SUMMARY OF BUDGET ESTIMATES AND COMMITTEE RECOMMENDATIONS

For fiscal year 2020, the Committee recommends total budget authority of $1,094,433,048,000 for the Departments of Labor, Health and Human Services, and Education, and Related Agencies. This amount includes $178,299,000,000 in current year discretionary funding subject to discretionary spending caps and $1,842,000,000 in cap adjustments for healthcare fraud and abuse control, Unemployment Insurance Trust Fund program integrity, and for program integrity at the Social Security Administration, in accordance with the allocation for this bill.

Fiscal year 2019 levels cited in this report reflect the enacted amounts in Public Law 115–245, the Consolidated Appropriations Act, 2019, adjusted for comparability where noted.

OVERVIEW

The Labor, Health and Human Services, and Education, and Related Agencies [Labor-HHS-Education] appropriations bill constitutes the largest share of non-defense discretionary spending, 29 percent of the total in fiscal year 2020. Total spending in this bill subject to discretionary spending caps is $223,000,000 above the comparable fiscal year 2019 level. In addition, the bill includes $9,427,000,000 in spending offset by savings from changes in mandatory programs, $1,712,000,000 more than the fiscal year 2019 level. The funding level for this bill has required the Committee to make difficult funding decisions and consider the appropriate role and jurisdiction of Federal programs.

The priorities and considerations of the Committee in developing this bill are summarized in the section below:

NATIONAL INSTITUTES OF HEALTH

This is the fifth straight year the Committee has provided a substantial increase toward National Institutes of Health [NIH] research, starting this pattern in the fiscal year 2016 Senate bill. The Committee recommendation includes $42,084,000,000 for NIH, an increase of $3,000,000,000 or 7.7 percent.

Over the past year, NIH-funded research has led to significant progress on vaccines for Ebola and the Zika virus, developed blood tests to detect cancer, led to the first-ever drug specifically for postpartum depression, and potentially cured sickle cell disease. This is a time of promise in biomedical research and the United States should remain the leader of this era. To do so, the Committee continues to commit the funding necessary to accomplish this goal. Therefore, the Committee ensures a net increase of $3,000,000,000 over the previous year for NIH, despite the loss of $219,000,000 due to reductions in funding made available through the 21st Century Cures Act.

Since fiscal year 2016, the Committee has provided NIH with an increase of $12,000,000,000 or 40 percent. This year’s resources have been targeted toward several specific research programs, including:
All of Us.—The Committee includes $500,000,000, an increase of $161,000,000, for the All of Us precision medicine program in fiscal year 2020. This funding includes additional funds to make-up for the decrease in 21st Century Cures Act funding and an additional amount to ensure that enrollment in the program continues on schedule.

Alzheimer’s Research.—The Committee prioritizes finding a treatment and ultimately a cure for Alzheimer’s disease and provides an additional $350,000,000, more than quadrupling the research investment in the last 5 years. With this increase, NIH is expected to spend $2,818,000,000 in fiscal year 2020.

BRAIN Initiative.—The Committee continues to strongly support this program, which has the potential to unlock some of the most fundamental questions about how the brain functions. The bill provides $500,000,000 in fiscal year 2020, an increase of $71,000,000.

Childhood Cancer Data Initiative.—$50,000,000 is provided for the first time in fiscal year 2020. This initiative will provide $500,000,000 specifically toward childhood cancer research over the next 10 years as requested in the President’s budget.

Next Generation Research Initiative.—In addition to supporting targeted areas of science, the Committee continues its focus toward programs and activities that support and sustain young and mid-career researchers in the NIH research pipeline. The bill provides $100,000,000 in fiscal year 2020 specifically for the Next Generation Research Initiative. In fiscal year 2018, NIH met and surpassed its goal to fund 1,100 early-stage investigators by funding 1,287 through numerous Institutes and Centers’ focused programs. In fiscal year 2018, $648,755,798 was provided to support these programs. However, the Committee understands the importance of ensuring there is a focus on and commitment toward these researchers and, therefore, provides a dedicated funding source to ensure young and mid-career scientists remain in the research community.

Finally, the Committee continues to place a high value on support for all Institutes and Centers and allowing NIH to maintain flexibility to pursue unplanned scientific opportunities and address unforeseen public health needs. The Committee recommendation provides increases to every Institute and Center and is estimated to support over 12,900 new and competing grants in fiscal year 2020.

ENDING THE HIV EPIDEMIC

An estimated 40,000 Americans are newly diagnosed with HIV every year and, since 1981, more than 700,000 Americans have lost their lives to the disease. Further, the United States government spends up to $20,000,000,000 in annual direct health expenditures for HIV prevention and care.

The Committee supports the new budget request to use readily available tools and strategies to reduce the number of new HIV infections in the United States by 75 percent in 5 years and by 90 percent in 10 years.

According to the Department of Health and Human Services, of the 3,007 counties in the United States, more than 50 percent of new HIV diagnoses occur in just 48 counties, Washington, D.C.,
The National Institutes of Health (NIH) remains an area of high priority for the Committee. Prior to the first substantial NIH increase in more than a decade provided in fiscal year 2016, 22 percent of NIH’s purchasing power was lost during that time. Over the past 4 years, the Committee has been able to restore 13 percent, but there is more to be done.

Therefore, the Committee provides $42,084,000,000 for NIH activities within the jurisdiction of this bill, an increase of $3,000,000,000 or 7.7 percent, above fiscal year 2019. Within the total appropriation, the Committee provides $492,000,000 in budget authority authorized in the 21st Century Cures Act. The Committee also provides an additional $219,000,000 to make-up for the funding reduction to NIH in the 21st Century Cures Act in fiscal year 2020.

The total also includes $1,564,105,000 in transfers available under section 241 of the PHS Act. The Committee continues a reform to section 241 allocations such that no NIH funding will be removed from NIH under this authority. This reform ensures that section 241 transfers are a benefit to NIH rather than a liability. In addition, it improves the transparency of NIH’s budget so that the enacted total is truly the amount the Committee expects to be used for biomedical research.

The Committee remains steadfast in its commitment to fund research on Alzheimer’s disease and increases funding by $350,000,000 to a total of approximately $2,818,000,000 in fiscal year 2020; restores and increases funding by $161,000,000 for the All of Us precision medicine initiative to ensure that enrollment in this groundbreaking study is not lost due to a reduction in 21st Century Cures Act funding; increases funding for antibiotic resistance by $50,000,000 to conduct research on resistance and fund new vaccines and treatments effective against drug-resistant microbes; increases funding for the BRAIN Initiative by $71,000,000; and continues to provide funding to modernize the storage, management, and standardization of NIH-funded biomedical data science.

In addition, every Institute and Center receives an increase above fiscal year 2019 to continue investments in innovative research that will advance fundamental knowledge and speed the development of new therapies, diagnostics, and preventive measures to improve the health of all Americans. The Committee recognizes that many revolutionary discoveries often come from unexpected, untargeted research. The Committee continues to support these basic advances through the general increase to all Institutes and Centers and also targets investment toward clinical and translational research that moves basic discoveries from “bench-to-bedside.”

The Committee rejects the budget’s request to create a new National Institute for Research on Safety and Quality by consolidating the Agency for Healthcare Research and Quality into the NIH. It also rejects the budget’s proposal to cap the percentage of an investigator’s salary that can be paid with NIH grant funds at 90 percent.
The Committee recommendation includes $6,351,863,000 for the National Cancer Institute [NCI], including $195,000,000 appropriated from the NIH Innovation Account. Of this amount, $30,000,000 is available for repairs and improvements to the NCI facility in Frederick, Maryland.

Cancer Immunotherapy. —The Committee continues to be encouraged by new breakthroughs in cancer immunotherapy, which are improving outcomes for an increasing number of cancer patients. As new and effective individual treatments are identified, the Committee urges NCI to prioritize research that will serve as the basis for improved, less toxic cancer immunotherapy for more patients.

In particular, the Committee highlights the need to understand how best to combine immunotherapy treatments, the optimal duration of therapy for each treatment, and why some patients develop resistance to cancer immunotherapy while others do not. Research on resistance should include outcomes in which the therapy never works (primary resistance) and outcomes in which the therapy is initially effective, but then stops working (secondary resistance). Further, the Committee urges NCI to prioritize research and trials for innovative immunotherapeutic approaches. In some cases, however, the side effects of such treatments are far different than those associated with chemotherapy and are associated with altered cytokine levels. Focusing on targeted cytokine management therapies and early recognition of cancer immunotherapy-related side effects can result in resolution of these side effects before permanent damage is done, and allows for continued cancer treatment. The Committee encourages development of therapeutic approaches that can be applied with minimal to no side effects that would help maintain the patient’s quality of life and could be used as a safe adjunct to existing therapies. The Committee urges NCI to prioritize research on the underlying mechanisms of cancer immunotherapy with the hope that continued advances in our understanding of these approaches will lead to wide applicability across cancer types and patient populations.

Childhood Cancer Data Initiative. —The Committee strongly supports the budget request to focus $50,000,000 a year toward pediatric cancer research over the next 10 years. The full budget request provided in the bill will facilitate a connected data infrastructure and integrate multiple data sources to make data work better for patients, clinicians, and researchers.

Deadliest Cancers. —The Committee remains concerned that while more effective screening methods and treatments have lowered overall cancer incidence and death rates, several cancer types with particularly low survival rates have limited screening methods, and effective treatments for these cancers are also limited. The Recalcitrant Cancers Research Act of 2012 defined “recalcitrant cancers” as those with a 5 year survival rate below 50 percent. These cancers account for nearly half of all cancer deaths in the United States and include cancers of the brain, esophagus, liver,
lung, ovary, pancreas, and stomach. The Committee notes that in 2020 NCI will report on the effectiveness of the scientific frameworks process NCI undertook for pancreatic adenocarcinoma and small cell lung cancer to improve prevention, detection, diagnosis and treatment. NCI developed these frameworks at Congress’ direction for cancers with a 5 year survival rate of less than 20 percent and expected toll of at least 30,000 deaths per year in the United States. The Committee appreciates that NCI has led scientific planning efforts in recent years to explore research opportunities related to pancreatic cancer, small cell lung cancer, liver cancer, and glioblastoma. Given the high cost recalcitrant cancers exact on society and the lack of diagnostic and treatment resources currently available to help patients, the Committee directs NCI develop a scientific framework using the process outlined in the Recalcitrant Cancer Research Act of 2012 for stomach and esophageal cancers. These cancers have 5 year survival rates below 50 percent and are collectively expected to kill approximately 27,000 Americans in 2020. The Committee also urges NIH and NCI to continue to support research with an emphasis on developing screening and early detection tools and more effective treatments for all recalcitrant cancers. The Committee expects to receive an update on NCI-supported research to advance these goals in the fiscal year 2021 CJ. Also, the Committee directs NIH to add esophageal and stomach cancers to future Research, Condition, and Disease Categorization reports. Finally, the Committee recognizes that while overall cancer death rates continue to decline, successful treatment for some cancers, including many forms of childhood cancer, remains elusive. The Committee encourages NCI to place a high priority on researching these cancers, which include anaplastic astrocytoma, diffuse intrinsic pontine glioma, glioblastoma, juvenile myelomonocytic leukemia, high-risk neuroblastoma, recurrent osteosarcoma, rhabdomyosarcoma, and diffuse anaplastic Wilms tumors. The Committee requests an update on the progress being made for childhood cancer research in the fiscal year 2021 CJ.

*Early Onset Colorectal Cancer.*—The Committee notes that while overall colorectal cancer incidence rates have been decreasing over the last 20 years, there has been an increase in adults ages 20–54. The Committee urges NCI to research why rates of colorectal cancer are increasing for this population. As part of this research, the Committee encourages NCI to expand its knowledge of the natural history of the disease to help advance the development of improved screening modalities and treatment.

*Gynecologic Cancer Clinical Trials.*—Clinical trials have significantly improved survival for women with gynecologic cancers, including ovarian, endometrial, cervical, and vulvar cancers. The Committee supports continued investment in federally-funded clinical trials for gynecologic cancers and encourages NCI to work with stakeholders to address priorities for the gynecologic oncology clinical trials scientific agenda, including consideration of the availability of trials for these patients. Given the high mortality rates for certain gynecologic cancers, the Committee requests NCI provide an update on access to gynecologic cancer clinical trials in its fiscal year 2021 CJ.
Liver Cancer.—The Committee commends NCI for increasing resources focused on liver cancer and its inter-Institute work to encourage more research focused on liver cancer, but urges greater prioritization on addressing the threat of liver cancer, the second deadliest cancer with a 5 year survival rate of 20 percent. The Committee also notes that the link between hepatitis B infection and primary liver cancer is well established with up to 60 percent of global liver cancer cases caused by the hepatitis B virus and, therefore, encourages continued close collaboration with NIAID and NIDDK and active participation in the Director’s newly established Trans-NIH Hepatitis B working group. The Committee requests an update on NCI’s activities in these areas in the fiscal year 2021 CJ.

Melanoma.—The Committee encourages NCI to support research from development of experimental models to identify mechanisms and associated biomarkers of risk for development of melanoma, new technologies for early detection as well as trials that develop population-based evidence for screening, including ophthalmologic, and sun protection practices. Discovery of biomarkers of response and resistance is critical at this point in melanoma research. The Committee urges NCI to support mechanistic research into response and resistance to therapy. The Committee further encourages research to understand mechanisms that underlie clinical dormancy to provide an effective means of preventing tumor recurrence and improving quality of life and longevity of survivors. The Committee is aware symptomatic brain [CNS] and leptomeningeal [LMD] metastases remain difficult to treat and may become the last frontier in systemic therapy in melanoma and other cancers. The Committee urges NCI to support research through national registries to better understand natural history, epidemiology, as well as patient reported and clinical outcomes in these rare melanoma subtypes. The Committee requests an update on these requests in the fiscal year 2021 CJ.

Pancreatic Cancer Research.—In 2016, pancreatic cancer rose to become the third leading cause of cancer-related death in the U.S., claiming the lives of nearly 42,000 Americans. Despite progress in combating other forms of cancer, the 5 year survival rate for pancreatic cancer is just 9 percent, in large part because there are no reliable early detection methods or effective treatment options. To help turn the tide against this deadly cancer, Congress in 2012 passed the Recalcitrant Cancer Research Act (Public Law 112–239), calling for the development of a scientific framework for certain recalcitrant cancers. The Committee looks forward to NCI’s submissions of the 5 year updates to the reports required by the Recalcitrant Cancer Research Act of 2012. The Committee encourages NCI to continue to support research efforts to advance progress for patients diagnosed with pancreatic cancer and other cancers with
low 5 year survival rates. The Committee requests an update on pancreatic cancer research in the fiscal year 2021 CJ.

Pediatric Cancer.—The Committee encourages NCI and NIH to continue to prioritize pediatric cancer research. The Committee recognizes NCI’s efforts to implement sections of the Childhood Cancer STAR Act, develop a new Childhood Cancer Data Initiative, and continue to support and expand new and innovative research efforts to advance progress for children with cancer. These include the Pediatric MATCH precision medicine trial and a pediatric immunotherapy translational science network established through the Cancer Moonshot, in addition to NCI’s long-standing support for the Children’s Oncology Group, the Childhood Cancer Survivor Study, the Pediatric Preclinical Testing Consortium, and several other critical programs. The Committee also commends NIH for its efforts to coordinate pediatric research across its Institutes and Centers through the recently established Trans-NIH Pediatric Research Consortium. The Committee understands NCI participates in the Consortium, and that childhood cancer research is an important part of the pediatric research portfolio across NIH. The Committee requests an update in the fiscal year 2021 CJ on opportunities to enhance childhood cancer research efforts, including coordination efforts already underway through the Trans-NIH Pediatric Research Consortium.

