Funded Research

and Development Center in Frederick, MD due to the increasing maintenance backlog of this site.

Breast Cancer.—The Committee is aware of recent news coverage highlighting studies about mammography screening for breast cancer that questions the use and validity of screening for discovering cancers. Although the majority of scientific studies have corroborated the value of early detection of breast cancers through screening, other studies have concluded that screening sometimes results in false positives and over treatment. This has created a less clear picture of the benefits of screening and may lead women to avoid periodic mammography, an experience some women already view as uncomfortable. From 1990 to 2010, deaths from breast cancer decreased by 34%. This drop in breast cancer mortality has been attributed to both improvements in treatment and earlier detection of cancers. However, in 2013, 230,000 new cases of breast cancer were diagnosed in the United States and almost 40,000 women died from breast cancer. Given the current controversies over screening and the need to validate new screening technologies versus existing technologies, it is clear that a new, comprehensive study of these issues is warranted. The Committee encourages NCI to support research to address these issues and to hopefully provide women and physicians with a clearer, more informed picture of how breast cancer imaging should be considered as part of the overall women's health care environment and urges the Secretary not to implement changes to the breast cancer screening recommendations until this research is completed.

Cancer Disparities.—The Committee requests NCI and the National Institute on Minority Health and Health Disparities (NIMHD) to prepare a joint update for the fiscal year 2017 budget request on efforts underway and planned to end this disparity, including activities to focus on research, prevention, and treatment of cancer in minority communities.

Colorectal Cancer.—The Committee encourages support of meritorious scientific research on colorectal cancer to better understand the biology of young-onset colorectal cancer. Specifically, the Committee requests an update in the fiscal year 2017 budget request related to research activity on the biology of young-onset colorectal cancer in adults under the age of 50.

Gastrointestinal Cancer.—The Committee continues to be concerned about gastric cancer, particularly among young adults and supports gastric cancer being studied in The Cancer Genome Atlas (TCGA). The Committee notes that research on gastric cancer is less advanced than that of many other cancers. The Committee therefore encourages NCI to consider requesting applications for gastric cancer research that leverages the use of genomic data from the TCGA.

Heavy Ion Cancer Therapy and Research—The Committee understands NCI recently issued a planning grant for a Heavy Ion Therapy and Research. The Committee encourages NCI to coordinate with other federal agencies on the need and potential funding sources in determining the scientific justification to move forward or retrofit any existing facilities.

Liver Cancer.—The Committee continues to be concerned with the lack of a focused liver cancer research program. The NCI is urged to support a Specialized Program of Research Excellence on

liver cancer, as well as liver cancer program projects. The Committee encourages more focus on the development of biomarkers to serve as early detection markers of cancer to therefore offer the prospect of improved outcomes.

Melanoma.—The Committee encourages NCI to develop a 5-year plan across NCI's divisions, and coordinate with other federal agencies and advocates to align melanoma research resources. The Committee understands the NCI MATCH Trial and Exceptional Responders Initiative may provide valuable insight to benefit melanoma subpopulations knowledge and encourages use of these mechanisms. The Committee requests an update in the fiscal year 2017 budget request on these efforts.

NCI Designated Cancer Centers.—The Committee requests an update in the fiscal year 2017 request on how NCI supports or plans to support Institutional Development Award programs in states to broaden the NCI designated cancer center representation within these states.

NCI Precision Medicine Initiative (PMI).—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.

Office of Cancer Survivorship.—The Committee requests a report in the fiscal year 2017 budget request on actions planned or on-going to focus resources and attention to the youngest of cancer survivors.

Pancreatic Cancer.—The Committee encourages NCI to prioritize support for meritorious research for pancreatic cancer generally and specifically related to early detection of pancreatic cancer. The Committee encourages a focus on promising research to test members of high-risk pancreatic cancer families, including non-invasive screening methods. The Committee requests an update in the fiscal year 2017 budget request on these efforts.

Pediatric Low Grade Astrocytoma Research (PLGA).—The Committee encourages continued research efforts toward the identification of new therapies for PLGA patients, to include clinical trials. The Committee urges NCI and NIH to seek public/private partnerships opportunities on PLGA research. The Committee requests an update in the fiscal year 2017 budget request on on-going and planned activities across NIH.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

Mission.—NHLBI provides leadership for a national research program in diseases of the heart, blood vessels, lungs, and blood, in blood resources, and in sleep disorders through support of basic, clinical, and population-based research. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Chronic Obstructive Pulmonary Disease (COPD).—The Committee commends NHLBI for convening an interagency meeting on federal COPD planning. The Committee is eager to review the forthcoming peer-reviewed publications and urges NHLBI to move forward efforts to address the rising burden of COPD in the U.S. Further, the Committee is aware that Alpha 1 Antitrypsin Deficiency (Alpha 1) is a major genetic risk factor for developing COPD. The Committee encourages NHLBI to convene a group of expert stakeholders and other federal agencies to develop a treatment algorithm for Alpha 1 related disease and a coordinated federal and private approach to increase knowledge that can improve the diagnosing of this disease.

