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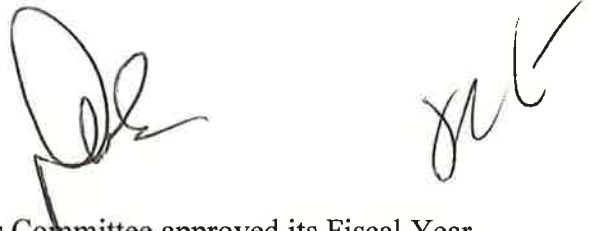
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September 8, 2017

MEMORANDUM

TO: Sleep Research Society
FR: Dale Dirks and Dane Christiansen
RE: FY 2018 Senate L-HHS Bill



On Thursday, September 7th, the Senate Appropriations Committee approved its Fiscal Year (FY) 2018 Labor-Health and Human Services-Education (L-HHS) Appropriations Bill. The Senate bill is more generous in terms of funding for medical research, public health, and education than the L-HHS bill put forward by the House Appropriations Committee in July.

The Senate bill continues robust investment in the National Institutes of Health (NIH) by advancing another \$2 billion increase to bring the agency's annual funding up to \$36.1 billion. The bill also continues to direct substantial resources toward activities to address the opioid epidemic as well as provides a modest increase to the size of Pell grants.

The House and Senate continue to manage all twelve annual appropriations for FY 2018. With FY 2017 set to expire at the end of the month, Congress is currently readying a stop-gap funding measure known as a Continuing Resolution or "CR" to keep the federal agencies operating at their FY 2017 funding level. Such action will give lawmakers until mid-December to finalize and enact all FY 2018 spending bills, including the L-HHS bill.

We will continue to keep you updated as the process moves forward.

The FY 2018 Senate L-HHS bill proposes:

- \$79.4 billion in discretionary funding for the U.S. Department of Health and Human Services (HHS), an increase of \$1.7 billion over FY 2017 and \$2.24 billion more than the House.
 - \$36.1 billion for NIH, an increase of \$2 billion over FY 2017 and \$900 million more than the House.
 - \$400 million for the BRAIN initiative, an increase of \$140 million over FY 2017 and \$64 million more than the House.
 - \$370 million for the Precision Medicine Initiative/All of Us, a \$60 million increase over FY 2017 and \$30 million less than the House.
 - Language prohibiting capping "Facilities and Administrative" costs at 10%.

- \$7.18 billion for the Centers for Disease Control and Prevention (CDC), level-funded from FY 2017 and \$198 million more than the House.
 - Language rejecting proposals to consolidate disease-specific public health programs into a state-based block grant.
- \$6.46 billion for the Health Resources and Services Administration (HRSA), an increase of \$400 million over FY 2017 and \$800 million more than the House.
- \$324 million for the Agency for Healthcare Research and Quality (AHRQ), level-funded from FY 2017 and \$24 million more than the House.
- \$3.77 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA), level-funded from FY 2017 and \$306 million more than the House.
- \$746.77 billion for the Centers for Medicare and Medicaid Services (CMS) in discretionary and mandatory funding, level-funded from FY 2017 and \$56.73 million less than the House.
- \$68.3 billion in discretionary funding for the U.S. Department of Education (Ed), an increase of \$29 million over FY 2017 and \$2.4 billion more than the House.

Of specific interest to SRS the FY 2018 Senate L-HHS bill and accompanying committee report includes:

- \$7.18 billion for CDC, level-funded from FY 2017 and \$198 million more than the House.
 - \$1.07 billion for Chronic Disease Prevention and Health Promotion at CDC, a decrease of \$50 million from FY 2017 and \$25 million more than the House.
 - Committee recommendations regarding Chronic Fatigue Syndrome [please see attached].
 - Committee recommendations regarding Sleep Surveillance [please see attached].
- \$36.1 billion for NIH, an increase of \$2 billion over FY 2017 and \$900 million more than the House.
 - \$5.86 billion for the National Cancer Institute at NIH, an increase of \$187 million over FY 2017 and \$106 million more than the House.
 - Committee recommendations regarding Sleep Health and Cancer [please see attached].