Pediatric MATCH.—The Committee recognizes that cancer is the leading cause of death by disease amongst children and, after accidents, cancer is the second leading cause of death in children ages 1 to 14. In 2018 alone, cancer will affect over 17,000 children, and many of these diagnoses will be rare forms, which lack sufficient therapeutic options. Moreover, children with cancer can suffer more severe side effects from aggressive treatments than adult patients, and the majority of pediatric cancer survivors live with chronic conditions because of their treatments. Improvements in treatment are urgently needed to address this childhood health crisis. The Committee commends NCI’s efforts on the novel pediatric MATCH study to address some of these challenges, and appreciates that it will add to the body of scientific evidence necessary to determine the molecular targets substantially relevant to the growth or progression of pediatric cancer as required by the FDA Reauthorization Act of 2017. The Committee encourages NCI to continue its efforts on the pediatric MATCH study and trials. The Committee requests an update in the fiscal year 2021 CJ.

Precision Medicine.—The Committee strongly supports precision medicine initiatives that are critical to delivering the right treatment to the right patient at the right time. At its core, precision medicine aims to understand and treat the underlying cause of disease in individual patients. Once the underlying cause of a patient’s disease is identified, this information can then be used to gain new insights into the underlying basic biology and disease pathogenesis, which will ultimately foster the development of medicine targeted to those patient populations most likely to benefit. The Committee strongly believes that NIH needs to focus cancer precision medicine efforts towards comprehensive drug screening and precision clinical trials and has included sufficient funding to do so. Therefore, the Committee directs NCI to fund an initiative
to foster the clinical demonstration of novel methodologies for individualizing identification of cancer therapeutics. Programs should be at a NCI-designated Comprehensive Cancer Center at institutions that have demonstrated institutional investment in precision medicine, have a strong existing track record in NIH-supported cancer funding and have the expertise to conduct in-depth genomic analysis of cancer tumors and do comprehensive drug repurposing screens of all FDA-approved drugs on at least one tumor type. Additionally, regional multi-institutional consortia that serve populations with significant health disparities and traditionally underserved populations are strongly encouraged.

*Psycho-Social Distress Complications.*—According to the Institute of Medicine, nearly 50 percent of all cancer patients experience distress. Further, studies suggest that distress in cancer patients leads to higher healthcare costs, less compliance with treatment pathways, and poorer health outcomes. While significant advancements have been made in cancer care, the Committee is concerned that the unaddressed psycho-social needs of patients are adversely impacting the effectiveness and cost of care, as well as the individuals' overall well-being. As such, the Committee encourages NCI to ensure that all of its designated cancer centers are managing and measuring patients for distress as an integral piece of their treatment and follow-up care. The Committee requests an update on NCI's activities in this area in the fiscal year 2021 CJ, especially as they relate to recommendations made in the 2008 Institute of Medicine report, "Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs."

*Rare Cancers.*—Rare cancers, defined as those cancers that have fewer than six new cases per 100,000 Americans per year, represent over 30 percent of all cancers. Pediatric cancers, all forms of which are rare, account for around 1 percent of new patients per year. Rare cancers present unique research challenges for many reasons, including the difficulty in accruing enough patients to clinical trials, and the lack of industry focus on these cancers due to the relatively small number of patients diagnosed with each cancer. The Committee commends NCI's investment in the Rare Tumor Patient Engagement Networks, including NCI CONNECT and MyPART, and in particular in the NCI Experimental Therapeutics Program, with a focus on supporting the most promising new drug discovery and development projects, with priority given for development of therapeutic agents for pediatric cancers. The Committee is particularly interested in the preliminary results of the NCI DART trial ("Dual Anti-CTLA–4 & Anti-PD–1 blockade in Rare Tumors Trial"), the first federally-funded immunotherapy study devoted entirely to rare cancers, with over 35 cohorts targeting very rare to exceedingly rare types of cancers. The Committee requests an update on the DART study in the fiscal year 2021 budget request. Finally, the Committee encourages a trans-NIH collaboration, which includes NCATS, to accelerate therapies for rare cancers and to support broader sharing of genomic-related rare cancers data to accelerate research and drug development for these cancers.

*Specialized Programs of Research Excellence [SPORE].*—The Committee notes that SPOREs is one of NCI's cornerstone efforts to promote collaborative, interdisciplinary translational cancer re-
search. The Committee continues to support the SPORE grant program as it works to bring basic research into practical treatments. The Committee commends NCI’s investment in this area and notes the increasing multi-Center nature of this program, with now over 70 percent of the NCI SPOREs being multi-Center (involving more than one Institute), and 45 percent of those multi-Center sites involve more than two Institutes. Likewise, the Committee notes that several of the existing SPOREs focus on related organ site diseases (such as the Gastrointestinal, Neuroendocrine, and Sarcoma SPOREs), and another SPORE focuses on a specific pathway called hyperactive RAS in the context of mutations in the NF1 gene. The Committee requests an update on the NCI SPOREs program in the fiscal year 2021 CJ.

**STAR Act.**—The Committee includes $25,000,000 in funding for continued implementation of sections of the Childhood Cancer Survivorship, Treatment, Access, and Research [STAR] Act. Funding is in addition to the funds allocated in fiscal year 2019 to expand existing biorepositories for childhood cancer patients enrolled in NCI-sponsored clinical trials to collect and maintain relevant clinical, biological, and demographic information on children, adolescents, and young adults, with an emphasis on selected cancer subtypes (and their recurrences) for which current treatments are least effective. Funding provided this year will allow NCI to continue to conduct and support childhood cancer survivorship research as authorized in the STAR Act. The Committee was pleased to see NCI issue a Request for Applications in fiscal year 2019 to encourage research proposals directly aligned with areas of emphasis outlined in the STAR Act.

**Surveillance, Epidemiology, and End Results [SEER] Registry.**—The Committee supports efforts to modernize the SEER Registry and fill in key data gaps, such as metastatic recurrence. The Committee encourages NCI to advance this effort in a systematic and meaningful way that ultimately improves SEER Registry infrastructure and capabilities.

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Appropriations, 2019 ................................................................. $3,494,359,000
Budget estimate, 2020 ............................................................. 3,002,696,000
Committee recommendation .................................................... 3,694,771,000

The Committee recommendation includes $3,694,771,000 for the National Heart, Lung, and Blood Institute [NHLBI].

**Alzheimer’s Disease and Vascular Dementia.**—The Committee recognizes the value that well characterized, longitudinal, population-based cohort studies provide in bringing to light more information about the risk factors related to dementia. By studying participants over time, much can be learned about cognitive decline and early biomarkers that will help us understand the role of environmental and genetic factors in disease development and progression. In time, however, mature cohorts naturally dwindle as participants pass away, requiring that the research mission be adjusted to continue to leverage the previous science and build upon it. Therefore, the Committee encourages NHLBI to continue supporting its ongoing cohort studies of cardiovascular disease and to work with other Institutes, including NIA, to incorporate analyses.
of cognitive decline in these cohorts. NIH is also encouraged to consider funding a pilot project on next generation cohorts, with the goal of determining the feasibility of recruiting next generation participants to continue study into the development and progression of risk factors and to detect early signs of cognitive decline.

Aortic Aneurysm and Fibrosis.—The Committee is encouraged by the focus on fibrosis research within NHLBI’s strategic plan, and further supports research in fibrosis, which is a significant comorbidity with conditions that cause aortic aneurysm, like Marfan syndrome, vascular Ehlers Danlos, and Loeyz-Dietz syndrome. The Committee requests updates from NHLBI on this research in the fiscal year 2021 CJ.

Chronic Disease Precision Medicine.—Chronic diseases and conditions, such as heart disease, hypertension, and obesity are among the most common, costly, and preventable of all health conditions. Therefore, the Committee directs NHLBI to fund an initiative to address chronic diseases through translational science and the application of a precision medicine approach and has included sufficient funding to do so. Programs should focus on diseases and disorders relating to heart, lung, blood, and sleep, and access to populations with significant health disparities. Programs should have a proven track record of NIH funding in all of these areas, as well as have NIH-funded programs for health disparities research. Additionally, regional multi-institutional consortiums are strongly encouraged.

Chronic Obstructive Pulmonary Disease (COPD)/Pulmonary Rehabilitation.—COPD is a major cause of morbidity and mortality for many people, especially in rural areas. Pulmonary rehabilitation is an effective non-medication treatment for COPD and well-designed and continuing research in pulmonary rehabilitation has the potential to reduce hospitalizations and improve survival. The Committee believes that continued and significant research into pulmonary rehabilitation by NHLBI is critical to harness this potential and strongly urges NHLBI to support this research.

Congenital Heart Disease (CHD).—The Committee commends NHLBI for its continued work to better understand causation, improve treatments and outcomes, and integrate registry data and research datasets to facilitate research on congenital heart disease across the lifespan. The Committee encourages NHLBI to prioritize CHD activities outlined in its strategic plan, including improving understanding of outcomes and co-morbidities, modifying treatment options across the lifespan, and accelerating discovery, analysis, and translation by leveraging CHD registries and networks. The Committee requests NHLBI include in its fiscal year 2021 CJ a report on steps being taken on these efforts.

Fibrotic Diseases.—The Committee remains concerned about the human and economic toll of fibrotic diseases, such as pulmonary fibrosis, and encourages NIH to vigorously support dedicated funding and research into fibrotic diseases affecting different organs, including the lungs, liver, kidneys, heart, skin, and bones. NIH should ensure enhanced coordination among its Institutes as they conduct necessary, expanded single organ or cross-organ fibrotic disease research to save lives and reduce healthcare expenses in future years. The Committee also encourages NIH to explore natu-
rally occurring fibrotic disease in domestic animals to investigate opportunities to improve human and animal lives. Since many fibrotic diseases are individually rare diseases, a strategy that provides collaboration across disease and organ areas is recommended. The Committee requests a report on the current NIH Fibrosis Interest Group and its progress no later than 90 days after the passage of this act. The Committee encourages the Interest Group to continue its efforts to bring together key stakeholders, at the NIH and elsewhere, to develop strategic paths forward to maximize efforts in fibrotic disease research. The Committee also encourages NIH to enhance its patient-centered clinical research into pulmonary fibrosis to include traditional observational and interventional studies looking at reducing healthcare utilization such as hospitalizations, improving symptoms such as cough, and prolonging life, and directs NIH to include an update in its fiscal year 2021 CJ on its work relating to idiopathic pulmonary fibrosis following the November 2012 NHLBI workshop: “Strategic Planning for Idiopathic Pulmonary Fibrosis.” The Committee also commends CDC on its recent work identifying and studying clusters of pulmonary fibrosis in workers, including dentists and miners, and encourages NIH and CDC to collaborate on such findings to include further research efforts and data sharing that could lead to better understanding of this disease and life-saving treatments. The Committee also encourages NIH to create a funding mechanism to fund fibrosis research across all organs, building on the progress and leveraging data that has and may result from NHLBI funded projects.

Heart Disease.—Heart disease is the leading cause of death for both men and women in the U.S. Despite significant progress over the last half century, the Committee is concerned that this largely preventable disease continues to place a high burden on our Nation’s health and economy. The Committee is discouraged that new evidence shows that previous declines in cardiovascular disease have stalled or even reversed for certain demographics. Despite this disturbing trend, NIH only invests 4 percent of its budget on heart disease research. Therefore, the Committee supports a NIH-wide prioritization of heart research to significantly strengthen the fight against heart disease. The Committee commends the Institute for its work focused on congenital heart disease, high-risk populations, and on the relationship between high blood pressure and age-related cognitive impairment and dementia. Further, the Committee supports NHLBI’s research on South Asians, who are four times more likely to have heart disease than the general public; experience heart attacks 10 years earlier; and have higher mortality rates from heart disease than any other ethnic group.

Hemophilia.—The Committee commends NHLBI for its May 2018 State of the Science Workshop on Factor VIII Inhibitors and asks NHLBI to provide the Committee with the final report and national blueprint for future research from this meeting. Inhibitors, an immune response to treatment, are associated with increased risks from bleeding, including increased hospitalizations, morbidity and mortality. The Committee encourages NHLBI to take steps to implement the research blueprint in collaboration with the hemophilia patient, provider, and research communities.
Pediatric Cardiomyopathy.—The Committee commends NHLBI for its long-standing commitment to the Pediatric Cardiomyopathy Registry [PCMR]. The data and samples from the PCMR are now being leveraged to support additional research projects, some of which are also funded by NHLBI. The Committee strongly encourages NHLBI to continue to support cardiomyopathy research.

Postural Orthostatic Tachycardia Syndrome [POTS].—POTS is an autonomic nervous system disorder that impacts an estimated 1,000,000–3,000,000 Americans, with approximately half of patients developing POTS in adolescence. While the POTS population is fairly young, research has shown that POTS causes disability similar to congestive heart failure and COPD. Approximately 25 percent of individuals with POTS are unable to work or attend school, contributing to a significant economic impact on families of affected individuals and the U.S. economy. Last year, Congress encouraged NHLBI and NINDS to jointly host a symposium with participants from NIAID, NIDDK, and NICHD and leading external researchers and stakeholders to examine the current state of POTS research, and directed NIH to provide a report to the House and Senate Committees on Appropriations that reflects the participants’ findings on: (1) the current state of POTS research; (2) priority areas of focus for future POTS research through 2025; (3) a summary of ongoing or upcoming efforts by NIH to advance the scientific understanding of POTS; and (4) an estimate of the level of funding that would be needed annually to achieve objectives (2) and (3). The Committee is pleased that planning for a stakeholders meeting is underway and looks forward to receiving the report. The Committee expects NIH to submit the report to the Committee no later than 7 days after enactment. Additionally, given the scope and severity of the impact POTS has on the U.S. population, the Committee strongly encourages NIH to include an estimate of annual NIH funding allocated to POTS research in its publicly available Estimate of Funding for Various Research, Condition and Disease Categories annual report.

Reducing Residual Cardiovascular Risk.—Data compiled by the American Heart Association in conjunction with the CDC, NIH, and other government sources indicate that cardiovascular events account for one of every three deaths in the United States; about 2,300 Americans die of cardiovascular disease each day. Progression of cardiovascular disease to death, heart attack, stroke, or other adverse event is expensive, painful, and results in a loss of productivity. Cholesterol therapies, such as statins, have been successful in reducing risk of cardiovascular disease in many Americans, but substantial residual and untreated risk remains for these individuals beyond cholesterol management. A landmark clinical trial called REDUCE-IT has demonstrated a 25 percent relative risk reduction in major adverse cardiovascular events beyond cholesterol management, from the use of highly purified and stable eicosapentaenoic acid in addition to statin therapy. The Committee is concerned that, despite these statistics, many individuals do not regularly access treatments for residual risk beyond statin therapy. The Committee commends NIH, particularly through NHLBI, for playing an important role in bridging the knowledge gap and encouraging healthcare professionals and their patients to take action
toward well-informed decisions for care. The Committee urges NIH to devote funding, particularly through the “know your numbers” campaign, to promote awareness among physicians and patients of the residual cardiovascular risks beyond statin therapy and the importance of taking preventative action to reduce this risk.