Pulmonary Hypertension (PH).—The Committee applauds NHLBI for leading research efforts that have helped prolong life for individuals affected by PH and encourages continued research related to the underlying mechanisms of PH, particularly idiopathic pulmonary arterial hypertension as additional gains may benefit patient health and wellness.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

Mission.—The mission of NIDCR is to improve the nation's oral, dental and craniofacial health through research and research training. NIDCR accomplishes its mission by performing and supporting basic and clinical research; conducting and funding research training and career development programs to ensure that there is an adequate number of talented, well-prepared, and diverse investigators; and coordinating and assisting relevant research and research-related activities. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

Mission.—NIDDK supports research in three major disease categories: diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. NIDDK supports a coordinated program of fundamental and clinical research and demonstration projects relating to the causes, prevention, diagnosis, and treatment of diseases within these categories. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Focal Segmental Glomerulosclerosis (FSGS).—The Committee commends NIDDK for partnering with NCATS on the Nephrotic Syndrome (NS) Study Network with the goal of developing precision medicine for NS. The Committee encourages continued support for studies on the mechanisms of the FSGS/NS disease process.

Gestational Diabetes.—The Committee recognizes the importance of research related to gestational diabetes and encourages NIDDK to continue to support highly meritorious research on gestational diabetes.

Inflammatory Bowel Disease.—The Committee commends NIDDK for hosting a conference on inflammatory bowel disease in children which could lead to further research in this area. The Committee encourages NIDDK to continue efforts to identify the etiology of the disease in order to inform the development of cures for inflammatory bowel disease.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

Mission.—NINDS supports and conducts basic, translational, and clinical neurological research and research training to increase understanding of the brain and improve the prevention and treatment of neurological and neuromuscular disorders. The NINDS mission encompasses over 600 disorders, including stroke, head and spinal cord injury, epilepsy, multiple sclerosis, and neurodegenerative disorders such as Parkinson's disease. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Brain Aneurysms.—The Committee notes that brain aneurysm research appears to be a lower priority. The Committee requests an update in the fiscal year 2017 budget request on on-going and planned research related to this issue.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.—The human brain remains one of the greatest mysteries in science and one of the greatest challenges in medicine. Neurological and psychiatric disorders, such as Alzheimer's disease, Parkinson's disease, autism, epilepsy, schizophrenia, depression, and traumatic brain injury, exact a tremendous toll on individuals, families, and society. 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 it 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.

Dystonia Research.—The Committee commends NINDS for its leadership of dystonia research. The Committee encourages NINDS to continue to prioritize dystonia research that can advance the pace of clinical and translational research to find better treatments and a cure.

Hydrocephalus Research.—The Committee encourages NIH, under the direction of the NINDS, to conduct a state of the science workshop to investigate the status of current federally and non-federal supported hydrocephalus specific research projects. The Committee requests the fiscal year 2017 budget request include a summary of the key recommendations and other findings from the workshop.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Mission.—NIAID supports and conducts basic, applied, and clinical research and research training programs in infectious, immunologic, and allergic diseases. NIAID-supported research includes research on HIV/AIDS, malaria, tuberculosis, sexually transmitted infections, neglected tropical diseases, emerging and re-emerging infectious diseases, asthma, allergic and autoimmune diseases, and transplantation. The goals of NIAID research are to increase the understanding of disease pathogenesis and the immune system, to improve disease diagnosis, to develop new and improved drugs to treat such diseases, and to develop new and improved vaccines and other approaches to prevent such diseases, many of which significantly affect public health. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

National Strategy for Combating Antibiotic Resistant Bacteria (CARB).—The Committee directs the Department to work with the Departments of Defense, Agriculture, Veterans Affairs and the Food and Drug Administration (FDA) to both track and store antibiotic resistance (AbR) genes and the mobile genetic elements from AbR bacteria. This information, along with metadata, including geographic information system coordinates describing where they were isolated, is essential to monitor emerging AbR bacteria, assess their threat to public health and develop mitigation strategies. The Committee further directs the Department to include in their fiscal year 2017 request the progress being in implementing the above language and the overall CARB national strategy initiative.

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 in-

cludes specific goals and annual milestones to support this initiative within 180 days of enactment.

Biodefense Spend Plan.—The Committee appreciates ASPR's completion of the 5-year spending plan for the medical countermeasure (MCM) enterprise, but notes concerns on the level of detail included in the spend plan for NIAID's biodefense activities. The spend plan offered little insight into the NIAID's spending priorities for the numerous MCM candidates in its portfolio. The Committee requests NIAID, working with ASPR, to provide more detail on NIAID's future goals for MCM research, including its efforts to transition these projects to advanced research at BARDA, and identify how NIAID coordinates with BARDA's on advanced development and procurement priorities. Further, the Committee requests a summary of this information be included in the fiscal year 2017 budget request. The Committee encourages NIAID to focus on biodefense MCM candidates that have received a Material Threat Determination from the Department of Homeland Security.