- \$3.32 billion for the National Heart, Lung, and Blood Institute at NIH, an increase of \$105 million over FY 2017 and \$60 million more than the House.
 - Committee recommendations regarding the National Center on Sleep Disorders Research [please see attached].
 - Committee recommendations regarding Sleep Phenotypes [please see attached].
- \$2.54 billion for the National Institute on Aging at NIH, an increase of \$483 million over FY 2017 and \$80 million more than the House.
 - Committee recommendations regarding Sleep Health and Alzheimer's [please see attached].
- \$1.79 billion for the Office of the Director at NIH, an increase of \$129 million over FY 2017 and \$89 million more than the House. This amount includes \$575.29 million for the Common Fund.
 - Committee recommendations regarding Chronic Fatigue Syndrome [please see attached].
 - Committee recommendations regarding Facilities & Administrative Costs [please see attached].
 - Committee recommendations regarding Sleep Disorders [please see attached].

[COMMITTEE PRINT]

NOTICE: This is a draft for use of the Committee and its staff only, in preparation for markup.

Calendar No.

115TH CONGRESS <i>1st Session</i>	SENATE	REPORT 115-000
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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATION BILL, 2018

SEPTEMBER 00, 2017.—Ordered to be printed

Mr. BLUNT, from the Committee on Appropriations, submitted the following

REPORT

[To accompany S. 0000]

The Committee on Appropriations reports the bill (S. 0000) making appropriations for Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2018, and for other purposes, reports favorably thereon without amendment and recommends that the bill do pass.

Amounts to new budget authority

Total of bill as reported to the Senate	\$969,052,391,000
Amount of 2017 appropriations	913,165,612,000
Amount of 2018 budget estimate	939,907,451,000
Bill as recommended to Senate compared to:	
2017 appropriations	+ 55,886,779,000
2018 budget estimate	+ 29,144,940,000

evaluation is aligned for all of the Action Plan's objectives. The Committee asks that the annual Public Law 109-95 report to Congress display the amount of funding by objective to the Action Plan on Children in Adversity.

* - *Chronic Fatigue Syndrome.*—The Committee applauds CDC's efforts to collaborate with disease experts in its multi-site study to resolve the case definition issues and urges CDC to complete that effort. The Committee encourages CDC to partner with other HHS agencies, disease experts, and key medical societies to implement a proactive dissemination plan that counters medical misinformation and stigma and addresses other key barriers to clinical care. *

Chronic Pain.—The Committee commends CDC for including chronic pain in the Healthy People 2020 initiative. The Committee encourages CDC to analyze data collected from the chronic pain questions included in the 2017 National Health Interview Survey and to clarify the incidence and prevalence of various pain syndromes differentiated by patient age, comorbidities, socioeconomic status, race, and gender. The Committee further encourages CDC to collect data on direct and indirect costs of pain treatment and effectiveness of evidence-based treatment approaches and include this information in the fiscal year 2019 CJ.

Diabetes Prevention Program.—The Committee recommendation includes \$22,500,000, level with fiscal year 2017, for the Diabetes Prevention Program. This program promoting lifestyle interventions has proven to reduce the risk of developing diabetes by 58 percent in individuals at high risk.

Division of Diabetes Translation [DDT].—The Committee recognizes the work of CDC's DDT to address the diabetes epidemic and encourages CDC to continue to ensure that the prevention needs of those Americans with, and at risk for, diabetes and prediabetes are met. The Committee believes these activities must include clear outcomes and ensure transparency and accountability that demonstrate how funding was used to support diabetes prevention and specifically how diabetes funding reached State and local communities. Additionally, the Committee encourages CDC to support the translation of research into better prevention, care, and surveillance. The Committee encourages CDC to explore opportunities to expand virtual delivery of the National Diabetes Prevention Program's lifestyle change program in rural areas where patients have provider care access challenges.