Sickle Cell Disease.—Sickle cell disease is an inherited disorder affecting red blood cells that impacts approximately 100,000 African-Americans in the United States. The disease causes extensive bone and organ damage. It is a disabling disease on many levels. Frequent, chronic, and progressive pain crises, along with other medical complications of the disease, make living a normal existence for afflicted individuals very difficult. Advances in medical care have increased the average life expectancy to 45 years, but many individuals succumb to the disease long before, and significant variations exist in the standard of care provided across the country. The Committee encourages NHLBI to continue to make the study of sickle cell disease a priority. The Committee strongly encourages NHLBI to prioritize and implement robust investment to drastically spur, strengthen, accelerate, and coordinate sickle cell disease research. 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 is needed to augment the limited treatment options available if we are to have a real impact on sickle cell disease. Further, while the Committee is aware that NHLBI is funding very promising areas of innovation related to curative gene therapies, the Committee strongly encourages NHLBI to increase its focus on disease-modifying therapies that could improve day-to-day care for the vast majority of patients and address issues such as organ damage and pain management. Lastly, the Committee encourages NHLBI to support translational research and implementation science to improve the care of patients as they transition from childhood medical care to adult.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Appropriations, 2019 ................................................................. $462,230,000
Budget estimate, 2020 ............................................................ 397,493,000
Committee recommendation ..................................................... 486,756,000

The Committee recommendation includes $486,756,000 for the National Institute of Dental and Craniofacial Research [NIDCR].

Temporomandibular Disorders [TMD].—The Committee commends NIDCR for its work with the Office of the Director and the National Academies of Sciences, Engineering, and Medicine in the comprehensive project, Temporomandibular Disorders: From Research Discoveries to Clinical Treatment. It also appreciates NIDCR’s participation in the TMJ Patient-Led RoundTable to advance collaboration to work toward the common end of providing safe and effective treatments that improve patients’ quality of life. The Committee encourages continued collaboration with governmental agencies and other stakeholders in the project. The Committee continues to be concerned that over 36,000,000 people, primarily women in their childbearing years, are affected physically,
financially, and emotionally by TMD. The Committee is aware that TMD are primarily a multisystem disorder with overlapping conditions influenced by multiple biological and environmental factors rather than solely an orofacial pain condition. The Committee is cognizant that NIDCR’s budget on TMD is a small percent of its overall budget despite the burden of this condition on individuals and society at large. The Committee urges NIDCR to increase funding that will expand the science base and enable increasing multidisciplinary research to advance this field. The Committee requests an update on TMD funding and the preliminary recommendations that came forth from the multiple TMJ public-private scientific meetings supported by NIH and NIDCR in the fiscal year 2021 CJ.

**NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES**

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<th>Appropriations, 2019</th>
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<tr>
<td>Budget estimate, 2020</td>
<td>$1,746,493,000</td>
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<td>Committee recommendation</td>
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The Committee recommendation includes $2,155,327,000 for the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK].

*Celiac Disease.*—The Committee recognizes the serious issue of Celiac disease which affects more than 3,000,000 Americans, and that the number afflicted is growing. To that end, the Committee urges NIH to devote sufficient, focused research to the study of Celiac disease. Today, the only known treatment for this disease is a gluten-free diet. However, recent private sector research has revealed that such a treatment is insufficient for many who suffer from Celiac disease. Therefore, the Committee strongly encourages NIDDK to dedicate sufficient resources to better coordinate existing research and focus new research efforts toward understanding causation and ultimately, finding a cure. The Committee requests an update on these activities in the fiscal year 2021 CJ.

*Chronic Diseases and Health Disparities.*—Kidney disease, type 2 diabetes, and obesity are among the most common, costly, and preventable of all health conditions. As of 2012, about half of all adults had one or more chronic health conditions, with 25 percent of adults suffering with two or more chronic health problems. The Committee strongly believes that NIH needs to focus chronic disease efforts on those populations most affected, particularly vulnerable populations and underrepresented minorities. Therefore, the Committee has included sufficient funding for an initiative to address chronic diseases and health disparities in these areas. The program must focus on kidney disease, obesity, diabetes, exercise medicine, and health disparities. Programs should have a strong existing track record of NIH funding in all of these areas, such as NIH-funded Nutrition Obesity Research Center, Diabetes Research Center, Obesity Health Disparities Research Center, and O’Brien Kidney Center. Additionally, regional multi-institutional consortia are strongly encouraged.

*Diabetes.*—The Committee commends the efforts of NIDDK to prioritize the discovery and validation of biomarkers and urges NIDDK to continue to prioritize this important work that will ac-

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celerate the designing and conducting of clinical trials to prevent, treat, and cure type 1 diabetes. Given the growing prevalence of diabetes, the Committee is concerned that additional research is needed to determine how to improve the treatment of a common complication, diabetic foot ulcers, to reduce amputations, and urges NIDDK to support such efforts. Further, given the aging population, the Committee urges NIDDK to work with NIA to explore the relationship between diabetes and neurocognitive conditions, such as dementia and Alzheimer’s disease. Finally, the Committee supports efforts to utilize adult-derived, non-embryonic pluripotent stem cells for developing and commercializing the use of the stem cell-derived islets for both drug discovery and testing platforms and therapeutic delivery to patients with diabetes.

**End-Stage Renal Disease [ESRD]**.—The Committee recognizes the work in supporting critical kidney research that NIDDK has accomplished, including ESRD. The Committee continues to encourage NIDDK to work with stakeholders to facilitate new opportunities for research.

**Glomerular Diseases**.—The Committee recognizes the work that the Cure Glomeruloneuropathy initiative and the Nephrotic Syndrome Study Network are supporting to obtain insights into these diseases that could lead to breakthroughs for critical clinical trials. The Committee encourages NIDDK to continue supporting research that has proven to lead to new therapies.

**Hepatitis B Virus [HBV]**.—The Committee notes that infection with HBV is a serious public health threat and 1 in 20 Americans has been infected and more than 2,000,000 are chronically infected, increasing by 70,000 a year. Based on findings from the National Academies of Sciences, Engineering, and Medicine in 2017, 158,000 will die if left undiagnosed and untreated. In view of this public health threat, the Committee remains concerned that NIH spending on HBV research has decreased from $48,000,000 in fiscal year 2014 to an estimated $42,000,000 in fiscal year 2019, despite declarations from the National Academies of Sciences, Engineering, and Medicine in 2017 that the elimination of HBV is within reach. Additionally, the hepatitis B research community convened a virtual consensus conference to prepare a “Roadmap for a Cure” that resulted in articles published in 2018 in two peer reviewed scientific journals, Hepatology and Antiviral Research, identifying the most urgent research questions that must be answered to find a cure for HBV. The Committee urges NIDDK to pursue the many critical research opportunities identified by the scientific community and to work in coordination with other NIH Institutes on HBV research planning.

**Inflammatory Bowel Diseases [IBD]**.—The Committee continues to encourage NIDDK to incorporate patient centricity in IBD research, including support for a translational “bedside-to-bench” systematic research initiative that leverages patient priorities and perspectives with respect to biomedical research, such as personalized medicine approaches, to address a patient-identified clinical need. Specifically, the Committee recognizes interactions among food, the gut, and the brain/nervous system as an area of high interest to patients and relevant to multiple chronic gastrointestinal...
diseases that is supported by a growing body of evidence, and identifies it as a potential topic for further research.

Liver Diseases.—The Committee notes the emphasis that NIDDK has placed on liver disease research, including transplantation issues, through the annual Recent Advancements and Emerging Opportunities report and related research plans. NIDDK is encouraged to continue to feature liver diseases research considering recent progress and improvements for liver disease patients.

Medical Foods.—The Committee applauds the efforts of the Office of Nutrition research and the development of the NIH-Wide Strategic Plan for Nutrition Research. The Committee notes the significance of medical foods to managing a variety of nutrition and chronic disease health challenges, including outside of traditional digestive and metabolic diseases, and encourages further incorporations of research topics associated with medical foods and patient care into emerging research activities.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Appropriations, 2019 ................................................................. $2,270,064,000
Budget estimate, 2020 .............................................................. 2,026,031,000
Committee recommendation ......................................................... 2,490,494,000

The Committee recommendation includes $2,490,494,000 for the National Institute of Neurological Disorders and Stroke [NINDS], including $70,000,000 appropriated from the NIH Innovation Account. NINDS' funding level includes $250,000,000 in funding for research related to opioid addiction, development of opioid alternatives, pain management, and addiction treatment.

Advancement of Non-Opioid Pain Therapies.—Approximately 50,000,000 Americans suffer from chronic pain; living with chronic pain can be life-altering, deeply impacting people on many levels. The current state of chronic pain management is often inadequate for many patients, and places an economic burden on the healthcare system, costing the United States $560,000,000,000 a year. Management of chronic pain often requires both non-pharmacological treatment as well as medicines. Unfortunately, the current pharmacological options do not meet the needs of all patients, and additional treatments are needed. The Committee requests an update on the progress of the development and advancement of non-opioid chronic pain therapies in the fiscal year 2021 CJ.

Cerebral Palsy [CP].—The Committee commends NINDS for implementing Funding Opportunity Announcements [FOAs] for clinical research supporting observational studies that are well-suited for the study of CP. The Committee strongly encourages NIH to prioritize and implement additional FOAs to significantly strengthen, accelerate, and coordinate cerebral palsy research to address priorities across the lifespan identified in the 5 to 10 year CP Strategic Plan developed by NINDS and NICHD. FOAs should target basic and translational discoveries, including genetics, regenerative medicine, and mechanisms of neuroplasticity, as well as clinical studies aimed at early intervention, comparative effectiveness, and functional outcomes in adults. NIH is also encouraged to coordinate with other agencies, including CDC, to support additional research on preventing, diagnosing and treating CP.

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Dystonia.—The Committee notes the conference on dystonia held by NINDS to revitalize the dystonia research portfolio. The Committee encourages NINDS to follow the recommendations, including identifying new research and therapeutic needs that will lead to a better understanding of dystonia etiology and evaluation of the current status of translational research that may lead to more treatment options for those affected by dystonia.

Helping to End Addiction Long-Term (HEAL) Initiative.—The Committee supports the development of the HEAL initiative, a multi-Institute and multi-agency effort to bolster research to improve treatments for opioid misuse and addiction, and enhance pain management. In addition, the Committee recognizes that migraine is the second leading cause of global disability and that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, the Committee strongly urges NIH to consider funding opportunities for fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension.

Opioid Misuse and Addiction.—The bill includes $250,000,000 for targeted research related to opioid misuse and addiction, development of opioid alternatives, pain management, and addiction treatment. The Committee remains concerned about the growing epidemic of opioid misuse and addiction in this country. The widespread availability of prescription opioids has contributed to the millions of Americans who suffer from addiction disorders. Although NIH has studied the effectiveness and risks associated with long-term opioid use for chronic pain, little research has been done to investigate new and alternative options to treat chronic pain, other than with highly addictive opioid painkillers and muscle relaxants. The Committee directs NIH to expand scientific activities related to research on medications used to treat and reduce chronic pain, and the transition from acute to chronic pain.

Parkinson’s Disease.—The Committee commends NINDS within NIH for taking critical steps in identifying priority research recommendations to advance research on Parkinson’s disease, which impacts between 500,000 and 1,500,000 Americans and is the second most prevalent neurodegenerative disease in the United States. The ultimate success of these recommendations will depend on targeted research initiatives and increased research capacity, even if innovative support and funding mechanisms are required. The Committee recognizes that NINDS is prioritizing public health concerns with severe gaps in unmet medical needs and supports the research recommendations set forth by the NINDS planning strategy to bring us closer to better treatments and a cure for Parkinson’s disease. The Committee also encourages NINDS to submit a report of its progress on implementing these recommendations in the fiscal year 2021 CJ.

Postural Orthostatic Tachycardia Syndrome (POTS).—POTS is an autonomic nervous system disorder that impacts an estimated 1,000,000–3,000,000 Americans, with approximately half of patients developing POTS in adolescence. While the POTS population is fairly young, research has shown that POTS causes disability
similar to congestive heart failure and COPD. Approximately 25 percent of individuals with POTS are unable to work or attend school, contributing to a significant economic impact on families of affected individuals and the U.S. economy. Last year, Congress encouraged NHLBI and NINDS to jointly host a symposium with participants from NIAID, NIDDK, and NICHD and leading external researchers and stakeholders to examine the current state of POTS research, and directed the NIH to provide a report to the House and Senate Committees on Appropriations that reflects the participants’ findings on: (1) the current state of POTS research; (2) priority areas of focus for future POTS research through 2025; (3) a summary of ongoing or upcoming efforts by NIH to advance the scientific understanding of POTS; and (4) an estimate of the level of funding that would be needed annually to achieve objectives (2) and (3). The Committee is pleased that planning for a stakeholders meeting is underway and looks forward to receiving the report. The Committee expects NIH to submit the report to the Committee no later than 7 days after enactment. Additionally, given the scope and severity of the impact POTS has on the U.S. population, the Committee strongly encourages NIH to include an estimate of annual NIH funding allocated to POTS research in its publicly available Estimate of Funding for Various Research, Condition and Disease Categories annual report.

**Stroke.**—Due in large part to NIH funded research, the stroke mortality rate has decreased by 71 percent since 1969. Despite this remarkable progress, strokes cost Americans $37,000,000,000 annually in healthcare bills and lost productivity at work. Furthermore, after more than 4 decades of steep decline, stroke death rates in the U.S. have recently slowed, stalled, or reversed among some groups. This is particularly concerning since stroke research only makes up 1 percent of the NIH budget. The Committee encourages NINDS to prioritize studies that help develop interventions to reduce health disparities in stroke and to advance promising stroke prevention, treatment, and rehabilitation research, including endovascular therapy and tele-rehabilitation. The Committee also urges continued collaboration with the other Institutes on research related to vascular contributions to cognitive impairment and dementia.

**Traumatic Brain Injury [TBI].**—The Committee understands research on regenerative medicine, including the use of adult stem cells, and on neuroplasticity may play an important role in developing treatments for TBI. The Committee strongly encourages NINDS to work with all relevant Institutes and Centers, including NIA, to support a robust and coordinated portfolio of TBI research that explores all promising avenues to facilitate functional repair of damaged circuitry in TBI, including research on regenerative medicine and neuroplasticity. The Committee requests an update in the fiscal year 2021 CJ on efforts in these specific areas of TBI research.

**NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Appropriations, 2019 ................................................................. $5,567,407,000
Budget estimate, 2020 .............................................................. 4,754,379,000
Committee recommendation .................................................... 5,937,816,000

September 17, 2019 (6:03 p.m.)
The Committee recommendation includes $5,937,816,000 for the National Institute of Allergy and Infectious Diseases [NIAID].

**Antimicrobial Resistance [AMR].**—The Committee recommendation includes $600,000,000 within NIAID for research related to combating AMR, an increase of $50,000,000. The Committee remains deeply troubled by the growing threat posed by antimicrobial resistant pathogens. In April, the United Nations issued a report that, like the 2016 review sponsored by the government of the United Kingdom and Wellcome Trust, warned that rampant overuse of antibiotics and antifungal medicines in humans, livestock, and agriculture could erase much of the improvement in public health achieved since the development of the first antimicrobials in the 1940s. The Committee recommendation includes $1,700,000 to fund a National Academies of Sciences, Engineering, and Medicine study to examine and quantify the long-term medical and economic impacts of increasing AMR in the United States. The review should examine progress made on the U.S. National Strategy and Action Plan for Combating Antibiotic-Resistant Bacteria including domestic and international strategies employed by NIH, CDC, FDA, ASPR, USDA, and USAID. The National Academies' report should make recommendations to address any gaps in research and development of therapeutics and diagnostics; efforts to move new products to market; animal and human surveillance, prevention efforts, international coordination and collaboration; and any other recommendations the Academies finds relevant to stopping the spread of AMR. The Committee directs NIAID to report on trends in AMR-related Research Project Grants, including the success rates for such grants, and requests an update on these activities in the fiscal year 2021 CJ, including an overall assessment of the progress to date of efforts to address AMR.

**Food Allergies.**—The Committee recognizes the serious issue of food allergies, which affect approximately 8 percent of children and 10 percent of adults in the United States. The Committee commends the ongoing work of NIAID in supporting approximately 17 clinical sites for this critical research, including seven sites as part of the Consortium of Food Allergy Research. The Committee urges NIH to support robust investment to expand its clinical research network to add new centers of excellence in food allergy clinical care and to select such centers from those with a proven expertise in food allergy research.