Valley Fever.—The Committee commends NIH and CDC on the continued joint efforts to combat coccidioidomycosis, also known as Valley Fever. Specifically, the Committee supports ongoing efforts by NIH and CDC to conduct a Randomized Controlled Trial (RCT) to identify an effective treatment for Valley Fever, encourage development of a vaccine, and help increase awareness of this disease among medical professionals and the public. The Committee looks forward to when patients can begin enrolling in the RCT later this year.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

Mission.—NIGMS supports research and research training in the basic biomedical sciences. Institute grantees, working in such fields as cell biology, biophysics, genetics, developmental biology, pharmacology, physiology, biological chemistry, bioinformatics, and computational biology study normal biological processes to better understand what goes wrong when disease occurs. In this way, NIGMS supports the development of new knowledge, theories, and technologies that can then be applied to the disease-targeted studies supported by other NIH components. NIGMS-supported basic research advances also find applications in the biotechnology and pharmaceutical industries. The Institute's training programs help develop scientists needed in industry and academia and increase the diversity of the biomedical workforce. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs.

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.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

Mission.—The NICHD conducts and supports basic, translational, and clinical research on the reproductive, developmental, and behavioral processes that determine and maintain—and rehabilitation that restores and improves—the health and well-being of children, adults, families and populations. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs.

Capacity for Data Collection on Severe Maternal Morbidity.—The Committee understands there are no uniform definitions of severe maternal morbidity and that uniform definitions would help Federal, State and local agencies and research institutions establish standardized and interoperable processes for surveillance, data collection, and research. The Committee encourages NICHD to work with CDC to hold a multi-stakeholder consensus workshop to identify uniform definitions for severe maternal morbidity.

Preterm Birth.—The Committee applauds NICHD's work with leading global health organizations to develop a research agenda aimed at reducing preterm birth. Public and privately funded research that spans the range of discovery, development, and delivery science is needed in order to identify the causes of premature birth. The Committee urges NICHD to continue to invest in biomedical and clinical research related to the prevention of preterm birth and the care and treatment of preterm infants.

NATIONAL EYE INSTITUTE (NEI)

Mission.—NEI conducts and supports basic and clinical research, research training, and other programs with respect to blinding eye diseases, visual disorders, and mechanisms of visual function, preservation of sight, and the special health problems and needs of individuals who are visually-impaired or blind. The Committee expects NEI to systematically coordinate closely with other HHS agencies to share new scientific information, specifically aimed at the prevention of blindness and increase awareness to the community and providers through various other HHS outreach programs.

Accelerate Cures Related to Retina Disease.—The Committee directs NEI to create a challenge program to advance the speed of basic research to cure retina disease by creating a forum for the NEI Director to survey the field of basic retina research discoveries to provide rewards for research not otherwise funded through NEI or other NIH supported competitive awards. The Committee expects NEI to provide an update and timeline in the fiscal year 2017 budget request to describe how the program will be advertised, funding allocated, and criteria to evaluate submissions for possible

challenge rewards to further incentive non-NIH supported researchers to accelerate basic research through this mechanism. The Committee further expects NEI to distribute the findings of this program widely to the NEI research community to further promote the leveraging of federal and non-federally supported retina research.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

Mission.—The mission of NIEHS is to prevent and reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease. In addition, NIEHS is responsible for the research of the National Toxicology Program whose mission is to coordinate toxicity testing across the Federal government and to evaluate substances of public health concern. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL INSTITUTE ON AGING (NIA)

Mission.—NIA supports and conducts biomedical, social and behavioral research with respect to the aging process and the diseases and other special problems and needs of older Americans. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Alzheimer's Disease.—In 2012, the National Plan to Address Alzheimer's Disease was released to address the major challenges presented by Alzheimer's disease by 2025. Since then, although Alzheimer's research has received annual increases for federally funded Alzheimer's research, it is still funded less than the annual level needed to accomplish the goal of the national Alzheimer's plan. The Committee accelerates funding for Alzheimer's disease research to $886,000,000, an increase of $300,000,000 over fiscal year 2015 as an important next step to ensure success of this critical initiative to develop preventative treatments and cures. The Committee recognizes that initiatives of this nature must be adequately funded to assure achievement of the goals and plan milestones. The Committee expects NIH will ensure the fiscal year 2017 request provides the appropriate level of funding to keep on this path. Further, the Committee encourages the distribution of a reasonable portion of Alzheimer's research support to meritorious IDeA program researchers.

The Committee requests NIA to convene a working group of stakeholders, including patient advocacy organizations and nonprofit funders of Alzheimer's and dementia research, within 180 days of enactment of this act to develop possible frameworks and strategies for a direct public-private partnership to fund meritorious research proposals on Alzheimer's Disease that are not supported directly by NIH. NIH shall provide a report annually in its fiscal year 2017 and out year budget requests identifying the total level of NIH peer-reviewed research supported by qualified third-party Alzheimer's Disease researchers through such a partnership.