Early Child Care Collaboratives.—The Committee recognizes that the early care and education setting is important for promoting healthy habits in young children. The Committee provides \$4,000,000 to the National Early Child Care Collaboratives to enable training of early care and education providers in implementation of healthy eating and physical activity best practices, including strategies for engaging families. Funds will also support technical assistance for integration of healthy eating and physical activity best practices into existing State and local professional development systems' early care and education settings, and health initiatives. The Committee also encourages the program to serve a mix of rural, suburban and urban areas, including areas with high childhood obesity rates.

sources of States with recognized leadership in areas of electronic medical records, telehealth, and innovative delivery of education tools. CDC shall provide an update on these activities in the fiscal year 2019 CJ.

Psoriasis and Psoriatic Arthritis.—The Committee recognizes the growing body of evidence linking psoriatic disease, which impacts more than 8,000,000 Americans, to other comorbidities such as cardiovascular disease, mental health and substance abuse challenges, kidney disease, and other conditions. The Committee encourages CDC to develop an action plan not later than 6 months after the enactment of this act as to how it can leverage existing programs and resources to build upon the agency's Public Health Agenda for Psoriasis and Psoriatic Arthritis.

Pulmonary Hypertension [PH].—The Committee understands that PH causes heart failure and death. CDC is encouraged to support education, outreach, and awareness activities that promote early and accurate diagnosis of PH.

Racial and Ethnic Approach to Community Health [REACH].—The Committee eliminates the REACH program due to funding constraints. Funding continues to be provided to other programs that conduct outreach to reduce ethnic disparities in health status.

Safe Motherhood Initiative.—Preterm birth affects more than 500,000 babies each year in the United States and is the leading cause of neonatal mortality. The Committee commends CDC for funding State-based perinatal collaboratives that focus on improving birth outcomes using known preventative strategies such as reducing early elective deliveries.

Skin Cancer Education and Prevention.—The Committee is concerned with the growing number of people diagnosed with preventable forms of skin cancer, which is now the most commonly diagnosed cancer in the United States. Every year in the United States, nearly 5,000,000 people are treated for skin cancer. Melanoma causes more deaths than any other type of skin cancer, resulting in over 9,000 deaths each year. The Committee encourages CDC to provide increased collaboration and partnership with local governments, business, health, education, community, nonprofit and faith-based sectors in this effort.

*— *Sleep Surveillance.*—The Committee is pleased by CDC's work on a national public health awareness campaign for sleep. The Committee encourages CDC to ensure that funding for surveillance activities on sleep disorders and sleep health is maintained in addition to these awareness efforts.] *

Stroke Prevention.—States in the Stroke Belt have age-adjusted stroke mortality rates that are significantly higher than the national average. The Committee encourages the Division to further focus its resources in the Stroke Belt, including the development of a comprehensive strategy to address stroke mortality and morbidity in the region. CDC shall provide an update on these efforts in the fiscal year 2019 CJ.

WISEWOMAN.—The Committee lauds the WISEWOMAN program that helps uninsured and under-insured low-income women ages 40 to 64 decrease, prevent, or control heart disease and stroke by providing preventive health services, referrals to local health care providers, lifestyle programs, and health counseling services

composition. To further support such collaborations, the NCI is encouraged to consider research expertise in ethnic and racial diversity and its impact on cancer development and outcomes in evaluating applications for NCI-designated cancer centers.

* - *Sleep Health and Cancer.*—The Committee understands the complex intersection between sleep health and cancer development, cancer progression, and remission. The Committee encourages NCI to continue to explore the role of sleep health in cancer development and progression. *

Translational Research Program.—The Committee notes the SPORE program is NCI's cornerstone effort to promote collaborative, interdisciplinary translational cancer research. The Committee continues robust support for the SPORE grant program as it works to bring basic research into practical treatments. The Committee requests an update in the fiscal year 2019 CJ on the SPORE program.