**Hepatitis B Virus [HBV].**—The Committee notes that infection with HBV is a serious public health threat and 1 in 20 Americans have been infected and more than 2,000,000 may be chronically infected, increasing by 70,000 a year. Based on findings from National Academies of Sciences, Engineering, and Medicine in 2017, 188,000 will die if left undiagnosed and untreated. In view of this public health threat, the Committee remains concerned that NIH research spending on HBV decreased from $48,000,000 in fiscal year 2014 to an estimated $42,000,000 in fiscal year 2019, despite the Academies' report that the elimination of hepatitis B is within reach. Additionally, the hepatitis B research community convened a virtual consensus conference to prepare a "Roadmap for a Cure" that resulted in articles published in 2018 in two peer reviewed scientific journals, Hepatology and Antiviral Research, identifying the
most urgent research questions that must be answered to find a
cure for hepatitis B. The Committee commends NIAID for plans to
publish several funding opportunity announcements on HBV in fis-
cal year 2019 and urges additional targeted calls for HBV research
to fund the many critical research opportunities identified by the
scientific community in the Roadmap for a Cure. The Committee
urges active participation and leadership by NIAID in the Direc-
tor’s newly established Trans-NIH Hepatitis B working group and
requests that NIAID submit within 180 days of enactment of this
bill into law, a research plan to pursue a cure for HBV in coordina-
tion with the other Institutes.

HIV/AIDS.—The Committee fully supports the role NIAID will
play in the budget request for “Ending the HIV Epidemic.” NIAID
remains a critical component of this initiative through the Centers
for AIDS Research and AIDS Research Centers that will inform
HHS partners on best practices, based on state-of-the-art bio-
medical research findings, and by collecting and disseminating data
on the effectiveness of approaches used in this initiative.

Lyme Disease and Other Tick-Borne Diseases.—With an esti-
imated 300,000 new cases of Lyme disease each year in the United
States, and tens of thousands more suffering from other tick-borne
diseases, improved understanding and treatment of these diseases
is essential for the health and well-being of Americans. The Com-
mittee encourages NIH to issue requests for grant applications for
research to investigate causes of all forms and manifestations of
Lyme disease and other high-consequence tick-borne diseases, in-
cluding post-treatment symptoms, as well as research to develop
diagnostics, preventions, and treatments for those conditions, in-
cluding potential vaccine candidates. The Committee notes that in
patients who suffer from long-term complications associated with
Lyme disease, clear treatment pathways are not yet defined. The
Committee urges NIAID, in coordination with CDC, to study the
long-term effects on patients suffering from post-treatment Lyme
disease syndrome, or “chronic Lyme disease.” Specifically, the Com-
mittee urges NIAID to evaluate the effectiveness of laboratory tests
associated with the detection of Borrelia burgdorferi to diagnose the
disease early, which can improve the treatment of patients suf-
fering from Lyme disease. The Committee is also aware of prom-
ising vaccine innovations to combat Borrelia and requests a report
within 90 days of enactment on agency activities to support Lyme
vaccine development. The Committee also encourages NLM, in co-
ordination with NIAID, to update its terminology in line with new
research to more accurately reflect the long-term effects of Lyme
disease.

Medical Countermeasures.—The Committee supports the continu-
ation of NIAID’s medical countermeasures program, but expects
the Institute to make sure any future contractor selected for the
program can refine its animal models, particularly small animal
models, to support the establishment of adequate countermeasure
efficacy to expedite approval by the FDA. This requires close co-
ordination with NIAID and the adequate level of technical per-
sonnel to carry out the program’s important mission.

Microbicides.—The Committee recognizes that with NIH and
USAID leadership, research has shown the potential for
antiretroviral [ARV] drugs to prevent HIV infection in women. The Committee encourages NIAID to continue coordination with USAID, the State Department, and others to advance ARV-based microbicide development efforts with the goal of enabling regulatory approval of the first safe and effective microbicide for women and supporting an active ARV-based microbicide pipeline to produce additional solutions to prevent HIV and to help end the epidemic.

**Sexually Transmitted Infections [STIs].—**The Committee continues to be concerned about the prevalence of STIs, especially with the increase in their resistance to multiple classes of antibiotics. The Committee commends NIAID for its efforts in developing new antibiotics specifically to treat gonorrhea and encourages NIAID to continue its work in this area for new diagnostics, treatments, and cures. Further, the Committee encourages NIAID to continue to accelerate the development of screening tests, vaccines, and new treatment options for syphilis, for both adults and newborns.

**Threat of Emerging Infectious Diseases.**—The Committee notes NIH's progress in advancing scientific discovery and public health by leveraging the incredible growth in the volume, speed of delivery, and complexity of large biomedical datasets. The Strategic Plan for Data Science released by NIH in June 2018, articulates a vision for making big data sustainable, interoperable, accessible, and usable by the broader scientific community. The usage of machine learning, data-driven dynamical modeling, and other big data techniques to identify early warning signals for outbreaks of rare diseases is an integral part of scientific research on the ecology and evolution of infectious diseases. The Committee recognizes the threat of Emerging Infectious Diseases from animals and urges NIH to support further research in disease mapping and forecasting in order to identify early warning signals for outbreaks of emerging diseases. The Committee expects the fiscal year 2021 budget request to include a progress report on the use of machine learning and validated mechanistic models to advance critical biomedical research, improve decision support for epidemiological interventions and enhance human health.

**Universal Flu Vaccine.**—The Committee provides not less than $165,000,000, an increase of $25,000,000, to advance basic, translational, and clinical research to develop a universal influenza vaccine.

**Valley Fever.**—The Committee notes the recent increase in the number of Valley fever infections in Western States and urges NIAID to prioritize research on this fungal disease.

**NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES**

Appropriations, 2019 .......................................................... $2,819,509,000
Budget estimate, 2020 ....................................................... 2,472,838,000
Committee recommendation .............................................. 2,969,113,000

The Committee recommendation includes $2,969,113,000 for the National Institute of General Medical Sciences [NIGMS], which includes $1,564,105,000 in transfers available under section 241 of the PHS Act.

**Institutional Development Award [IDeA].—**The Committee provides $380,758,000 for the IDeA program, an increase of...
$19,185,000. The Committee believes the IDeA program has made significant contributions to biomedical research and has led to the creation of a skilled workforce and made the IDeA program an essential component of NIH’s research portfolio. The Committee supports this important investment, which extends NIH’s reach nationwide. Further, the Committee recognizes the importance of the Centers of Biomedical Research Excellence and the IDeA Networks of Biomedical Research Excellence programs and expects funding to be maintained for both. These programs are essential to the overall success of the IDeA program.

Maximizing Access to Research Careers (MARC).—The Committee recognizes the importance of the MARC program and encourages the continuation and enhancement of efforts underway with our Nation’s HBCUs. The Committee also recognizes the important work of those HBCUs located in rural parts of the U.S. in educating significant numbers of underserved students in STEM fields, and it encourages the NIH to continue and strengthen its engagement of institutions located in this region.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Appropriations, 2019 ................................................................. $1,506,426,000
Budget estimate, 2020 ............................................................... 1,296,732,000
Committee recommendation ...................................................... 1,587,278,000

The Committee recommendation includes $1,587,278,000 for the Eunice Kennedy Shriver National Institute of Child Health and Human Development [NICHD].

Congenital Syphilis (CS).—The Committee is concerned about the rise in CS rates and the lifelong health effects the disease can have on the child. CS can cause death, bone deformity, blindness, deafness, or brain and liver issues. The Committee encourages NICHD to increase research in this area and to work with NIAID on new testing, diagnosis, and treatment efforts.

Endometriosis.—The Committee is aware that endometriosis is a chronic disease originating in the female reproductive system affecting 10 percent of women of reproductive age worldwide. Endometriosis is most often misdiagnosed as irritable bowel disease. Endometriosis has been linked to ovarian cancer. The Committee also recognizes that endometriosis is the third-leading cause of female infertility in the United States. The Committee encourages NICHD to increase its support for research to improve early and more accurate diagnostic rates and for education to inform healthcare providers and their patients regarding diagnosis and treatment of endometriosis.

Impact of Technology and Digital Media on Children and Teens.—The Committee recognizes that children and teens’ lives increasingly involve widespread technology use and consumption of digital media. The Committee is aware of the need for robust research into how young people’s use of technologies and media sources such as social media, mobile devices, and interactive video games impact development of children and adolescents. The Committee encourages NIH to prioritize research into how these types of stimuli affect young people’s cognitive, physical, and socio-emo-
tional outcomes, including attention, sleeping routines, and anxiety.

Population Research.—NICHD has a clear mandate to support a robust research portfolio focusing on maternal and child health, the social determinants of health, and human development across the lifespan. Population research, now commonly termed “population science,” is cited explicitly in the Institute’s authorizing statute as a key tenant of the Institute’s broader mandate. Accordingly, over the decades, NICHD has supported innovative and influential population science initiatives, including: (1) large-scale longitudinal surveys, with population representative samples, such as the National Longitudinal Survey of Adolescent Health and Fragile Families and Child Well Being Study; (2) a nationwide network of population science research and training centers; and (3) numerous scientific research initiatives that have advanced our understanding of specific diseases and conditions, including obesity, autism, and maternal mortality, and, further, how socioeconomic and biological factors jointly determine human health. Given these significant scientific contributions, the Committee urges NICHD to reaffirm its commitment to supporting population research, as well as the NICHD Population Dynamics Branch, as part of its revised 2020–2024 strategic plan.

Prenatal Opioid Use Disorders and Neonatal Abstinence Syndrome (NAS).—The Committee recognizes the growing burden of NAS and the healthcare costs associated with it. The Committee is aware of the need for more information regarding long-term health and developmental outcomes related to NAS, the wide variation in clinical practice and health systems support, as well as the challenges associated with post-discharge care. The Committee encourages NIH to coordinate with other agencies at HHS to support additional research on prevention, identification, and treatment of prenatal opioid exposure and NAS, including the best methods for screening and treating pregnant women for opioid use disorder and the best methods for screening for NAS. Additionally, the Committee encourages NIH to build on the ACT NOW study to enhance understanding of the impact of pharmacological and non-pharmacological treatment techniques on costs and outcomes in the short-term and longitudinally. The Committee further encourages NIH to coordinate with other agencies at HHS to support research on innovative care models to optimize care and long-term outcomes for families.

Research in Pregnant and Lactating Women.—The Task Force on Research in Pregnant Women and Lactating Women issued a report to the Secretary of HHS outlining 15 recommendations to facilitate the inclusion of pregnant and lactating women in clinical research. The Committee commends the Secretary for extending the Task Force and believes this extension should be for at least an additional 2 years to continue to work towards healthcare professionals and consumers having accurate information on the safety and efficacy of drugs taken by these populations. NICHD should oversee its part of the implementation of the already released recommendations working with other relevant Institutes, CDC, and FDA. The Committee requests a progress report be provided in fiscal year 2021 CJ.
The Committee recommendation includes $840,163,000 for the National Eye Institute [NEI].

Age-Related Macular Degeneration [AMD].—The Committee recognizes the tremendous strides in the treatment of patients with the “dry” form of AMD, the leading cause of vision loss among people age 65 and older, and commends NEI for its planned first-in-human clinical trial that would test a stem cell-based therapy from induced pluripotent stem cells. The human trial would convert a patient’s own blood cells to induced pluripotent cells, which are then programmed to become retinal pigment epithelial cells which nurture the photoreceptors necessary for vision and which die in the geographic atrophy stage of macular degeneration. The Committee is pleased that NEI has launched a prospective international study of patients that uses the latest advances in retinal imaging to identify biomarkers of the disease and targets for early therapeutic interventions.

Audacious Goals Initiative [AGI].—The Committee commends NEI’s leadership through its AGI, which aims to restore vision through regeneration of the retina by replacing cells that have been damaged by disease and injury and restoring their visual connections to the brain. The Committee is pleased that, to-date, NEI has funded novel imaging technologies to help clinicians observe the function of individual neurons in human patients and follow them over time as they test new therapies; efforts to identify new factors that control regeneration and comparing the regenerative process among model organisms; the development of models for evaluating survival and integration of regenerated photoreceptors and retinal ganglion cells in systems that are closer to human visual anatomy and function than current; and proof-of-principle projects aimed at the development of new models that emulate human visual system anatomy, physiology, and disease processes.

Blepharospasm.—The Committee continues to encourage NEI to continue pursuing collaborations with stakeholders on cross-cutting research opportunities that affect all forms of dystonia including blepharospasm.

Glaucoma.—The Committee recognizes NEI’s Glaucoma Human Genetics Collaboration Heritable Overall Operational Database Consortium—which includes the most thoroughly characterized population of people with known glaucoma status—for its identification of 133 genetic variants that predict within 75 percent accuracy a person’s risk for developing glaucoma related to elevated intraocular pressure [IOP]. The Committee commends the recent FDA approval of two new drug therapies emerging from decades of NEI research into the role of high IOP as a causal risk factor for primary open-angle glaucoma, the most common form of the disease and a leading cause of vision loss and blindness. Targeting the eye’s trabecular meshwork—which is one of the pathways responsible for regulating fluid flow within the eye—the new generation
of therapies reflects an expanding menu of drugs that lower IOP and better meet the needs of patients.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Appropriations, 2019 ................................................................. $774,627,000
Budget estimate, 2020 ......................................................... 666,554,000
Committee recommendation .................................................. 815,729,000

The Committee recommendation includes $815,729,000 for the National Institute of Environmental Health Sciences [NIEHS].

Hurricane Harvey Research.—The Committee includes $3,000,000 for the continued funding and expansion of research on the health effects of environmental exposures directly related to the consequences of Hurricane Harvey in 2017. The research should focus on the full Hurricane Harvey-affected region, conduct follow-up health research on affected populations on registrants, link to relevant government and nonprofit intervention research programs, and provide critical information on disaster preparedness through data sharing and analysis.

NATIONAL INSTITUTE ON AGING

Appropriations, 2019 ................................................................. $3,090,668,000
Budget estimate, 2020 ......................................................... 2,654,144,000
Committee recommendation .................................................. 3,606,040,000

The Committee recommendation includes $3,606,040,000 for the National Institute on Aging [NIA].

Alzheimer’s Disease.—The Committee provides an increase of $350,000,000 for Alzheimer's research, bringing the total funding level in fiscal year 2020 to $2,818,000,000. By 2050, the cost to treat and care for those suffering from Alzheimer’s disease is expected to rise to as high as $1,100,000,000,000 a year. Without a medical breakthrough to prevent, slow, or stop the disease, Medicare- and Medicaid-related costs could more than quadruple.

Diversity of Clinical Trials.—The Committee remains concerned about the underrepresentation of persons from underrepresented populations in research, particularly clinical trials for Alzheimer’s. The Committee directs NIH to report to the Committees on Appropriations within 180 days of enactment on how it is implementing the actions outlined in the National Strategy for Recruitment and Participation in Alzheimer’s and Related Dementias Clinical Research, including NIA resources that have been dedicated to these efforts.

Enhanced Partnerships for Alzheimer’s Studies.—The Committee commends NIA for its leadership in supporting longitudinal, population-based cohort studies into the causes of dementia. Because rural, poor, and minority populations may be at enhanced risk for dementia, the value and application of these studies is enhanced when they include individuals from various geographic, ethnic, socio-economic, and generational backgrounds. Therefore, the Committee directs NIA to diversify its cohort studies, with the specific goal of better understanding disease burden and biomarkers by race and geographic region. The Committee believes this could be accomplished through enhanced partnerships between existing NIA-funded Alzheimer’s Disease Research Centers [ADRC] and non-ADRC dementia centers in high-risk geographic regions or
through the creation of new long-term cohorts in under-represented groups/regions.