Finally, the Committee notes continued support for Alzheimer's Disease Research Centers.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

Mission.—NIAMS conducts and supports basic and clinical research and on the more than 100 forms of arthritis; osteoporosis and other bone diseases; muscle biology and muscle diseases; orthopedic disorders, such as back pain and sports injuries; and numerous skin diseases. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Lupus Research Plan.—The Committee commends NIAMS for leading the effort to review the current state of the science, evaluate progress on the existing lupus research plan and develop a new action plan for lupus research. The Committee applauds the broad solicitation of input across NIH and the greater research and advocacy community, and encourages special attention for efforts in this research area.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

Mission.—NIDCD funds and conducts research in human communication. Included in its program areas are research and research training in the normal and disordered mechanisms of hearing, balance, smell, taste, voice, speech and language. The Institute addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. In addition, NIDCD is actively involved in health promotion and disease prevention, and supports efforts to create devices that substitute for lost and impaired sensory and communication functions. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

Mission.—NINR supports and conducts scientific research and research training to reduce the burden of illness and disability; improve health-related quality of life; enhance end-of-life and palliative care; and establish better approaches to promote health and prevent disease. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

Mission.—NIAAA supports research to generate new knowledge to answer crucial questions about why people drink; why some individuals are vulnerable to alcohol dependence or alcohol-related diseases and others are not; the relationship between genetic and environmental factors involved in alcoholism; the mechanisms whereby alcohol produces its disabling effects, including organ

damage; how to prevent alcohol abuse and associated damage, especially in the underage population; and how alcoholism treatment can be improved. NIAAA addresses these questions through a program of biomedical, behavioral, and epidemiologic research on alcoholism, alcohol abuse, and related problems. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs.

Fetal Alcohol Syndrome (FAS) Research.—The Committee was pleased that NIAAA's budget request proposed increases in research on how alcohol interferes with human development and the various underlying aspects of alcohol-induced fetal damage. The Committee encourages NIH to consider the benefits and methods to support a clearinghouse and improved coordination with federal and private sector partners to best facilitate the translation of science into public health promotion strategies and interventions benefiting individuals living with FAS.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

Mission.—NIDA-supported science addresses questions about drug abuse and addiction, which range from its causes and consequences to its prevention and treatment. NIDA research explores how drugs of abuse affect the brain and behavior and develops effective prevention and treatment strategies. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Adolescent Behavioral and Cognitive Development (ABCD).—The Committee applauds the Collaborative Research on Addictions at NIH initiative and the launch of the ABCD study. Unique in its scope and duration, the study will recruit 10,000 youth before they begin using alcohol, marijuana, nicotine and other drugs, and follow them over 10 years into early adulthood to assess how substance use affects the trajectory of the developing brain. The Committee 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.

Medications Development.—The Committee understands NIDA is considering new technologies for the development of next-generation pharmaceuticals. For example, NIDA is exploring approaches to develop viable immunotherapeutic or biologic (e.g., bioengineered enzymes) approaches for treating addiction. The Committee looks forward to hearing more about work in this area in the fiscal year 2017 budget request.

NIDAMED.—The Committee encourages its support for NIDAMED, an initiative designed to reach out to physicians, physicians in training, and other health care professionals to increase especially those treating our youth to better recognize the signs that lead to drug abuse and addiction.

Opioid Drug Abuse.—The Committee remains concerned about prescription drug abuse, specifically the misuse of orally adminis-

tered opioid drugs. According to some reports, more than 35 million Americans have abused prescription opioids at some point in their lifetimes. The June 2011 Institute of Medicine report on relieving pain indicates that such abuse and misuse resulted in an annual estimated cost to the Nation of $72.5 billion. The Committee expects NIDA to continue to support meritorious scientific activities related to research on medications to alleviate pain with reduced abuse liability and, as appropriate, to work with private partners on innovative research into such medications. In addition, NIDA should continue to fund research to better prevent and treat prescription drug abuse and to coordinate with CDC to help identify scientific research gaps. The Committee requests an update in the fiscal year 2017 budget request on the activities related to addressing the opioid drug abuse problem.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

Mission.—NIMH is responsible for basic and clinical research to improve diagnosis, treatments, and overall quality of care for persons with mental illnesses. Disorders of high priority to NIMH include schizophrenia; depression and manic depressive illness; obsessive-compulsive disorder; anxiety disorders and other mental and behavioral disorders that occur across the lifespan, which include childhood mental disorders such as autism and attention-deficit/hyperactivity disorder; eating disorders; and other illnesses. NIMH supports and conducts fundamental research in neuroscience, genetics, and behavioral science. In addition to laboratory and controlled clinical studies, NIMH supports research on the mental health needs of special populations and health services research. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Community Based Participatory Research (CBPR).—The Committee is aware that 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 fiscal year 2017 budget request on any CBPR activities its supports and the most appropriate role for CBPR within the NIMH portfolio.