Translational Science of Natural Products for Cancer.—The Committee has recognized the importance of moving natural products and their derivatives through development and testing, with the goal of accelerating the designation of Investigational New Drug to promising natural products that can treat cancer. The Committee directs NCI to continue to support this work.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Appropriations, 2017	\$3,217,081,000
Budget estimate, 2018	2,534,803,000
Committee recommendation	3,322,774,000

The Committee recommendation includes \$3,322,774,000 for the National Heart, Lung, and Blood Institute [NHLBI].

Alzheimer's Disease and Vascular Dementia.—The Committee recognizes the importance of well characterized, longitudinal, population-based cohort studies in providing insights into risk factors related to dementia, with special focus on minority populations where disease burden is greatest. As the participants in these studies have aged, much has been learned about cognitive decline and the role of mid-life risk factors, but key challenges remain, particularly in the identification of biomarkers and in understanding the role of environmental versus genetic factors. Therefore, within the provided funds, the Committee directs NHLBI to recruit and examine the subsequent generations of such cohorts, as studying the adult children of these extensively characterized cohort members may provide new insights into risk identification and accelerated prevention efforts. The project shall conduct clinical examinations, including brain imaging, of this second generation of participants.

Asthma.—The Committee notes with concern the evidence suggesting a causal link between air pollution and the development of asthma. The Committee urges NHLBI and the NIEHS to explore this potential causal link and any interventions necessary to prevent the development of asthma.

Congenital Heart Disease [CHD].—The Committee commends NHLBI for its continued work to better understand causation and appropriate treatments for those with the most life threatening congenital heart defects through its biomedical research program 'Bench to Bassinet' and the critical multi-centered infrastructure of

prioritization of heart research to significantly increase, expand, intensify, and stimulate its investment commensurate with the impact on public health, the economy, and innovative scientific opportunities. The Committee commends NHLBI for its leadership in launching a Strategic Vision and directs the Institute to accelerate the implementation of the heart research recommendations and priorities, including heart failure and cardiac rehabilitation.

Hemophilia.—The Committee encourages NHLBI to bring together leading hemophilia researchers and clinicians, as well as its Federal partners from CDC, FDA, and HRSA to create a national scientific agenda for clinical and translational research for the prevention and eradication of inhibitors, a costly complication affecting people with hemophilia.

Longitudinal Study of Cardiovascular Health in African Americans.—The Committee commends NHLBI for accomplishments made by its longitudinal study of cardiovascular health in African Americans. This 16-year study has provided new insights into and better understanding of the burden of cardiovascular disease among African Americans in the United States. With this increased understanding comes knowledge of the gaps in a number of other health conditions that affect African Americans disproportionately, such as obesity, diabetes, hypertension, chronic kidney disease, and heart failure. Additionally, research has revealed that some of these chronic conditions may have an impact on healthy aging, including cognition and risk of dementia and may have transgenerational effects. Therefore, the Committee encourages NHLBI to continue to follow-up with all current study participants, conduct broader examinations for these participants, and explore enrollment of a new group of participants, including children and grandchildren of current study participants. An expanded study will provide researchers more information about the roles of familial factors and shared environments in the development and progression of cardiovascular disease and other conditions. The new round of examinations should include measurements that utilize the latest technology, such as Magnetic Resonance Imaging, to assess the status of the heart, muscles, and adiposity and to evaluate structural brain changes that may be related to hypertension, diabetes, and other chronic disorders.

National Center on Sleep Disorders Research [NSCDR].—The Committee commends NHLBI and NSCDR for recent efforts to reinvigorate collaborations on important research in sleep, sleep disorders, and circadian rhythms. NHLBI and NSCDR are encouraged to continue to show leadership in this area and further incorporate sleep into relevant research activities across NIH Institutes and Centers.