**EUREKA Prize.**—The Committee is pleased that the Institute has launched its inaugural EUREKA prize competition, the Improving Care for People with Alzheimer's Disease and Related Dementias Using Technology. The Committee requests a report within 180 days of enactment on the initial prize, including the number of submissions received and any unexpected challenges or impediments encountered in executing the challenge, as well as lessons learned that could be applied to future Alzheimer's or other prize challenges. The Committee also requests that the report include any recommendations to enhance the model going forward.

**Population Research.**—The Committee applauds NIA for supporting an innovative and productive population aging research portfolio. In particular, the Committee praises the Institute for sustaining its investment in demographic surveys, such as the Health and Retirement Survey and the National Health and Aging Trends Study, critical behavioral and social research infrastructure programs, such as the Centers on the Demography and Economics of Aging and the Roybal Centers for Translational Research, and high priority research networks focused on topics such as the biodemography of aging, stress measurement, and early adversity and later life reversibility. These surveys, programs, and networks are instrumental to the NIA mission. In fiscal year 2020, the Committee urges NIA to pursue its plans to renew and expand the Demography and Economics of Aging Centers Program and to reaffirm the Institute’s commitment to supporting population aging research overall as part of its revised strategic directions document, Aging Well in the 21st Century: Strategic Directions for Research on Aging.

**NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES**

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<th>Appropriations, 2019</th>
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<td>Budget estimate, 2020</td>
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The Committee recommendation includes $637,097,000 for the National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIAMS].

**Alopecia Areata.**—The Committee notes NIAMS’ leadership in continuing autoimmune research to advance treatment development for alopecia areata and related conditions. The Committee requests an update from NIAMS on developments from cross-cutting autoimmune research projects in the fiscal year 2021 CJ.

**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 such research at NIAMS.
The Committee recommendation includes $500,270,000 for the National Institute on Deafness and Other Communication Disorders [NIDCD].

NATIONAL INSTITUTE OF NURSING RESEARCH

Appropriations, 2019 ............................................................................. $163,729,000
Budget estimate, 2020 ........................................................................... 140,301,000
Committee recommendation ................................................................. 172,417,000

The Committee recommendation includes $172,417,000 for the National Institute of Nursing Research [NINR].

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Appropriations, 2019 ............................................................................. $527,121,000
Budget estimate, 2020 ........................................................................... 452,419,000
Committee recommendation ................................................................. 556,010,000

Mobile Assessment Technology Research for Addictive Behaviors.—The need to address the grand challenge of addiction is compelling. Therefore, the Committee notes the importance of bringing to bear a multifaceted research approach to target the causes and consequences of substance misuse and addiction in both urban and rural settings. Advancements in mobile and distributed wireless technology represent an important and still under-utilized avenue for studying, treating and preventing substance-related problems. There is particular potential for utilizing these technologies for research and treatment advances in the areas of binge drinking, addiction treatment, and the prevention of substance-related consequences. As such, the Committee encourages the Institute to support meritorious research to improve the prevention and treatment of substance misuse, addiction, and related consequences through the use of mobile technologies.

NATIONAL INSTITUTE ON DRUG ABUSE

Appropriations, 2019 ............................................................................. $1,411,465,000
Budget estimate, 2020 ........................................................................... 1,296,379,000
Committee recommendation ................................................................. 1,490,498,000

The Committee recommendation includes $1,490,498,000 for the National Institute on Drug Abuse [NIDA]. This includes $250,000,000 in funding for research related to opioid addiction, development of opioid alternatives, pain management, and addiction treatment.

Addressing the Opioid Crisis in Rural Regions.—The Committee encourages NIDA to continue its partnership with CDC, SAMHSA, and the Appalachian Regional Commission in support of research to help communities develop comprehensive approaches to prevent and treat consequences of opioid injection, including substance use disorders, overdose, HIV, and hepatitis infections, as well as sexu-
ally transmitted infections. These projects will serve as models for addressing the consequences associated with opioid injection that can be implemented by health systems in similar rural communities in the United States.

Barriers to Research.—The Committee is concerned that restrictions associated with Schedule I of the Controlled Substance Act effectively limit the amount and type of research that can be conducted on certain Schedule I drugs, especially marijuana or its component chemicals, and new synthetic drugs and analogs. At a time when we need as much information as possible about these drugs to find antidotes for their harmful effects, we should be lowering regulatory and other barriers to conducting this research. The Committee directs NIDA to provide a brief report on the barriers to research that result from the classification of drugs and compounds as Schedule I substances no later than 120 days after enactment.

Cannabis Research.—The Committee believes that cannabidiol [CBD] and cannabigerol [CBG], compounds found in cannabis, may provide beneficial medicinal effects. However, there is insufficient scientific information about the long-term effects of these compounds. Additional, coordinated research on a national scale could help determine the toxicology and medicinal effects of CBD and CBG. The Committee encourages NIH to consider additional investment in studying the medicinal effects and toxicology of CBD and CBG.

HEALthy Brain and Child Development [BCD] Study.—The Committee recognizes and supports the HEALthy BCD Study, which will establish a large cohort of pregnant women including those affected by the opioid crisis and follow them and their children for at least 10 years. This knowledge will be critical to help predict and prevent some of the known impacts of pre- and post-natal exposure to drugs or adverse environments, including risk for future substance use, mental disorders, and other behavioral and developmental problems.

Methamphetamine Medication-Assisted Treatments [MATs].—The Committee is concerned with the rise in methamphetamine use and addiction in the United States. While there are currently approved MATs for alcohol and opioid addiction there remains no approved MAT for methamphetamine addiction. The Committee urges the Institute to continue their ongoing trials to expeditiously find and approve a MAT for methamphetamine.

Opioid Misuse and Addiction.—The Committee continues to be extremely concerned about the crisis of prescription opioids, heroin, and illicit synthetic opioid use, misuse, addiction and overdose in the United States. Approximately 174 people die each day in this country from drug overdose (over 100 of those are directly from opioids), making it one of the most common causes of non-diseaserelated deaths for adolescents and young adults. This crisis has been exacerbated by the availability of illicit fentanyl and its analogs in many communities, and along with the widespread availability of prescription opioids, has contributed to the millions of Americans who suffer from addiction disorders. The bill includes $250,000,000 for targeted research related to opioid misuse and addiction, development of opioid alternatives, pain management,
addiction treatment. Although NIH has studied the effectiveness and risks associated with long-term opioid use for chronic pain, little research has been done to investigate new and alternative options to treat chronic pain, other than with highly addictive opioid painkillers, and muscle relaxants. The Committee directs NIH to expand scientific activities related to research on medications used to treat and reduce chronic pain, and the transition from acute to chronic pain. Further, the Committee urges NIH to: (1) continue funding research on medication development to alleviate pain and to treat addiction, especially the development of medications with reduced misuse liability; (2) as appropriate, work with private companies to fund innovative research into such medications; (3) report on what is known regarding the transition from opioid analgesics to heroin and synthetic opioid use and addiction within affected populations; (4) conduct pilot studies to create a comprehensive care model in communities nationwide to prevent opioid misuse, expand treatment capacity, enhance access to overdose reversal medications, and enhance prescriber practice; (5) test interventions in justice system settings to expand the uptake of medications for treating opioid use disorder [OUD] and methods to scale up these interventions for population-based impact; and (6) develop evidence-based strategies to integrate screening and treatment for OUD in emergency department and primary care settings. In addition, NIH should continue to sponsor research to better understand the effects of long-term prescription opioid use, especially as it relates to the prevention and treatment of opioid misuse and addiction. Further, the Committee is pleased NIDA has started to investigate the links among respiratory health, disease and deaths from opioids to determine if addressing underlying respiratory physiology can prevent death due to respiratory failure during overdoses.

Raising Awareness and Engaging the Medical Community in Drug Use, Misuse, and Addiction Prevention and Treatment.—Education is a critical component of any effort to curb drug use and addiction, and it must target every segment of society, including healthcare providers (doctors, nurses, dentists, and pharmacists), patients, and families. Medical professionals must be in the forefront of efforts to curb the opioid crisis. The Committee continues to be pleased with the NIDAMED initiative, targeting physicians-in-training, including medical students and resident physicians in primary care specialties (e.g., internal medicine, family practice, and pediatrics). NIDA should continue its efforts in this space, providing physicians and other medical professionals with the tools and skills needed to incorporate substance use and misuse screening and treatment into their clinical practices.

Substance Abuse Treatment Outcomes.—The Committee acknowledges growing anecdotal evidence that suggest a strong correlation between successful substance use treatment outcomes and stable housing arrangements, especially for those facing mental health challenges or of limited economic means. The Committee strongly encourages NIDA to support research to assess how affordable housing impacts substance abuse treatment outcomes and costs in regions of the country acutely affected by the opioid crisis. In New England, for example, according to the Federal Reserve Bank of...
Boston, each State in the six-State region spends more per capita than the national average on opioid related costs including criminal justice, medical treatment, and medical complications, and where treating opioid use disorder on an emergency and long-term basis comprises the majority of fiscal costs.

NATIONAL INSTITUTE OF MENTAL HEALTH

Appropriations, 2019 ................................................................. $1,876,686,000
Budget estimate, 2020 ............................................................... 1,630,422,000
Committee recommendation ....................................................... 2,076,244,000

The Committee recommendation includes $2,076,244,000 for the National Institute of Mental Health [NIMH], including $70,000,000 appropriated from the NIH Innovation Account.

Suicide Prevention and Risk Detection Algorithms.—The Committee is alarmed by new data from CDC that indicates that suicide rates have increased nationwide by 30 percent since 1999. Data also shows that the suicide rate among children, and especially minority children, has significantly risen over the past decade. NIMH has made some encouraging breakthroughs in research on risk detection algorithms. These tools hold promise for developing assessments that will improve the understanding of when people are at higher risk for suicide and prevention efforts to address future attempts. The Committee continues to encourage NIMH to prioritize its suicide screening and prevention research efforts to produce models that are interpretable, scalable, and practical for clinical implementation, including mental and behavioral healthcare interventions, to combat suicide in the United States. In assessing research opportunities, the Committee encourages NIMH to consider the recommendations included in the Action Alliance for Suicide Prevention’s A Prioritized Research Agenda for Suicide Prevention. The Committee directs NIMH to provide an update on these efforts in the fiscal year 2021 CJ.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Appropriations, 2019 ................................................................. $577,364,000
Budget estimate, 2020 ............................................................... 495,448,000
Committee recommendation ....................................................... 607,999,000

The Committee recommendation includes $607,999,000 for the National Human Genome Research Institute [NHGRI].

Computational Genomics and RNA Molecules.—The Committee is encouraged by recent advances in computational genomics and computational biology that are helping scientists understand what causes disease and how disease progresses. One such example is new evidence about how a person’s sex and ancestral origins affect the individual’s RNA molecules and their impacts. However, the Committee recognizes that more research on these links could uncover new and important biological discoveries, improve our understanding of disease processes and herald highly personalized approaches to diagnosis, prognosis and therapy. The Committee, therefore, urges NHGRI to continue to support research on RNA molecules and the mechanisms through which they affect biological processes that cause disease.

Emerging Centers of Excellence in Genomic Sciences.—The Committee looks forward to receiving NIH’s analysis of NHGRI’s fund-
ing through the RM1, UM1, and other grant mechanisms to ensure NHGRI is effectively supporting capacity-building in genomics research and supporting diverse and innovative institutions, especially in academic medical research institutions that are making significant investments in genomics tools and research, but have not yet been the recipient of a RM1 or UM1 award. In addition, the Committee requests that NHGRI provide update reports on how the Institute is executing the Emerging Centers of Excellence program.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Appropriations, 2019 ................................................................. $389,451,000  
Budget estimate, 2020 ............................................................. 335,986,000  
Committee recommendation ....................................................... 411,496,000  

The Committee recommendation includes $411,496,000 for the National Institute of Biomedical Imaging and Bioengineering [NIBIB].

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

Appropriations, 2019 ................................................................. $146,464,000  
Budget estimate, 2020 ............................................................. 126,081,000  
Committee recommendation ....................................................... 154,695,000  

The Committee recommendation includes $154,695,000 for the National Center for Complementary and Integrative Health [NCCIH].

Pain Management.—The Committee is encouraged by the continued collaboration between NCCIH, VA, DOD, and other NIH Institutes to develop and test efficacious non-pharmacological approaches to pain management and comorbidities—including opioid misuse, abuse, and disorder—in military personnel, veterans, and their families. The Committee is particularly encouraged by recent studies assessing brain activity and pain receptors associated with mindfulness meditation and studies that will assess provider adherence to CDC opioid prescribing practices. While VA has made some notable progress in advancing more appropriate opioid prescribing practices, opioid abuse continues to persist among young veterans. As such, the Committee believes it is critical that we continue to support research on non-pharmacological treatments to ensure the best quality of care for our Nation’s veterans and servicemembers, and urges NIH, VA, and DOD to continue to expand this research. The Comprehensive Addiction and Recovery Act (Public Law 114–198) calls for an expansion of research and education on and delivery of complimentary and integrative health to veterans, and the NCCIH can play an important role in coordinating efforts with the VA, DOD, and other relevant agencies. The Committee requests an update on these studies and the activities of the multi-agency partnership with DOD and VA in the fiscal year 2021 CJ.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Appropriations, 2019 ................................................................. $314,292,000  
Budget estimate, 2020 ............................................................. 270,870,000  
Committee recommendation ....................................................... 339,968,000  

September 17, 2019 (6:03 p.m.)
The Committee recommendation includes $330,968,000 for the National Institute on Minority Health and Health Disparities (NIMHD).

**Focal Segmental Glomerulosclerosis (FSGS).**—The Committee encourages NIMHD to collaborate with other ICs and stakeholders to expand research opportunities on the APOL1 gene that causes African Americans to be disproportionately affected by FSGS.

**Mental Health.**—To address the multiple causes of suicide, the Committee urges NIMHD to develop a behavioral health approach focusing on at-risk populations and building the mental health workforce at the community level. Improved understanding of the impact of social exclusion, economic deprivation, and substance abuse on mental health suicidal behavior, among urban and rural Americans is necessary to reduce death by suicide. The proposed model should improve mental healthcare access to underserved populations, including those in rural areas, while simultaneously providing training to potential rural behavioral health providers.

**Neuroscience Research in African Americans.**—The Committee recognizes that in studies of brain disorders, underrepresented minority groups, including African Americans, make up less than 5 percent of research cohorts and the current large-scale genomic datasets omit 10 percent of the African genome. The Committee urges the NIH Neurobiobank to work with NIMHD and relevant extramural partners to develop the infrastructure needed to accelerate the discovery of novel therapeutic targets for neuropsychiatric disorders utilizing post-mortem brain datasets from ethnic minority groups, including African Americans.

**Research Centers in Minority Institutions (RCMIs).**—The Committee recognizes the important role of the RCMI program in developing the infrastructure required to enhance biomedical research conducted at historically minority-serving institutions. This infrastructure is critical to supporting the development of new investigators through innovative pilot grant funding and sustaining an established workforce conducting world-class biomedical research through direct support for cutting-edge science that emphasizes the advancement of minority health and the reduction of health disparities. Therefore, the Committee recommends that the RCMI Program budget be increased to $66,544,000 to ensure that critical infrastructure development and scientific discovery in historically minority graduate and health professional schools continues to be enhanced to meet these critical needs. In addition, the Committee also recognizes the importance of the RCMI Coordinating Center in ensuring that collectively, institutions can engage in multi-site collaborative research.