Early Detection and Prevention of Psychosis.—The Committee applauds NIMH's early detection and intervention efforts involving psychosis in young people and encourages NIMH to coordinate with other ICs to expand these efforts.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

Mission.—NHGRI provides leadership for the development of resources and technology to accelerate genome research and its application to human health. NHGRI-supported activities include basic and translational research to understand the sequence and function of both human and non-human genomes, human genetic variation, and the genetic and environmental basis of disease. Also central to NHGRI research goals are training programs and a strong focus on the ethical, legal, and social implications of genomic science and medicine. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new

scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

Mission.—The NIBIB mission is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

Mission.—NIMHD conducts and supports research, training, and other programs aimed at reducing the disproportionately high incidence and prevalence of disease, burden of illness and mortality experienced by certain American populations, including racial and ethnic minorities and other groups, such as the urban and rural poor, with disparate health status. The Committee expects the Institute to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

Research Centers in Minority Institutions (RCMIs).—The Committee continues to support RCMIs and expects the RCMIs to receive no less than $55,319,000, which is the fiscal year 2015 level plus the general increase provided to NIMHD.

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM)

Mission.—NCCAM was established to stimulate, develop, and support rigorous and relevant research of high quality and open, objective inquiry into the safety and effectiveness of complementary and alternative medicine (CAM) practices and to train individuals to apply the tools of exacting science to CAM systems and modalities in order to provide health care professionals and the American public with reliable information about these practices. The Committee expects the Center to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

Mission.—NCATS was established to advance translational sciences, coordinating and developing resources that leverage basic research in support of translational science and developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities. NCATS also includes the Office of Rare Disease Research (ORD) that was established in recognition of the need to provide a focal point of attention and coordination at NIH for research on rare diseases. ORD works within the authorized mission of NCATS

to provide an increase focus on rare disease research and orphan products development; develops a centralized database on rare diseases research; and stimulates rare diseases research by supporting scientific workshops and symposia to identify research opportunities. The Committee expects the NCATS to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs.

Bridging Interventional Development Gaps BrIDGs Program.—The Committee understands the BrIDGs program has supported new drug interventions and encourages NCATS to look for opportunities to encourage additional success.

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.

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.

JOHN E. FOGARTY INTERNATIONAL CENTER (FIC)

Mission.—FIC was established to improve the health of the people of the United States and other nations through international collaborations in the biomedical sciences. In support of this mission, the FIC pursues the following four goals: (1) mobilize international research efforts against global health threats; (2) advance science through international cooperation; (3) develop human resources to meet global research challenges; and (4) provide leadership in international science policy and research strategies. The Committee urges FIC to coordinate systematically and closely with other HHS agencies on any efforts to disseminate research results in a manner that uses the various existing HHS outreach programs.

NATIONAL LIBRARY OF MEDICINE (NLM)

Mission.—The NLM collects and organizes information important to biomedicine; serves as a national information resource for medical education, research, and health service activities; enhances access to biomedical literature through electronic services; serves the public by providing electronic access to reliable health information for consumers; supports and directs the national network of libraries of medicine; provides grants for research in biomedical communications, medical library development, and training health information specialists; conducts and supports research in biomedical informatics and computational biology; and creates information resources for genomics, molecular biology, toxicology, medical images, environmental health, emergency preparedness and response, and health services research. The Committee expects the Institute to systematically coordinate through other HHS agencies to share

new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

OFFICE OF THE DIRECTOR (OD)

Mission.—The OD provides leadership to the NIH research enterprise and coordinates and directs initiatives that cross-cut NIH. OD is responsible for the development and management of intramural and extramural research and research training policy, the review of program quality and effectiveness, the coordination of selected NIH-wide program activities, and the administration of centralized support activities essential to the operations of NIH. 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.

The Committee has provided bill language for specific funds authorized by the recently enacted Gabriella Miller Kids First Research Act within the Common Fund to support the second year of the 10-year Pediatric Research Initiative. 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.

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 10 years. The Committee appreciates NIH's efforts to support only bio-medical research within the Common Fund.

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.

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.

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.

Marijuana Research.—The Committee is concerned that as more states in the nation choose to enact laws that allow access to and use of marijuana for medical purposes the fact remains that there is no significant body of medical and scientific research validated by NIH or NIDA on the actual medical efficacy of marijuana. Consequently, despite anecdotal evidence to the contrary, it is entirely possible that Americans may be putting their health at risk when using marijuana for medicinal purposes. The Committee believes it is time to settle the matter of whether or not marijuana has medical benefits that can be validated and documented by scientific research. The Committee directs the NIH to report back to the Committee within 120 days after enactment with a plan by which the NIH could engage the appropriate institutes, including NIDA but not only NIDA, but other agencies the Director determines are appropriate (e.g., FDA) to construct long- and short-term studies on the potential benefits and detriments of the use of marijuana for medical purposes. The marijuana to be used in the studies shall be supplied by NIDA for control purposes.

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.

Review of Maternal Deprivation Studies.—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.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

The mission of DPCPSI is to coordinate and facilitate trans-NIH research initiatives and emerging areas of scientific opportunities and public health challenges. The Division houses these NIH offices: the Office of Research on Women's Health; the Office of AIDS Research; the Office of Dietary Supplements; the Office of Behavioral and Social Sciences Research; the Office of Disease Prevention; and the Office Research Infrastructure Programs. 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.

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.