Postural Orthostatic Tachycardia Syndrome [POTS].—With an estimated 1,000,000 to 3,000,000 Americans suffering from POTS, a neurological disorder that affects mostly adolescent and adult women, there are no effective treatments to address this often misdiagnosed and debilitating condition. The level of disability resulting from POTS can be similar to that occurring in multiple sclerosis and congestive heart failure, but little research funding has been dedicated to date to improving understanding of POTS. Due to the lack of effective treatments, many patients are unable

to attend school or work, resulting in significant impacts to the U.S. economy. The World Health Organization recently approved the first unique ICD code for POTS, which when implemented, will hopefully enable more precise epidemiological research on the disease. The Committee expects NHLBI and NINDS to work with stakeholders to stimulate the field and develop strategies that will increase our understanding of POTS and lead to effective treatments.

Pulmonary Hypertension [PH].—The Committee applauds NHLBI for identifying the study of underlying mechanisms of disease of PH as one of its areas of focus within its recent strategic vision plan for research. The Committee encourages NHLBI to continue its focus in this area, particularly on idiopathic pulmonary arterial hypertension, so that additional gains can be made that benefit patient outcomes and further improve survivability for affected individuals.

Sickle Cell Disease.—The Committee encourages NHLBI to prioritize the study of sickle cell disease. Academic medical centers located in States with significant populations of sickle cell patients have made progress in treating the disease through NIH sponsored clinical trials and through blood and marrow transplantation for sickle cell disease, which is currently the only therapy that can cure the disease. However, more research dollars are needed to augment the limited treatment options available if we are to have a real impact on sickle cell disease.

* - *Sleep Phenotypes.*—The health consequences of sleep disorders such as obstructive sleep apnea and insomnia include increased risk of hypertension, cardiovascular disease and obesity. The Committee is encouraged by the Institute's efforts to improve our understanding of sleep disorders and urges the Institute to partner with other NIH Institutes to continue advancing research for sleep phenotypes and biomarkers that further explore health disparities and the intersection between chronic diseases and sleep. *

Thoracic Aortic Disease.—The Committee is concerned about sudden, preventable death caused by thoracic aortic aneurysm and dissection attributed to structural cardiovascular disorders, such as Marfan syndrome, and encourages NHLBI to further study the mechanisms of disease and opportunities to improve patient health.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Appropriations, 2017	\$425,751,000
Budget estimate, 2018	320,749,000
Committee recommendation	439,738,000

The Committee recommendation includes \$439,738,000 for the National Institute of Dental and Craniofacial Research [NIDCR].

Temporomandibular Disorder [TMD].—The Committee recognizes NIDCR's leadership in TMD pain research, which has led to establishing TMD as a multisystem disorder with overlapping pain and non-pain conditions. The Committee encourages NIDCR to continue its leadership as a critical member of the Trans-NIH Working Group on Chronic Overlapping Pain Conditions by promoting and advancing integrated research on these conditions. In addition, as the oral disability associated with TMD affects a patient's nutritional health status, the Committee encourages NIDCR to improve

and disparities in dementia risk and ultimately lead to improved diagnostic, treatment, and prevention strategies in high risk populations.

Population Research.—The Committee recognizes the Institute’s leadership in making data, especially longitudinal data, available to the broader research community. NIA’s investments in data infrastructure, such as the ground-breaking Health and Retirement Study [HRS], have spurred significant scientific research findings as well as important interagency and international collaborations. In fiscal year 2018, the Committee urges NIA and SSA to continue working jointly to support the HRS. The Committee also encourages the Institute to consider recommendations recently issued by an outside expert Committee regarding NIA’s major surveys and to adopt innovations that will enhance data quality and accessibility. The Committee also urges NIA to pursue data collection and dissemination and research activities via its support of the prestigious Centers of Demography and Economics of Aging.