**Rural African American Aging Research.**—African Americans in rural areas are characterized by major health disparities, having lower life expectancy and higher mortality rates, and greater morbidity, earlier onset, and faster progression of aging-related diseases compared to Whites. Rural health challenges, including those stemming from lack of access to health-promoting resources, transportation barriers, and limited socioeconomic opportunities, translate into greater health risk. Although racial and rural disparities in health have been well-documented, there remain major gaps in our understanding of how psycho-social stressors, particularly...
those salient and unique to the experiences of rural African Americans, contribute to multi-system aging across biological systems. Most of the research on African Americans has examined urban samples; likewise, studies on rural communities have focused disproportionately on white populations. The Committee encourages NIMHD to support extramural collaboration to support epidemiologic aging research studies in rural contexts. The Committee supports an interdisciplinary approach to establish partnerships with rural stakeholders and service providers; implementing a multi-stage probability sampling design for rural populations, and creating a sophisticated recruitment and project management and database system; and conduct the subsequent research involving collection of biological and physiological aging measures, specifically in rural areas through the application of novel methods to collect bio-specimens in participants’ homes. The examination of associations between psycho-social stressors and multi-system profiles of biological aging as indexed by markers of inflammation, telomere length, vascular function, and cognitive aging among rural African Americans should be a priority.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

Appropriations, 2019 ................................................................. $78,189,000
Budget estimate, 2020 .............................................................. 67,235,000
Committee recommendation ....................................................... 82,338,000

The Committee recommendation includes $82,388,000 for the Fogarty International Center [FIC].

Global Infectious Diseases.—Disease outbreaks such as Ebola, Zika, and Dengue have shown the importance of the Center’s essential role in global infectious disease health research training to help developing countries advance their own research, health solutions, and tools. FIC has developed important partnerships to fight malaria, neglected tropical diseases, and other infectious diseases, and also to have the capabilities to detect and treat infectious diseases that are not endemic to the United States before they travel to the United States thus protecting Americans here at home. The Committee urges FIC to continue this important work building relationships with scientists abroad to foster a stronger, more effective science workforce and health research capacity on the ground, helping to detect infectious diseases and building the capacity to confront those diseases while improving the image of the U.S. though health diplomacy in their countries.

NATIONAL LIBRARY OF MEDICINE

Appropriations, 2019 ................................................................. $442,365,000
Budget estimate, 2020 .............................................................. 380,469,000
Committee recommendation ....................................................... 465,837,000

The Committee recommends $465,837,000 for the National Library of Medicine [NLM]. Of the funds provided, $4,000,000 is for the improvement of information systems, to remain available until September 30, 2021.
The Committee recommendation includes $849,159,000 for the National Center for Advancing Translational Sciences [NCATS]. The Committee includes bill language allowing up to $60,000,000 of this amount to be used for the Cures Acceleration Network [CAN].

**Clinical and Translational Science Awards [CTSA].—**The Committee provides $589,436,000, an increase of $29,700,000, and encourages NCATS to fund, through the existing CTSA hubs, programs to address disparities and the significant burden of diseases, and other conditions that disproportionately affect minority and special populations. Accelerating this capacity will reduce the burden of disease and promote health equity. Applying the CTSA model to address long-standing regional health disparities can provide innovative, multi-disciplinary approaches to reducing the burden of disease among vulnerable populations.

**Full Spectrum of Medical Research.**—The Committee applauds NIH efforts to support and advance the full spectrum of medical research, which ensures breakthroughs in basic science are translated into therapies and diagnostic tools that benefit patient care while disseminating cutting-edge information to the professional community. The Committee notes the importance of flagship initiatives, including the CTSA program, to these important efforts.

**OFFICE OF THE DIRECTOR**

The Committee recommendation includes $2,344,022,000 for the Office of the Director [OD]. Within this total, $638,751,000 is provided for the Common Fund and $12,600,000 is included for the Gabriella Miller Kids First Research Act.

**Adult Cellular Therapies.**—The Committee encourages NIH, in coordination with FDA, to explore the feasibility and utility of an outcomes database for adult cellular therapies that are either FDA-approved or are being administered under FDA Investigational New Drug or Investigational Device Exemption protocols.

**All of Us Precision Medicine Initiative.**—The Committee strongly supports the All of Us precision medicine initiative. The bill provides $500,000,000, an increase of $161,000,000 above the fiscal year 2019 level. Funding provided in the 21st Century Cures Act is reduced by $37,000,000 in fiscal year 2020. Ensuring sustained, consistent funding for this study is important, therefore, the Committee has chosen to replace this reduction and increase base funding in the program. Further, the Committee encourages NIH to continue to work with a broad array of children’s hospitals and networks to leverage their expertise and ensure greater diversity in pediatric recruitment and enrollment.

**Amyotrophic Lateral Sclerosis [ALS].**—The Committee directs the NIH Director to facilitate further efforts involving at a minimum,
NINDS and NIA, to study ALS disease mechanisms and identify genes to facilitate the expeditious development of targeted therapies. These trans-NIH efforts shall bring together research results that will be available to academic researchers, nonprofit organizations, and industry researchers, and will supplement, not supplant, existing NIH-supported activities for ALS research. The near-term research opportunity to find a cure is real for ALS. Any such breakthroughs will have significant benefits for related neurological conditions including TBI, Parkinson’s, and Alzheimer’s. The Committee directs NIH to report to the Committees on Appropriations of the House of Representatives and the Senate within 180 days of enactment on progress in furthering these research areas, specifically on key areas of focus for fiscal years 2020–2024.

Autism.—The Committee remains interested in the recent advances in autism research and supports the work of the Interagency Autism Coordinating Committee, including the Strategic Plan for Autism Spectrum Disorder recommendations related to growth in overall research funding. The Committee encourages NIH to continue to aggressively invest in research consistent with the objectives outlined in the Strategic Plan. The Committee also encourages NIH to support greater investment in research and collaborations focused on addressing the gaps outlined in the Strategic Plan, including studies to understand the intersection of biology, behavior, and the environment.

Autoimmune Conditions.—Autoimmune diseases are more common in women than in men, typically manifesting in their childbearing years. They include conditions such as rheumatoid arthritis, multiple sclerosis, lupus, celiac disease, inflammatory bowel disease, and type 1 diabetes and together affect an estimated 5–7 percent of Americans. Many affected women live with a second autoimmune illness or other condition. Despite the impact of these diseases and conditions on a domestic population ranging between 15,000,000–25,000,000, there is no single office within NIH tasked with coordinating research across the agency, or examining the complex interplay among these diseases and conditions. The 2010 NASEM study on Women’s Health Research identified autoimmune conditions as “the leading cause of morbidity in women, greatly affecting quality of life.” Despite their impact, the report found that “little progress has been made in understanding the conditions better, in identifying the risk factors, or in developing diagnostic tools, better treatments, or cures.” The Committee recommendation includes $1,500,000 for NIH to contract with the National Academies of Science, Engineering, and Medicine to identify and review NIH’s research efforts in this broad area of predominantly women’s health. The review should explore NIH’s research in autoimmune and coexisting disorders, including any barriers to such research, and the most promising areas for future research that would benefit the greatest number of patients. The review should also identify trends among the population suffering from these conditions, and any significant barriers to accurate diagnoses. Finally, the National Academies’ report should make recommendations for how NIH could improve and better coordinate research into these diseases and conditions, including the potential effects of establishing dedicated research entities within or external to NIH.
Big Data.—For the past 3 years, the Committee has encouraged NIH to make the changes and investments necessary to take advantage of the vast amounts of data it and its grantees are producing. Advancing life sciences today has a much more fundamental dependency on data computation and infrastructure, and an increasing use of collaborative scientific initiatives. The scale and interconnected nature of the science fills these programs with promise, but only if they can utilize analysis platforms that are up to the challenge. Collaborating labs need to be able to share, see, understand and use each other’s data quickly, which calls for state-of-the-art storage and transfer capabilities, and toolsets to enable computation. At the same time, the complexity of biological systems and their relationship to disease requires investigating larger and more complex data sets requiring massive storage, industry-grade information management and in-depth data processing, and privacy and security standards to protect patients and human subjects, as necessary. NIH recognizes the need for large scale data generation and developed its STRIDES initiative to build partnerships with commercial cloud providers and its Data Commons Pilot to test its ability to store, access and share large data sets. However, overall it has little yet to show in the more challenging area of working with the data. At the Committee’s direction, NIH prepared a strategic plan that outlines in broad terms how it will meet this challenge, but it has struggled to recruit the talent to lead efforts to build an analysis platform. NIH leadership recognizes it needs additional focus on how to consolidate and deliver data to the research community in a more usable and computationally minable form, but appears stymied in how to do so. Part of the problem appears to be the salary restrictions of a civil service structure created when the differences in compensation among various skillsets was far narrower than it is today, one that never contemplated the costs of recruiting highly sought after elite technology talent. The Committee is increasingly concerned by these delays, and directs GAO to identify and review the options available to NIH for securing the talent it needs to lead and carry out these efforts. In its report, GAO should consider how other agencies meet similar challenges, and whether statutory changes are necessary. The Committee also directs GAO to review how NIH funds computational talent in its grant awards and whether its funding models adequately reflect the cost of these skillsets to grantees. GAO should assess NIH’s guidance for the resource sharing plan it requires for the typical grantee, and whether these plans are sufficient and can be sustained for ongoing analysis. The Committee urges NIH to engage industry, academic, and other Federal partners to take advantage of cross-enterprise artificial intelligence products, research and tools. Artificial Intelligence could play a vital role toward advancing the goals of the strategic plan by organizing, managing and making data usable to researchers, institutions and the public to drive outcomes. Finally, the Committee has included $30,000,000 to support the Chief Data Strategist’s work in fiscal year 2020, and expects NIH to provide a spending plan for these funds within 30 days of enactment of this act.  

Biomedical Research Facilities.—The Committee believes that the nation’s biomedical research infrastructure, including labora-
tories and research facilities at academic institutions, is out of date and insufficient. Therefore, the Committee continues $50,000,000 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.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.—The Committee recommendation provides $500,000,000 for the BRAIN initiative, an increase of $71,000,000. In the initial BRAIN 2025 report, released in June 2014, the working committee recommended an escalating budget to reach $500,000,000 per year by fiscal year 2019, which this bill achieves. Since the BRAIN Initiative’s inception, over 550 awards have been granted to hundreds of investigators from a wide range of fields, with the aim to find more effective treatments for a wide variety of brain disorders and diseases, such as Alzheimer’s disease, Parkinson’s, and epilepsy. BRAIN’s unique capacity to bring large, multi-disciplinary teams together, to generate and scale-up innovative technologies, and to produce large datasets that are available to scientists worldwide is revolutionizing our understanding of the human brain. The Committee has provided additional resources in fiscal year 2020 to significantly expand efforts to working with the BRAIN data, which up to this point has been a lower priority. Neuroscience and biosciences in general need additional focus on how to consolidate and deliver data to the research community in a more usable and computationally minable form. As an example, the BRAIN Initiative Cell Census Network represents a major NIH commitment to profiling the basic cellular components of the nervous system, but the bulk of funding is committed for data generation to a growing portfolio of independent laboratories, without sufficient resources for data processing, standardization, and robust analysis. The Committee expects to receive a report in the fiscal year 2021 CJ on the initiative’s achievements in its first 5 years of operation and its objectives for the next 5 years, including NIH’s plans to address the challenge of making large datasets usable.

Chronic Fatigue Syndrome (ME/CFS).—The Committee commends NIH on its new ME/CFS efforts, including its plans for a 2019 conference on accelerating research into ME/CFS and its formation of the National Advisory Neurological Disorders and Stroke Council Working Group. The Committee is concerned that the level of funding for ME/CFS remains very low considering the burden and incidence of disease. The Committee urges NIH to collaborate with disease experts and the patient community to identify additional opportunities to expedite progress. Specifically, the Committee recommends that NIH significantly increase ME/CFS investments such as: (1) new ME/CFS disease specific funding announcements, including those with set-aside funds, to deliver needed diagnostics and treatments as quickly as possible; (2) research to better define the clinical characterization of subsets of individuals...
with ME/CFS caused by different etiologies; and (3) mechanisms to incentivize researchers to enter the field.

Clinical Research Professional Competency.—The Committee believes that the quality of clinical trial outcomes is dependent on the knowledge and skill of clinical research professionals conducting the work. The Committee encourages NIH to continue considering the training needs of this workforce when determining best practices in conducting clinical trials.

Clinical Trials Policy.—The Committee has followed NIH’s efforts to improve transparency and stewardship of all clinical trials, including those trials that are basic science experiments involving human participants. The Committee supports NIH’s recent announcement to delay the implementation of certain registering and reporting requirements for basic experimental studies with humans. The Committee understands NIH received comments opposing the 2014 (and now Common Rule) definition from members of the basic science research community, as well as current and former members of NIH advisory councils. While the Committee supports efforts to increase transparency and improve oversight of clinical trials, it also seeks to ensure any changes are necessary to meet those goals, including considering existing viable, cost effective alternatives. The Committee urges NIH to continue its efforts, including working with the basic research community, to achieve a balanced registration and reporting strategy that meets the interests of study participants, investigators, and taxpayers. NIH is directed to report to the Committee no less than 60 days prior to moving forward with any new proposals for registering basic experimental studies with humans as clinical trials.

Cumulative Investigator Rate.—The Committee is pleased that its sustained investments in NIH in recent years have reversed the troubling decline in grant applicant funding rates that began in 2003 as the number of applicants dramatically increased while funding remained relatively flat. Applicants’ funding rates (as measured over 5-year windows) began to improve in fiscal year 2015 and reached 36 percent in fiscal year 2018 for NIH Research Project Grants and 41 percent for R01-equivalent grants. The Committee is encouraged by this trend, and directs NIH to include information on the Research Project Grant, R21, P01, and R01–Equivalent Cumulative Investigator Rate by NIH Institute/Center in its fiscal year 2021 CJ.

Directors Advisory Committees.—The Committee is concerned that despite the legal requirement of Federal statute (Title 42 of the U.S. Code, Subchapter III; Part B, Subsection 284A) that all NIH Director’s Advisory Councils have at least two representatives from the fields of public health and the behavioral or social sciences, recent reviews of the membership of Institute Director’s Advisory Councils reveal that none of the institutes are in compliance with this requirement. The Committee urges compliance with this statute and requests a report on the fields of public health and behavioral and social sciences that are represented on each advisory committee and measures planned and completed to comply with the requirements of this statute.

Diversity in the All of Us Research Program.—The Committee recognizes the importance of including populations historically
underrepresented in biomedical research in the All of Us program. By ensuring meaningful and broad inclusion, the program ensures more equitable benefit from future medical discoveries using All of Us data, including those in the field of cancer research. The Committee was pleased to learn that as of May 2019, 50 percent of the more than 193,000 participants who completed the initial steps of the protocol self-identified as members of racial/ethnic minority groups. Within the amount provided to All of Us, the Committee directs NIH to continue its efforts to recruit and retain participants from these historically underrepresented populations so that the All of Us scientific resources reflect the rich diversity of our country.

Duchenne Muscular Dystrophy.—Duchenne muscular dystrophy is a severe type of muscular dystrophy for which there is no cure and for which the average life expectancy is in the second decade. The Committee strongly encourages NIH to significantly expand its support for research on Duchenne muscular dystrophy, particularly accelerating and optimizing the clinical trial process through novel and innovative trial designs, such as platform trials, which might serve as a model for other rare diseases communities. The Committee also urges NIH to support methodological research on challenges, such as redosing, manufacturing supply, and potential immune response, associated with the advent of gene therapies for rare diseases, such as Duchenne.