Gabriella Miller Kids First Research Act.—The Committee includes funding within the Common Fund to support the Gabriella Miller Kids First Research Act, named after Gabriella Miller, who died in 2013 as a result of pediatric cancer. The Committee directs the NIH Director to use at least $12,600,000 of Common Fund resources in fiscal year 2016 to support pediatric research as authorized in the Gabriella Miller Kids First Research Act. The Committee encourages NIH to prioritize research relating to childhood cancer within the Kids First program and requests an update in the fiscal year 2017 budget request on the 10-year program, planned activities, and on-going research.

Office of Research on Women's Health

The Office of Research on Women's Health (ORWH) works in collaboration with the NIH ICs to promote and foster efforts to address gaps in knowledge related to women's health through the enhancement and expansion of funded research and/or the initiation of new investigative studies. ORWH is responsible for supporting the inclusion of women in clinical research funded by NIH, including the development of a computerized tracking system and the implementation of guidelines on such inclusion. ORWH is also involved in promoting programs to increase the number of women in biomedical science careers, and in the development of women's health and gender factors as a focus in biology.

Office of AIDS Research

The Office of AIDS Research (OAR) is authorized to manage trans-NIH AIDS research. The Director of OAR and the Director of NIH jointly determine the total for AIDS research within the NIH appropriation based on scientific need and meritorious scientific opportunity relative to NIH's overall plan. The Committee expects NIH to continue to track NIH AIDS funding.

The bill continues language permitting OAR to use up to $8,000,000 for construction or renovation of facilities, as authorized in title XXIII of the Public Health Service Act.

Office of Dietary Supplements

The Office of Dietary Supplements (ODS) was established in recognition that dietary supplements can have an important impact on prevention and health maintenance. In collaboration with other NIH institutes and centers and other federal agencies, ODS works to strengthen knowledge about dietary supplements by supporting and coordinating scientific research in the field.

Office of Behavioral and Social Sciences Research

The Office of Behavioral and Social Sciences Research (OBSSR) provides leadership and direction for the development of a trans-NIH plan to increase the scope of and support for behavioral and social sciences research and in defining an overall strategy for the integration of these disciplines across NIH institutes and centers; develops initiatives to stimulate research in the behavioral and social sciences arena and to integrate a bio-behavioral perspective across the research areas of NIH; and promotes studies to evaluate the contributions of behavioral, social and lifestyle determinants in the development, course, treatment, and prevention of illness and related public health problems.

Office of Science Education

The Office of Science Education (OSE) plans, develops, and coordinates a comprehensive science education program to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The Office develops curriculum supplements and other educational materials; maintains a website as a central source of information about NIH science education resources; establishes national model programs in public science education, and promotes science education reform as outlined in the National Science Education Standards and related guidelines.

Office of Disease Prevention

The Office of Disease Prevention (ODP) assesses, facilitates, and stimulates research into disease prevention and health promotion in collaboration with NIH and other public and private partners, and disseminates the results of this research to improve public health. ODP produces evidence-based consensus statements addressing controversial medical issues. The Committee expects ODP to disseminate consensus statements and disease prevention and health promotion information through appropriate HHS outreach programs.

Office of Research Infrastructure Programs

The Office of Research Infrastructure Programs (ORIP) provides support for research and a variety of research infrastructure needs, including animal models and facilities; research models, biological materials, and human biospecimens; training and career development for veterinarians engaged in research; the acquisition of state-of-the-art instrumentation through the Shared and High-End Instrumentation Programs; research resources grants to expand, re-model, renovate, or alter existing research facilities or to construct new research facilities; and coordinates science education activities.

Multi-institute Research Issues

Angelman Syndrome.—The Committee recognizes the promising scientific gains made in the pursuit of treatments for angelman syndrome. The Committee applauds the contributions of the angelman syndrome natural history study and the private partners working diligently to advance the growing body of angelman syndrome research towards practical treatments. Further research in this area holds great promise for both angelman syndrome and forms of autism also linked to misexpression of the UBE3A gene. The Committee encourages NIH to support angelman syndrome research and to consider meritorious research. The Committee encourages NIH to leverage Federal funds with public-private partnerships in the areas of angelman syndrome, autism, and UBE3A related disorders.

Anhydramnios.—The Committee requests NIH conduct a state of the science on anhydramnios research and possible treatments and provide an update in the fiscal year 2017 budget request.

Basic Biomedical 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.

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.

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.

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.

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.

Duchenne Muscular Dystrophy.—The Committee requests an update in the fiscal year 2017 budget request on NIH's plans to implement the recent changes to the Muscular Dystrophy CARE Act and summary of the outcome from the latest Muscular Dystrophy Coordinating Committee and timeframe for the next two meetings.

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.

Fragile X Research.—The Committee commends NICHD for leading the effort to map the molecular, physiological, biological, and genetic connections between fragile X (FX), the fragile X protein, and autism. The fragile X gene and its protein continue to present important insight into discovering the root cause of autism and disease modifying treatments for FX and autism. The Committee encourages NIH to explore ways to utilize FX and autism research in tandem to accelerate the pace of research toward identification of the commonality between the two conditions and the development of disease modifying treatments that will reduce health burdens.