* - *Sleep Health and Alzheimer’s.*—The Committee recognizes that poor sleep health and sleep disorders promote or influence the development of diseases that impair cognitive functioning, such as Alzheimer’s. The Committee encourages research to explore the linkages between the sleep cycle, cardiovascular system, and Alzheimer’s in an effort to inform prevention. *

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Appropriations, 2017	\$557,851,000
Budget estimate, 2018	417,898,000
Committee recommendation	576,178,000

The Committee recommendation includes \$576,178,000 for the National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIAMS].

Epidermolysis Bullosa.—The Committee recognizes the promising scientific gains and applauds private partners advancing research in pursuit of treatments for Epidermolysis Bullosa. The Committee encourages NIH to continue to support the intensification of such research at NIAMS. The Committee further encourages NIAMS to leverage Federal funds with public-private partnerships in the areas of Epidermolysis Bullosa and related disorders.

Scleroderma.—The Committee applauds NIAMS for its support of research into diseases that cause fibrosis in various organ systems, such as scleroderma. The Committee encourages NIAMS to prioritize research in this area and pursue collaborative opportunities with other ICs investigating fibrotic diseases.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Appropriations, 2017	\$436,875,000
Budget estimate, 2018	325,846,000
Committee recommendation	451,768,000

all of NIH benefits from them. In its fiscal year 2017 report, the Committee directed NIH to work with its external partners and stakeholders to provide the Committees on Appropriations of the House of Representatives and the Senate a detailed strategic plan by May 5, 2018, spelling out it how intends to make big data sustainable, interoperable, accessible, and usable. The plan is to include a roadmap to achieve these objectives, as well as milestones and estimates of the resources that will be necessary. The Committee expects to receive the strategic plan, which was first identified in the Senate report dated June 9, 2016, by the May deadline. The unanticipated delay in completing the fiscal year 2017 appropriations process means NIH will have had almost 2 years to prepare its plan, extra time that should make it possible to draft a comprehensive blueprint to help guide future investments in data science. In the interim, the Committee directs NIH to provide a status report in the fiscal year 2019 CJ describing the current status of the strategic plan and its progress in finding a suitable candidate to fill the Associate Director for Data Science [ADDS] vacancy. The Committee recognizes the importance of the ADDS to provide strategic vision and coordinate as an honest broker across NIH on data science issues, and encourages NIH to locate this position within the Office of the Director.

Botanical Products and Opioid Addiction.—The Committee commends the FDA for establishing guidelines and opening pathways for Investigational New Drug [IND] applications for botanical drugs. Over the past two decades, the dramatic increase in abuse of prescription opioids, non-synthetic opioids, and illicit synthetic opioids has grown to epidemic proportions. Scientific rationale and laboratory studies suggest a decrease in addictive potential when botanical derivatives, including cannabidiol extracts, are used with an opioid in treating patients. The Committee supports study of this integrative approach to treatment and urges NIH, including NIDA, NCCIH, and OCCAM, to support and facilitate trials aimed at reducing addiction under appropriate IND applications.

Brain Research through Application of Innovative Neuro-technologies [BRAIN] Initiative.—The Committee continues to strongly support the BRAIN initiative. The bill provides \$400,000,000 an increase of \$140,000,000 above fiscal year 2017, to expand the initiative consistent with the BRAIN 2025 report issued in 2014.

Children in NIH Research.—The inclusion of children in clinical research is essential to ensure that children benefit from important scientific advances. The Committee appreciates provisions of the 21st Century Cures Act that will now require NIH to systematically track enrollment data to determine if children are actually being enrolled appropriately in clinical research. The Committee recognizes that without better data collection and reporting it is unable to fully exercise its oversight role, and researchers and other stakeholders are unable to determine whether children as a whole, or particular pediatric subpopulations, are appropriately represented in federally funded biomedical research. The Committee directs NIH to expeditiously implement these new requirements.