Ethnic and Racial Diversity in Cancer Development and Outcomes.—The Committee recognizes that NIH’s Cancer Moonshot initiative aims to accelerate the discovery of new ways to cure cancers, including through an understanding and application of cancer genetic information to the prevention and treatment of cancer. The Committee urges NIH, including NIMHD and NCI, to continue to support research on the cause, prevention, and treatment of cancer in populations with diverse cultural, racial, and ethnic composition. To further support such collaboration in this research field, the Committee encourages NIH, through NCI, to continue to consider an Institution’s research efforts that specifically address the cancer burden, risk factors, incidence, morbidity, mortality, and inequities in the geographic area it serves, when considering applications from cancer centers for NCI designation. The Committee also recognizes NCI’s focus on minority and medically underserved communities through the NCI Community Oncology Research Program.

Foreign Threats to Research.—The Committee remains deeply concerned about foreign threats to the research infrastructure in the United States. In particular, the Chinese government has started a program to recruit NIH-funded researchers to steal intellectual property, cheat the peer-review system, establish shadow laboratories in China, and help the Chinese government obtain confidential information about NIH research grants. As the Federal Bureau of Investigation, HHS, and NIH continue to investigate the impact the Thousand Talents and other foreign government programs have had on the NIH research community, the Committee expects to be notified quarterly on the progress of the investigation, as well as institutions, scientists, and research affected. Further, the Committee directs NIH to carefully consider the NIH Advisory Committee’s recommendations, including to implement a broad
education campaign about the requirement to disclose foreign sources of funding and develop enhanced cybersecurity protocols. As recommended, NIH should use this campaign to help institutions develop best practices for how to handle these challenges, including training, communications materials, and how to improve vetting, education, and security. Further, NIH shall evaluate the peer-review system and their internal controls through a lens that takes into account national security threats. This includes holding those accountable who inappropriately share information from the peer-review process or illegally share intellectual property. The Committee appreciates the partnership between NIH and HHS' Office of National Security [ONS] on this issue and ONS's implementation of a formal NIH CI/Insider Threat program on NIH's behalf. The Committee believes this work should be expanded in fiscal year 2020 and directs NIH to allocate no less than $5,000,000 for this work that ONS does on behalf of NIH.

Fragile X [FX].—The Committee commends NIH for supporting research to understand the nature of FX and its association with other conditions such as autism. Given the inextricable connection between the FX protein and autism, the Committee urges the Director and his counterparts at each IC with an FX and autism portfolio to explore ways to create greater efficiency and synergy among these two research tracks to accelerate translational research toward a better understanding of both conditions and to shorten the time to bring effective treatments for both conditions to market including the funding for clinical trials for both disorders. The Committee encourages NIH to continue to fund FX research centers, supporting interdisciplinary research in important new areas. The Committee urges NIH to assure that the FX research centers program includes clinical and translational research that directly addresses the needs of affected children and their families, and that applicants for new centers may propose clinical trials as part of their research portfolio.

Frontotemporal Degeneration [FTD] Research.—The Committee encourage NIH to continue to support a multi-site network of clinical centers to study genetic and sporadic cases of FTD and maintain progress toward biomarker discovery and drug development in clinical trials using these well-defined FTD cohorts. A key component of this network will be the development of a data biosphere that supports wide sharing of robust datasets, generated with powerful -omic platforms. Data sharing will enable the broader community of researchers outside of the clinical networks, particularly early career scientists, to take on the challenges currently confronting Alzheimer's disease and related dementias disorders with a wider array of expertise. Research has revealed that all forms of dementia may have a variety of root causes and display multiple underlying pathologies. Research on the related dementias is critical for understanding basic disease mechanisms that may be common across multiple forms of dementia and therefore speed the translation of this information into much-needed therapeutics. While the continued support of biomedical research offers hope for the future, too many families and individuals living with dementia cannot find the help they need today. Therefore, the Committee also urges NIH to support research on the development of new and
improved dementia care practices and long-term supports and services. By supporting both types of research, NIH may advance progress toward future therapies and treatments while also helping people get the appropriate and effective care and support they need today.

*Gene-Environment Interactions in Neurodegenerative Disorders in the Diverse Populations of African Americans and Latinos.*—In the context of NIH’s robust neurological disease research portfolio, the Committee commends the leadership of NIH in advancing the relevant objectives of the 21st Century Cures Act and the BRAIN Initiative. The Committee is concerned and recognizes the need to better understand the interactions between genetic and environmental factors, in particular with elderly and diverse populations of African Americans and Latinos. The Committee encourages NIH to accelerate collaborative research across relevant Institutes and the research community to address the goal of determining the role of the interaction between environmental exposures to toxic chemicals and genetics and their impact on neurodegenerative disorders in diverse populations of African Americans and Latinos, to allow for earlier diagnosis and subsequent treatment to arrest the progression of these devastating neurodegenerative disorders.

*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 2021 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.

*Harassment Policies.*—The Committee recognizes that recent events make clear that harassment occurs in all workplaces, including science and medicine, and that changing the culture that fosters harassment will require sustained commitment and resources. The National Academy of Sciences, Engineering, and Medicine report released last year found sexual harassment is rampant in the labs and institutions supported by NIH and American taxpayers. The Committee commends NIH for taking steps to remind institutions of their obligations to implement and enforce policies for reporting sexual harassment, and to notify NIH when key personnel named on an NIH grant award have been removed because of harassment concerns. However, as the funder of the vast majority of biomedical research conducted in the U.S., the Committee believes NIH can and must play a more active role in changing the culture that has long ignored the problem. The Committee directs NIH to require institutions to notify it when key personnel named on an NIH grant award are removed because of harassment concerns. While it is essential for NIH to preserve the confidentiality of the individuals in these cases, the Committee directs NIH to integrate information about adjudicated cases regarding grantees and applicants into the grant award-making process, making clear there are significant ramifications for perpetrators. The Committee also directs NIH to support research in the areas identified in the Report, including the psychology underlying harassment and the experiences and outcomes of diverse groups when subjected to harassment. Additionally, the Committee directs NIH to collaborate with the National Academies to develop best practices for devel-
oping more diverse and inclusive cultures in the grantee research environments, including training individuals in institutions that receive NIH funds to recognize and address harassment, and evaluating the efficacy of various harassment training programs.

**Headache Disorders.**—The Committee recognizes: (1) that migraine is the second leading cause of global disability, but that NIH funding for migraine research is strongly incommensurate with this burden; and (2) that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, NIH has recently issued a FOA for research relevant to all types of pain, including migraine and headache disorders, and a few specific announcements that focus specifically on increasing research on back pain and hemodialysis-related pain. The Committee strongly urges the Director of NIH to issue a similar focused group of Requests for Applications to fund fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension.

**Hepatitis B.**—The Committee commends the Director's office for establishing a trans-NIH Hepatitis B Working Group to include representation from NCI, NIAID, NIDDK, and NIMHD to coordinate research agendas to fund the research necessary to find a cure for hepatitis B and improve liver cancer outcomes. The Committee urges the Director to use the NIH Common Fund to support the integrated trans-NIH research needed to fully address these conditions. The Committee notes that both the World Health Organization and the National Academies of Sciences, Engineering, and Medicine have declared that the elimination of hepatitis B is possible by 2030. Subsequent to that declaration, the hepatitis B research community convened a virtual consensus conference to prepare a “Roadmap for a Cure” that resulted in articles published in 2018 in two peer reviewed scientific journals, Hepatology and Antiviral Research, identifying the most urgent research questions that must be answered to find a cure for hepatitis B. Therefore, the Committee requests that the Office of the Director keep the Committee informed on progress of the Trans-NIH Hepatitis B Working Group and requests a status report be sent to the Committee within 90 days of enactment.

**Hepatitis C.**—The elimination of the deadly hepatitis C virus, which affects more than 2,400,000 Americans, is a top public health priority for both the Federal and State governments. The Committee is supportive of States’ efforts to implement innovative payment models and public health elimination initiatives that dramatically increase access to the medications that cure hepatitis C. The Committee urges NIH to prioritize research aimed at supporting hepatitis C elimination.

**Human Microbiome Project.**—The Committee commends the progress made by the Human Microbiome Project in identifying the role that microbial communities play in health and the treatment of many different digestive diseases. The Committee encourages OD to continue working collaboratively with NIDDK and other relevant Institutes and Centers to expand and advance this important research.
**IDeA States Pediatric Clinical Trials Network [ISPCTN].**—The Committee recognizes pediatric research requires the focus on the special needs of neonates, infants, children, and adolescents across a wide range of diseases and conditions and appreciates that pediatric research has been and continues to be an NIH priority. The Committee commends NIH for establishing the ISPCTN to provide medically underserved and rural populations with access to state-of-the-art clinical trials, apply findings from relevant pediatric cohort studies to children in IDeA State locations, and enhancing pediatric research capacity to address unmet pediatric research needs in underserved areas. The Committee provides $15,000,000 in additional funding to continue the ISPCTN program.

**Increasing Diversity in NIH Clinical Trials.**—The Committee recognizes efforts by NIH to reduce health disparities by addressing significant barriers to clinical trial participation and directs the agency to ensure eligibility criteria for clinical trials funded by NIH do not create unintentional barriers to participation for racial and ethnic minorities as well as for patients with certain healthcare conditions. Specifically, the Committee directs NIH to revise existing protocol templates and guidelines for clinical trials that receive funding by the agency to include eligibility criteria that avoids inappropriate exclusions of racial and ethnic minorities by taking steps to account for variations in health status across racial and ethnic minority groups when determining eligibility criteria as well as ensuring exclusions based on health status are scientifically justified and appropriate.

**Induced Pluripotent Stem Cell [iPSC].**—The Committee continues to stress iPSC technology as a critical tool in the realm of personalized medicine. The Committee notes that iPSCs are derived from adults or skin-sourced biopsies, providing increased opportunities to tailor human medicine, reduce clinical trial costs, and pre-screen for patient-specific efficacy. To date, inadequate funding is available for the translation of iPSC research into new therapeutics, diagnostics, and cures. The Committee is especially concerned that a funding gap between basic science and clinical trials may hinder the timely discovery of treatments for a wide range of diseases that currently lack clinical solutions. Accordingly, the Committee directs NIH to provide funding to support translational research, as well as promote regional, collaborative consortiums to advance scientific knowledge in the area of iPSC basic research. The Committee further instructs NIH to conduct an assessment of agency efforts to: (1) address the existing funding gap between basic science and clinical trial research; and (2) develop a framework that provides both new and existing grantees with funded opportunities for translational research. The Committee expects this information to be included in the fiscal year 2021 CJ.

**Inflammatory Bowel Diseases [IBD].**—The Committee recognizes that as many as 3,100,000 people in the United States are impacted by Crohn’s disease and ulcerative colitis and is concerned about the growing prevalence of IBD and other autoimmune diseases and disorders in the country. The Committee also recognizes that IBD is a complex, immune-mediated, chronic disease model relevant to other such disorders, and that multiple research topics must be explored to understand IBD including psychosocial issues;
health disparities; triggering environmental factors; the complex interplay between food, mind-gut, and immune response; and the maternal health of IBD patients as well as their children. The Committee encourages NIH to explore these and other research questions with multiple Institutes and Centers including NIDDK, NICHD, and NIMHD.

*Intellectual Property.*—The Committee encourages the NIH Director to work with the HHS Assistant Deputy Secretary for National Security to improve the security of intellectual property derived from NIH-funded research. In particular, NIH is encouraged to: improve the security of the peer review system; augment the application process to identify funding that applicants receive from a foreign government; and assist the HHS Inspector General and appropriate law enforcement agencies to identify violations of U.S. law or policy.

*Mitochondrial Disease Research.*—The Committee is aware that medical research continues to identify new mitochondrial disorders and to confirm the central role that mitochondrial dysfunction plays in a host of major diseases. Advancements in biomedical knowledge, clinical research, and care interventions have advanced to the point where the Director should now encourage additional research in this area through competitive award vehicles. Given that at least 17 Institutes, Centers, and Offices are involved in mitochondrial research, it is critical that the Director continue to support and empower efforts to coordinate this work, including through the trans-NIH Mitochondrial Disorders Working Group. The Committee strongly supports continuing the work of the North American Mitochondrial Disease Consortium and the Mitochondrial Disease Sequence Data Resource Consortium, and applauds the work of NINDS to develop the first set of Common Data Elements for mitochondrial disease to support further research, including through the BRAIN Initiative as well as the All of Us and Environmental influences on Child Health Outcomes research programs.

*Mucopolysaccharide Diseases (MPS).*—MPS and mucolipidosis [ML] are inherited, with death occurring for many in early childhood. These systemic diseases cause progressive damage to the bones, heart, respiratory system, and brain. The Committee continues to urge NIH to put a high priority on better understanding and treating MPS and ML diseases. The Committee commends NIH for allocating funds to discover, develop, define, and make available for research animal models of human genetic disease. The Committee encourages expanded research of treatments for neurological, chronic inflammation, cardiovascular, and skeletal manifestations of MPS, with an emphasis on gene therapy. The Committee thanks NINDS, NIDDK, and Office of Rare Diseases Research for again funding the Lysosomal Disease Network through the Rare Disease Clinical Network and for funding lysosomal research meetings. The Committee encourages NIH to increase funding to grantees to incentivize MPS research, particularly given the age and small population of current researchers. Understanding the manifestations and treatments of both the skeletal and neurological disease continues to be the greatest areas of unmet need.

*Neurofibromatosis (NF).*—The Committee supports efforts to increase funding and resources for NF research and treatment at
multiple NIH Institutes, including NCI, NINDS, NICD, NICHD, NIMH, NCATS, and NEI. Children and adults with NF are at significant risk for the development of many forms of cancer; the Committee encourages NCI to continue to support its NF research portfolio in fundamental laboratory science, patient-directed research, and clinical trials focused on NF-associated benign and malignant cancers. Because NF causes brain and nerve tumors and is associated with cognitive and behavioral problems, the Committee urges NINDS to continue to aggressively fund fundamental basic science research on NF relevant to nerve damage and repair. Based on emerging findings from numerous researchers worldwide demonstrating that children with NF are at significant risk for autism, learning disabilities, motor delays, and attention deficits, the Committee encourages NINDS, NIMH, and NICHD to expand their investments in laboratory-based and patient-directed research investigations in these areas. Since individuals with NF2 may develop hearing loss, the Committee encourages NIDCD to continue to expand its investment in NF2-related research. NF1 can cause vision loss due to optic gliomas. The Committee encourages NEI to expand its investment in NF1-focused research on optic gliomas and vision restoration.

**Next Generation Researchers Initiative.**—The Committee includes $100,000,000 in dedicated funding to continue to prioritize robust implementation of the Next Generation Researchers Initiative and to continue to expand the activities under the Initiative to improve and accelerate transitions into independent careers and enhance workforce diversity. The Committee directs NIH to collect, evaluate, and disseminate data, including best practices, on implementation of the Initiative’s policies as well as programs and pilots across all Institutes and Centers aimed at promoting the next generation of researchers, and to coordinate with relevant agencies, professional and academic associations, and others to inform programs related to the training, recruitment, and retention of biomedical researchers, as required under the law. The Committee applauds the National Academy of Sciences publication of the study, the Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through, and requests that NIH update the Committee within 180 days of enactment on NIH’s progress in advancing the recommendations in the study.

**News Briefings.**—Until recently, NIH provided the Committee with a summary of the day’s news articles on itself, health and medical news, global health updates, and other topics affecting its operations. The Committee found this service helped its staff remain well-informed of the many developments affecting NIH, its grantees, and medical research. Therefore, the Committee directs NIH to resume providing Committee staff with the daily NIH news briefings within 14 days of enactment.