Hepatitis B.—The Committee encourages NIAID and NIDDK to continue their long-standing commitment to advancing the scientific knowledge on hepatitis B and chronic hepatitis B. The Committee urges aggressive discovery to find ways to prevent and develop new therapies for hepatitis B that have the potential to be a cure. The Committee requests the NIH Director to consider establishing a hepatitis B specific Integrated Review Group (IRG) to review the grant applications associated with hepatitis B. The Committee also encourages development of an HBV Cure initiative, analogous to the HIV Cure initiative, to coordinate and accelerate the development of a cure for those afflicted with HBV.

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 re-

quests 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.

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.

Medication Assisted Treatment (MAT).—The Committee understands that NIDA supports 90 research projects totaling over $41 million related to MAT that include how to incorporate MAT into models of integrated healthcare. The Committee requests an update in the fiscal year 2017 request on research supported across NIH related to MAT, with specific review of MAT in primary care settings. In addition, the Committee expects NIH to conduct a review to identify the scientific gaps related to MAT research.

Minority Researchers.—The Committee continues to support the development of health professionals and scientists, including minorities, committed to researching and eliminating health disparities.

Mitochondrial Disease.—The Committee continues to support the study of mitochondrial function and primary mitochondrial disease. The Committee understands NIH supported a two-day workshop in March 2012 on primary mitochondrial diseases, which led to the development of a white paper and a working group on mitochondrial disease research with broad participation from various ICs. The Committee requests an update on the steps NIH has taken, on-going, and planned to further each of the white paper recommendations in the fiscal year 2017 budget request.

National Children's Study Alternative.—The Committee was disappointed that NIH determined it was not feasible for NIH to implement the National Children's Study (NCS) as originally conceived. The NCS was intended to be a 25 year longitudinal birth cohort observational study with the overall goal of improving child health and well-being and identifying antecedents of healthy adulthood by examining the effects of a broad range of environmental, behavioral, and biological factors. The Institute of Medicine's (IOM) June 2014 report noted the NCS' goals and mission had the potential to add to the scientific knowledge of children's health and development. 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 directed to work in consultation with pediatric groups to develop a series of alter-

native 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. NIH is expected to focus on at least prematurity, obesity, autism, asthma, and pediatric rare diseases like cancer. The Committee expects NIH to obtain data, biological samples, and specimens that can ultimately improve child health and well-being. The Committee understands that such a program can be built by leveraging existing cohort studies by expanding or adding study components; supporting projects with smaller cohorts that can investigate unique, disease-specific questions; expanding studies to increase sample size; and using or expanding pediatric networks and extant programs to include a focus on pediatric health.

The Committee directs NIH to draw on the lessons learned from the NCS as it develops a long-term plan for the NCS–A, and to establish an advisory panel with outside pediatric experts. Within 180 days of enactment, NIH is directed to submit and make public a NCS–A 10-year plan that includes milestones, goals, objectives, and projected funding estimates. The Committee urges NIH to review the plan at least every five years in a manner that obtains public input and that 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. In addition, NIH shall ensure it establishes and maintains a tracking system to ensure these funds do not supplant but supplement other children's research on-going or planned by NIH. Finally, NIH shall report on the NCS–A in the annual budget request.

Neurofibromatosis (NF).—The Committee continues to support NF research and treatment at multiple NIH ICs, including NCI, NINDS, NIDCD, NHLBI, NICHD and NEI. Children and adults with NF are at risk for the development of many forms of cancer. The Committee encourages NCI to continue its NF research portfolio in fundamental basic science, translational research and clinical trials focused on NF. The Committee appreciates NCI support to centers, clinical trials consortia, preclinical mouse models consortia and other NF-associated tumor sequencing efforts. The Committee encourages NIDCD activities in NF2 basic and clinical research. Further, the Committee notes NF1 can cause vision loss due to optic gliomas and encourages NEI to expand its investment in NF1 basic and clinical research.

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.

Precision Medicine Initiative (PMI).—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.

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.

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.

Psychotropic Medications and Children.—The Committee encourages NICHD, NIMH, CDC and the FDA to undertake a concerted effort to identify the research gaps and work with these agencies to determine the safety and efficacy of these medications, and to explore research into the biological evidence-base of psychosocial interventions that can be used instead of, or in combination with, psychotropic medications.

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.

Undiagnosed Disease Program (UDP).—The Committee continues support for the Undiagnosed Disease Network (UDN) within the UDP. The Committee requests an update in the fiscal year 2017 budget request on steps NIH has taken to develop public/private partnership for the UDN and how it can support physicians who are handling cases of undiagnosed diseases with new knowledge, consistent with applicable privacy laws, including HIPAA privacy and security law, through an ability to search for similar cases and to network and collaborate with physicians handling similar cases in order to accelerate the diagnosis, treatment options, and improve patient outcomes across the country. Further, the update should describe the criteria NIH uses to allow various level of access to the database based on the circumstances of the users' requirements.