Chronic Fatigue Syndrome [ME/CFS].—The Committee is pleased that NIH has begun to expedite research into ME/CFS, in-

cluding its intramural study and the RFAs for the collaborative research centers. However, the Committee is concerned that the level of funding is still very low considering the burden of disease and the current plan to expand research will take too long to produce FDA-approved treatments and diagnostic tests. The Committee urges NIH to collaborate with disease experts and the patient community to identify additional opportunities to expedite progress on this understudied disease. Specifically, the Committee recommends that NIH consider increasing research funding to be commensurate with disease burden and use that funding to further accelerate the research field through a set of intramural and extramural investments such as: (1) RFAs for biomarkers and treatment trials, (2) additional funding for investigator initiated studies and early stage investigator awards, (3) an initiative to reach consensus on the case definition, and (4) mechanisms to incentivize researchers to enter the field.

Chronic Overlapping Pain Conditions.—The Committee notes the strong evidence base demonstrating deleterious outcomes for patients with Chronic Overlapping Pain Conditions, which include hit-or-miss, ineffective, or even harmful treatments, poor health and quality of life outcomes, markedly increased disability rates and personal and societal financial burdens. The Committee is pleased with NIH's efforts to develop a chronic overlapping pain conditions screening tool. However, an expanded, coordinated, and collaborative initiative is needed to maximize the Federal research investment, reduce spending, and improve clinical practice. There is an urgent need to analyze the state of science on Chronic Overlapping Conditions, which will identify both research gaps and future research directions and collaborations. As such, the Committee urges the Director to consider the relevant recommendations of the Federal Pain Research Strategy to guide the development of a comprehensive effort that spans the basic, translational, and clinical research continuum to advance scientific understanding of chronic overlapping pain conditions, as well as the development and discovery of safe and effective treatments.

* - *Facilities and Administrative Costs [F&A].*—Central to the Administration's proposal to reduce Federal investments in biomedical research is its proposal to cap the F&A costs of grants, so-called "indirect costs," at 10 percent. The F&A cost of a grant is intended to cover the indirect costs of biomedical research, ranging from administration and facilities to the cost of equipment shared across multiple researchers. For example, at research facilities focused on making the next breakthrough in cancer treatment, indirect costs supply the air handlers that provide the precise conditions needed to generate therapeutic T cells for immunotherapy trials, complex data systems to analyze and protect patients' genomic data, and support for the next generation of scientific leaders. The methodology for negotiating indirect costs has been in place since 1965, and rates have remained largely stable across NIH grantees for decades. The Administration's proposal would radically change the nature of the Federal Government's relationship with the research community, abandoning the Government's long-established responsibility for underwriting much of the Nation's research infrastructure, and jeopardizing biomedical research nationwide. The Com-

mittee has not seen any details of the proposal that might explain how it could be accomplished without throwing research programs across the country into disarray. To avoid this possibility, the Committee has included bill language to prohibit HHS from developing or implementing a modified approach to funding F&A costs.

Fetal Tissue Donation Trial.—The Committee acknowledges the many differing views on the merits of human fetal tissue research. New bill language is included to direct NIH to begin a pilot to determine the adequacy of a fetal tissue donor network for supporting all related clinical research from human fetal tissue donated solely from stillbirths and spontaneous abortion.

Gabriella Miller Kids First Research Act.—The Committee provides the full budget request of \$12,600,000. The Committee requests that NIH provide information on how it has disbursed funding, including any personnel that are responsible for overseeing the allocation of designated research dollars, the criteria that NIH employed to ensure awards will advance the objectives of the act, and a description of the research projects that were funded in the fiscal year 2019 CJ.

Gestational Diabetes.—The Committee recognizes the importance of research funded by NIH related to gestational diabetes, a disease affecting up to 9.2 percent of all pregnant women. Given that both women with gestational diabetes and their babies face long-term health consequences as a result of the disease, such as increased risk of developing type 2 diabetes, the Committee urges NIH to explore additional opportunities for research on gestational diabetes.