**Organ Donation and Transplantation.**—The Committee includes $1,500,000 to contract with and fund a National Academies of Sciences, Engineering, and Medicine study to examine and recommend improvements to research, policies, and activities related to organ donation and transplantation. The report shall include: (1) identification of current challenges involved in modeling proposed organ allocation policy changes and recommendations to improve
modeling; (2) recommendations about how costs should be factored into the modeling of organ allocation policy changes; (3) a review of MELD or other factors that determine organ allocation and patient prioritization and recommendations to assure fair and equitable practices are established, including reducing inequities affecting socioeconomically disadvantaged patient populations; and (4) recommendations to update the OPTN's policies and processes to ensure that organ allocation decisions take into account the viewpoints of expert OPTN committees.

**Osteopathic Medical Schools.**—The Committee is concerned there is a lack of access to research funding for osteopathic medical schools through NIH. The Committee is aware that professionals with doctors of osteopathic [D.O.] medicine credentials represent a small fraction of all reviewers who serve in peer review (e.g. 29 reviewers with D.O. degrees served on Study Sections between October 2018 through August 2019). D.O.s receive only 0.1 percent of NIH grants although they make up 11 percent of the physician workforce and 26 percent of students entering medical school are osteopathic medical students. The Committee understands that osteopathic medicine is one of the fastest growing healthcare professions in the country, and realizes its vital role in treating our Nation's rural, underserved, and socioeconomically challenged populations.

**Pediatric Clinical Trials Authorized under Best Pharmaceuticals for Children Act.**—The Committee directs that no less than $25,000,000 be used toward research in preparation for clinical trials authorized by the Best Pharmaceuticals for Children Act.

**Pediatric Physician-Scientist Workforce.**—The Committee is concerned about the challenges in attracting and retaining researchers, particularly physician-scientists, to careers in pediatrics and the impact these challenges will have on the pace of innovation and discovery. The Committee encourages NIH to build upon the formation of the Trans-NIH Pediatric Research Consortium to develop a framework for a pediatric research training mechanism that would supplement and not supplant existing programs, cut across multiple Institutes and Centers and focus on supporting individual physician-scientists who have not yet achieved a level of research independence so they can be qualified to meet current and future needs in pediatric research.

**Pediatric Research.**—The Committee requests an update from the NIH Director within 120 days of enactment on how NIH will focus on the unique needs of children in its NIH-wide initiatives that span multiple Institutes and Centers, as well as its highest priority initiatives, including, but not limited to, the All of Us program, the BRAIN Initiative, and the Cancer Moonshot. The Committee asks that with respect to these major NIH initiatives, this update describe the inclusion of pediatric subjects, research relevant to pediatrics, specific funding allocations, support for pediatric physician scientists, and a strategy to more proportionally target funds within these initiatives to pediatric research. The Committee commends NIH for the establishment of the Trans-NIH Pediatric Research Consortium to help coordinate pediatric research at NIH. The Committee also requests an update on the activities of the Consortium and its plans to better coordinate pediatric research across the In-
stitutes, including identifying gaps and opportunities for collaboration.

Platform Technologies.—There is growing evidence of the importance of the role that “platform technologies” play in accelerating the pace of biomedical research and improving our ability to diagnose, treat, cure, and prevent diseases. Platform technologies can often lead to orders of magnitude improvement in dimensions of cost and performance, such as accuracy, resolution, throughput, flexibility, and ease-of-use. The Human Genome Project, for example, helped drive down the cost of sequencing the human genome from $100,000,000 to roughly $1,000, while today the BRAIN Initiative is investing in new and improved platform technologies to increase our understanding of how the brain encodes and processes information. The Committee is interested in whether, given the growing importance of platform technologies, there is more that NIH could and should do to increase the national investment in them. To help answer this question, the Committee directs NIH to provide a report in the fiscal year 2021 CJ that identifies: (1) the challenges that currently limit NIH’s ability to support the development of platform technologies, and how these might be addressed. Potential examples include: (a) low levels of engagement with researchers in the physical sciences, engineering, math, and computer science; (b) a culture that prioritizes hypothesis-driven as opposed to technology-driven proposals; (c) the structure of the NIH, which is organized primarily around specific diseases or organs of the body; (d) a typical size and duration of research grants that may not be aligned with the level of investment required for advances in platform technologies; and (e) difficulty in supporting high-risk, high-return ideas; (2) the specific unmet needs for basic, clinical and translational research that might motivate investment in transformational platform technologies that could be high-impact and timely, given recent scientific and technological advances and unmet medical needs; and (3) changes that NIH and Congress should consider with respect to its ability to identify and fund promising research proposals for platform technologies. Examples include: (a) recruiting NIH personnel and members of study sections with relevant expertise; (b) supporting workshops and the development of roadmaps for platform technologies; (c) increasing funding mechanisms that are appropriate for platform technologies that are relevant to multiple NIH Institutes, such as the Common Fund or NIBIB; (d) increasing NIH’s capacity to partner with industry on the development of platform technologies, such as use of Other Transactions authorities; (e) experimentation with different models for funding and managing research, such as the DARPA model for recruiting and empowering world-class program managers; (f) use of incentive prizes, milestone payments and open innovation techniques; and (g) funding non-profit research institutes that have an increased capacity to manage more complex research projects that require professional scientists, engineers, and product managers, not just graduate students and postdoctoral researchers. Given the importance of this issue, the Committee encourages NIH to engage the research community and industry as it develops its response to these questions and options.
Precision Medicine and the Pediatric Population.—The Committee recognizes the potential that precision medicine holds for all populations, including children, and encourages NIH to prioritize timely and meaningful enrollment for the pediatric population, including healthy children and those with rare disease, in the All of Us program. The Committee is encouraged that NIH impaneled a Child Enrollment Scientific Vision Working Group, which released a report that identifies scientific opportunities relevant to child health. The Committee requests an update within 60 days on the timing for the Special Populations Committee to provide recommendations regarding the practical considerations of child enrollment and data collection involving children. Additionally, the Committee directs that NIH provide an update on plans to ensure that the research cohort includes a sufficient number of children to make meaningful studies possible, the target date for enrollment to commence and how enrollment strategies will include input from pediatric stakeholders across the country with experience in pediatric clinical trial enrollment.

Rare Diseases.—The Committee is concerned with unknown costs resulting from undiagnosed and untreated rare diseases. As a result, the Committee directs GAO to study what is known about the total impact rare diseases have on the U.S. economy, including direct medical costs, non-medical costs, loss of income, and the societal consequence of undiagnosed and untreated rare disease. No later than 2 years after the date of enactment, GAO shall provide a report on its findings to the Committees on Appropriations of the House of Representatives and the Senate.

Research Transparency.—As demonstrated over the past 5 years, the Committee remains committed to funding NIH research and ensuring that our Nation’s researchers, particularly our scientists early in their career, have the support to make the scientific breakthroughs that may transform healthcare. However, it is critical that NIH can ensure funds are used for the most meritorious biomedical and behavioral research possible that fulfill the core research mission of NIH. Over the last 4 fiscal years, Members of the Committee have provided several examples of questionable spending stemming from research grants awarded by NIH, showing the need for enhanced oversight in the review and approval process. Therefore, NIH is directed to justify, in writing made available on a publicly accessible website, that each grant or agreement promotes efforts to seek fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

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 and management 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, including those associated with both paralysis and developmental delay. The Committee supports the specific efforts of NICHD to understand early human development; set the foundation for healthy pregnancy, and lifelong wellness of
women and children; and promote the gynecological, andrological and reproductive health for people with Spina Bifida. Additionally, NICHD is encouraged to identify sensitive time periods to optimize health interventions; improve health during transition from adolescence to adulthood; and ensure safe and effective therapeutics and devices.

**Stimulating Peripheral Activity to Relieve Conditions [SPARC] Initiative.**—The Committee applauds NIH for its cross-cutting SPARC Initiative and continues to recognize its potential for identifying new ways to treat many diseases and conditions. The Committee is pleased by the Initiative’s attention to research that aims to address gaps in treatments for patients suffering from gastrointestinal, genitourinary, cardiac, and other disorders and encourages NIH to work collaboratively across its Institutes and Centers on innovative ways to expand treatment options for these often burdensome conditions.

**Temporomandibular Disorders [TMD].**—The Committee commends the Office of the Director and NIDCR, for engaging the National Academy of Sciences in a comprehensive project: Temporomandibular Disorders: From Research Discoveries to Clinical Treatment. For the first time, the nation’s leaders in health and medicine will enlist experts to review all aspects of TMD, generating recommendations for research, regulation and policy that can profoundly affect the way that TMD/TMJ is understood, researched, diagnosed, treated, and prevented. The Committee believes that the work of the project will help facilitate wider acceptance that TMD are not simply a matter of teeth and jaws, but they are systemic medical conditions with complex biological, behavioral and environmental roots associated with central nervous system dysfunction and pain, in which patients often have overlapping systemic disorders. This conclusion resulted from the decade long OPPERA study, funded by NIDCR and NIH-supported public-private TMJ scientific meetings as well as other research. To continue to build on advances in coordinated research and treatment, the Committee asks OD, as it continues to work with the National Academies of Sciences on the study, to explore the creation of a NIH inter-Institute TMD working group and to report to the Committees on Appropriations of the House of Representatives and the Senate within 90 days following the publication of the final report.

**Traumatic Brain Injury [TBI].**—The Committee is aware that TBI and post-traumatic stress disorder [PTSD] continue to pose significant health challenges for many individuals in the United States, and that these medical conditions especially affect combat veterans. The Committee directs NIH to enhance its research efforts on alternative treatment methods for PTSD and TBI, including hyperbaric oxygen treatment [HBOT]. The Committee encourages NIH to partner with VA and DOD to research treatment alternatives such as HBOT for veterans living with PTSD and/or TBI.

**Trisomy 21.**—The Committee strongly supports the Investigation of Co-Occurring Conditions Across the Lifespan to Understand Down Syndrome [INCLUDE] Initiative and applauds the Director’s efforts with this funding mechanism. The Committee requests the Director provide a plan at the beginning of fiscal year 2020 that
includes a timeline description of potential grant opportunities and deadlines for all expected funding opportunities so that young investigators and new research institutions may be further encouraged to explore research in this space. This plan should also incorporate pipeline research initiatives specific to Down syndrome.

Tuberous Sclerosis Complex [TSC].—The Committee is encouraged by NIH’s updated TSC Research Plan published in 2016 and progress advancing the plan with both public and private support. NIH should encourage research opportunities in the five key areas prioritized by workshop participants: (1) understanding phenotypic heterogeneity in TSC; (2) gaining a deeper knowledge of TSC signaling pathways and the cellular consequences of TSC deficiency; (3) improving TSC disease models; (4) developing clinical biomarkers of TSC; and (5) facilitating therapeutics and clinical trials research. Because TSC impacts multiple organ systems, the Committee encourages the Director to coordinate the participation of multiple ICs on a research strategy aimed at addressing the numerous medical and neuropsychological burdens associated with TSC while deciphering the biology underlying phenotypic heterogeneity. Manifestations of TSC are highly variable among affected individuals, and TSC can be a model condition for developing precision medicine approaches to treat each individual’s symptoms to maximize the benefit-risk ratio. The Committee encourages the Director to apply recommendations from two recent NIH-sponsored workshops: the Neurodevelopmental Disorders Biomarkers Workshop held in December 2017 involving TSC and related neurodevelopmental disorders to take advantage of biomarker expertise and lessons learned across disease groups, and the workshop entitled Accelerating the Development of Therapies for Anti-Epileptogenesis and Disease Modification held in August 2018 for which TSC is a model disorder with the ability to diagnose TSC prior to onset of epilepsy.

Women and Gender Minorities in Clinical Research.—The Committee directs NIH to fund a National Academies of Sciences, Engineering, and Medicine study examining and quantifying the long-term medical and economic impacts of the inclusion of women and gender minorities in biomedical research and subsequent translational work, and has provided $1,200,000 to fund this effort. NIH is directed to report to the Committees on Appropriations of the House of Representatives and the Senate on this issue and it should include a review of the existing research on the long-term economic benefits of increasing the participation of women and gender minorities in clinical trials and biomedical research, including an analysis of fiscal implications of inclusion on the nation’s overall healthcare costs; examine new programs and interventions in medical centers that are currently working to increase participation of women of lower socioeconomic status and women who are members of racial and ethnic minority groups; identify programs that are positively addressing issues of underrepresentation; and analyze whether and how those programs are replicable and scalable; and identify more inclusive institutional and informational policies and procedures to improve health outcomes for gender minorities, including health referral forms, continuing education classes, and more.
Women's Health Research.—Women represent half of the U.S. population. As such, conditions and diseases that are specific to women's health, or those that present differently in women than men, must be a priority for federally-funded research. The Committee encourages NIH, under the leadership of the Office of Research on Women's Health and NICHD, to: (1) report on the total dollar amount of research invested in health conditions specific to women over the last 10 years, including but not limited to pregnancy, gynecologic oncology, and infertility; (2) provide a list of which Institutes provide the highest amount of funding toward health research on conditions specific to women; and (3) report on how and whether funding for research in this area is coordinated across the NIH. The Committee looks forward to a report from NIH in the fiscal year 2021 CJ.

BUILDINGS AND FACILITIES

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The Committee recommendation includes $300,000,000 for NIH buildings and facilities, an increase of $100,000,000. This funding will remain available for obligation for 5 years.

In fiscal year 2017, the Committee included a directive to NIH to enter into a contract with the National Academies of Sciences, Engineering, and Medicine to assess the capital needs of NIH's Bethesda Campus. NIH's Bethesda Campus houses the majority of the Intramural Research Program and comprise a multi-billion dollar public investment, including a 200-bed research hospital, numerous laboratories, outpatient clinics, administrative space, and facilities providing research support services, energy and transportation services, and other utilities. On August 26, 2019, NASEM released a report that stated there is a $1,300,000,000 backlog that is rapidly growing. In particular, the report states that the 12,000,000 facility square feet have an average "condition index" in the poor range, and that 72 percent of facilities are more than 20 years old.

The Committee takes this issue seriously and provides an increase of $100,000,000 in annual Buildings and Facilities funding. Since fiscal year 2018, the Committee will have more than doubled Buildings and Facilities funding for NIH. Unfortunately, these increases will make only a small dent in the increasing backlog. Therefore, the Committee has included new bill language to allow the Institutes and Centers of NIH to use up to 1 percent of IC funding for facility maintenance and construction. All 27 IC Directors have agreed to this funding structure.

Finally, the Committee directs NIH to provide a report with the fiscal year 2021 CJ describing the steps it has and will take to implement the report’s recommendations. The Committee is especially interested in the actions NIH is taking to apply the recommendations to update the Buildings and Facilities prioritization model, develop an annual budget request for Backlog of Maintenance and Repair, and strengthen its internal governance process, including assigning and empowering a senior leader to manage capital planning. In addition, the Committee directs NIH to provide quarterly...
update of its Buildings and Facilities maintenance and construction plans, including specific milestones for advancing projects, status of the project, cost, and priority. These updates should also highlight and explain any potential cost and schedule changes affecting projects.

### NIH INNOVATION ACCOUNT, CURES ACT

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<tr>
<th>Appropriations, 2019</th>
<th>$711,000,000</th>
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<tbody>
<tr>
<td>Budget estimate, 2020</td>
<td>$157,000,000</td>
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<tr>
<td>Committee recommendation</td>
<td>$157,000,000</td>
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The Committee recommendation includes $157,000,000 to be spent from the NIH Innovation Account for the following activities:

- **All of Us.**—$149,000,000.
- **Regenerative Medicine.**—$8,000,000.

The Committee report reflects distribution of the remainder of funding from the NIH Innovation Account to NCI, NINDS, and NIMH and expects NIH to transfer funding shortly after enactment of this act.

### NATIONAL INSTITUTE FOR RESEARCH ON SAFETY AND QUALITY

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<th>Appropriations, 2019</th>
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The Committee recommendation does not provide funding for the National Institute for Research on Safety and Quality.