Usher Syndrome.—The Committee continues to encourage support for research activities to prevent and correct the health related issues of Usher Syndrome. The Committee requests an update in the fiscal year 2017 budget request on the planned and on-going activities related to this syndrome. The update should address the funding level and manner in which the various ICs coordinate on common goals and objectives.

Vitiligo.—The Committee is concerned that although vitiligo is not a terminal or debilitating disease, it nonetheless can have serious effects on the lives of those afflicted with this skin-discoloring condition. The Committee is further concerned that this may lead to other conditions that have not been thoroughly considered including the impact on behavior and mental health consequences. The Committee requests an update in the fiscal year 2017 budget request on the epidemiology of the disease including incidence, causal factors, any associations with racial populations and hereditary occurrence. The update should include planned and on-going medical research to move towards a cure.

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.

Updates.—In addition the specific interest items, the Committee requests general updates in the fiscal year 2017 budget request for each of the listed disease, condition, or topic to describe the latest efforts ongoing and planned:

Administrative Burden Workgroup;
Aging Demographic Research;
Alcohol Dependence;
Amyloidosis;
Atrial Fibrillation;
Behavioral Science Research in NIMH;
Cerebral Palsy;
Chronic Pelvic Pain;
Congenital Heart Disease;
Diabetes;
Environmental Exposures;
Global Infections Disease Health Research;
Kennedy's Disease;
Kidney Disease;
Interstitial Cystitis;
Microbicides to Prevent HIV/AIDS;
Neglected Tropical Diseases;
NCI Scientific Frameworks for pancreatic ductal adenocarcinoma;
NCI Pancreatic Ductal Adenocarcinoma Progress Working Group;
Nanovaccines;
NIH Workforce Study;
Preterm Birth;
Preeclampsia;
Pulmonary Atresia;
Science, Technology, Education and Mathematics;
Sickle Cell Research;
Sleep and Circadian Health;
Scleroderma;
Spina Bifida;
Study Sections Pediatric Expertise;
Stroke-Induced Respiratory Dysfunction; and
Sturge-Weber Syndrome.

BUILDINGS AND FACILITIES

Mission.—The Buildings and Facilities appropriation provides for the design, construction, improvement, and major repair of clinical, laboratory, and office buildings and supporting facilities essential to the mission of the National Institutes of Health. The funds in this appropriation support the buildings on the main NIH campus in Bethesda, Maryland; the Animal Center in Poolesville, Maryland; the National Institute of Environmental Health Sciences facility in Research Triangle Park, North Carolina; and other smaller facilities throughout the United States.

The Committee notes NIH has a significant backlog of maintenance and repairs. The Committee encourages NIH and HHS to develop a coordinated plan to address the backlog with the Office of

Management and Budget in the fiscal year 2017 congressional budget request.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

The Committee recommends $3,642,710,000 for the Substance Abuse and Mental Health Services Administration (SAMHSA), which is $22,998,000 more than the fiscal year 2015 enacted program level and $21,577,000 below the requested program level.

The Committee includes bill language directing the Administrator of SAMHSA and the Secretary to exempt the Mental Health Block Grant and the Substance Abuse Prevention and Treatment Block Grant as a source for the PHS evaluation set-aside in fiscal year 2016.

The Committee does not include the requested bill language allowing the Administrator to transfer three percent or less of funds between any of the SAMHSA accounts.

MENTAL HEALTH

The Committee recommends $1,073,975,000 for Mental Health Services, which is $5,000,000 below the fiscal year 2015 enacted program level and $1,308,000 more than the requested program level.

Within the total provided for Mental Health Programs of Regional and National Significance, the Committee recommends the following amounts:

Budget Activity	FY 2016 Committee
Capacity:	
Seclusion and Restraint	$1,147,000
Youth Violence Prevention	23,099,000
National Child Traumatic Stress Initiative	45,887,000
Project Aware State Grants	39,902,000
Mental Health First Aid	14,963,000
Healthy Transitions	19,951,000
Children and Family Programs	6,458,000
Consumer and Family Network Grants	4,954,000
MH System Transformation & Health Reform	3,779,000
Project LAUNCH	34,555,000
Primary and Behavioral Health Integration	43,000,000
National Strategy for Suicide Prevention	2,000,000
Suicide Lifeline	7,198,000
Garrett Lee Smith—Youth Suicide Prevention	
State Grants	47,427,000
Campus Grants	6,488,000
Homeless Prevention Programs	28,696,000
Minority AIDS	8,224,000
Alaskan-Indian/American Native Suicide Prevention	2,931,000
Tribal Behavioral Health Intervention Grants	15,000,000
Criminal and Juvenile Justice Programs	4,269,000
Science to Service:.	
Garrett Lee Smith—Suicide Resource Center	6,681,000
Consumer & Consumer Support TACenters	1,918,000
Primary & Behavioral Health Care Integ. TA	1,991,000
Minority Fellowship Program	8,059,000
Disaster Response.	1,953,000
Homelessness	2,296,000
HIV/AIDS Education	771,000

Childhood Trauma.— The Committee appreciates SAMSHA's ongoing support of the National Child Traumatic Stress Network. A