Government-Wide Collaborations.—NIH, VA, and DOD collaborate frequently and successfully on various research activities. The Committee looks forward to the report in the fiscal year 2019 CJ focusing on the cooperative and strategic approach the agencies take in areas of biomedical research that overlap to maximize the potential of the research.

Hepatitis B [HBV].—The Committee recognizes that HBV infection is a serious public health threat. Though infection rates are less than one percent in the United States, Asian Americans and Pacific Islanders experience about 60 percent of the chronic HBV burden. Left undiagnosed and untreated, one in four of those with chronic HBV infection will die prematurely from cirrhosis, liver failure, and/or liver cancer. The Committee also notes that the link between HBV infection and primary liver cancer is well established, with up to 60 percent of global liver cancer cases caused by HBV. The Committee requests that OD ensure that NCI, NIAID, NIMHD, and NIDDK coordinate their strategic research agendas to work toward finding a cure for HBV. The Committee further requests an update on these efforts be included in the fiscal year 2019 CJ.

Imaging.—The Committee notes that imaging research occurs in multiple Institutes throughout the NIH and is an integral component of the Cancer Moon Shot, the Precision Medicine Initiative, and the BRAIN Initiative. The Committee requests that the Director produce an overview of imaging research across the NIH, including in the focused research fields mentioned above, and assess the quality of interactions in imaging research within NIH, and report the results in the fiscal year 2019 CJ.

tion research conducted at NIH. The Committee is encouraged by the release of NIH's new Rehabilitation Research Plan, looks forward to reviewing its first annual progress report, and is encouraged by its ongoing efforts to ensure that reporting of rehabilitation research is consistent with the definition of "rehabilitation research" included in the legislation.

Research Facilities.—Much of the Nation's biomedical research infrastructure, including laboratories and research facilities at academic institutions and nonprofit research organizations, is outdated or insufficient. For taxpayers to receive full value from their considerable investments in biomedical research, scientists must have access to appropriate research facilities. Therefore, \$25,000,000 is provided for grants or contracts to public, nonprofit, and not-for-profit entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities as authorized under 42 U.S.C. section 283k. The Committee urges NIH to consider recommendations made by the NIH Working Group on Construction of Research Facilities, including making awards that are large enough to underwrite the cost of a significant portion of newly constructed or renovated facilities.

* *Sleep Disorders.*—The Committee recognizes sleep disorders as a serious public health concern. Sleep disorders affects approximately 70,000,000 Americans and contribute to lost productivity, increase the risk for accidents, and are associated with other chronic illnesses, such as hypertension and mental health conditions. The Committee encourages the NIH to advance the work of the National Center on Sleep Disorders Research, which coordinates research activities across Institutes and Centers. The Committee also encourages NIH to facilitate implementation of the ongoing NIH Sleep Disorders Research Plan. *

Spina Bifida.—The Committee encourages NIA, NIDDK, NICHD, and NINDS to study the causes and care of the neurogenic bladder and kidney disease to improve the quality of life of children and adults with Spina Bifida; to support research to address issues related to the treatment of Spina Bifida and associated secondary conditions, such as hydrocephalus; and to invest in understanding the myriad co-morbid conditions experienced by individuals with Spina Bifida.

Temporomandibular Disorders [TMD].—The Committee understands that NIH-funded research has demonstrated that temporomandibular disorders [TMD] are primarily a multisystem disorder with overlapping conditions influenced by multiple biological and environmental factors rather than solely an orofacial pain condition. However, diagnosis and care of patients have not changed to reflect this major paradigm shift, with many patients continuing to receive treatments solely focused on teeth and jaws. Moreover, the medical community lacks education regarding the complexity and systemic aspects of TMD as well as its many co-morbid medical conditions. Patients are treated by a multitude of practitioners across numerous disciplines with treatments that have the potential to cause harm. To address these issues, the Committee requests that NIH provide an update on the state of TMD research, activities related to TMD education, and clinical studies of TMD in the fiscal year 2019 CJ.