

117TH CONGRESS }
1st Session } HOUSE OF REPRESENTATIVES { REPORT
117-96

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2022

JULY 19, 2021.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Ms. DELAURO, from the Committee on Appropriations,
submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 4502]

The Committee on Appropriations submits the following report in explanation of the accompanying bill making appropriations for the Departments of Labor, Health and Human Services (except the Food and Drug Administration, the Agency for Toxic Substances and Disease Registry and the Indian Health Service), and Education, and the Committee for Purchase from People Who Are Blind or Severely Disabled, Corporation for National and Community Service, Corporation for Public Broadcasting, Federal Mediation and Conciliation Service, Federal Mine Safety and Health Review Commission, Institute of Museum and Library Services, Medicaid and CHIP Payment and Access Commission, Medicare Payment Advisory Commission, National Council on Disability, National Labor Relations Board, National Mediation Board, Occupational Safety and Health Review Commission, Railroad Retirement Board, and Social Security Administration for the fiscal year ending September 30, 2022, and for other purposes.

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SUMMARY OF ESTIMATES AND APPROPRIATIONS

The following table compares on a summary basis the appropriations, including trust funds for fiscal year 2022, the budget request for fiscal year 2022, and the Committee recommendation for fiscal year 2022 in the accompanying bill.

2022 LABOR, HHS, EDUCATION BILL

[Discretionary funding in thousands of dollars]

Budget Activity	Fiscal Year—			2022 Committee compared to—	
	2021 Enacted	2022 Budget	2022 Committee	2021 Enacted	2022 Budget
Department of Labor	\$12,536,098	\$14,320,422	\$14,720,051	+2,183,953	+399,629
Department of Health and Human Services	\$96,962,754	\$119,972,989	\$119,845,125	+22,882,371	– 127,864
Department of Education	\$73,536,533	\$102,823,263	\$102,823,263	+29,286,730	– – –
Related Agencies	\$15,428,615	\$16,845,305	\$16,867,354	+1,438,739	+22,049

GENERAL SUMMARY OF THE BILL

For fiscal year 2022, the Committee recommends a total of \$237,466,000,000 in current year discretionary funding—the 302(b) allocation—and \$253,805,000,000 in overall programmatic funding, including offsets and adjustments. The fiscal year 2022 recommendation is an increase of \$55,236,000,000 above the fiscal year 2021 enacted level.

The Labor-HHS-Education bill supports some of the nation’s most critical programs that touch individuals and families throughout their lifespan, from Early Head Start to Social Security. Many of the bill’s programs have been severely strained over the past 18 months during the simultaneous public health and economic emergencies related to COVID–19. Fortunately, the President’s fiscal year 2022 budget proposes to invest significant resources in these critical programs that provide opportunities for millions of families. Through this bill, the Committee is moving ambitiously to help the country recover from the worst pandemic in a century and move forward to strengthen opportunities for every individual to have a better chance at a better life—with a good education, a good job, and access to affordable health care.

The Committee recommends historic investments in education programs, including meeting the Biden-Harris Administration’s commitment to more than double federal funding for Title I Grants to Local Educational Agencies in fiscal year 2022 to a new level of \$36,037,000,000. These investments will strengthen Federal sup-

port for high-poverty schools and support the delivery of a high-quality education for all students.

The Committee also recommends a historic investment in rebuilding our public health system. As the country recovers from the worst pandemic in a century, the Committee includes more than \$10,500,000,000 for the Centers for Disease Control and Prevention (CDC), an increase of nearly \$2,700,000,000, which is the largest increase in budget authority ever provided to the CDC. This includes a new flexible funding stream of \$1,000,000,000 for public health infrastructure and capacity, as well as an increase of \$250,000,000 for CDC's global health activities.

The Committee continues to build on investments made over the past six years in biomedical research by increasing funding for the National Institutes of Health (NIH) by \$6,500,000,000, including an increase of \$3,500,000,000 for basic biomedical research at existing NIH institutes and centers. As part of the Committee's investment in health research, the Committee also includes \$3,000,000,000 to support the President's request to establish the Advanced Research Projects Agency for Health, or ARPA-H, to accelerate the pace of scientific breakthroughs that have the potential to transform health care and address our most complex health challenges.

And the Committee invests in workforce training and worker protection agencies, including significant new investments to rebuild capacity to enforce federal labor laws to protect workers' paychecks, benefits, and ensure the health and safety of our workplaces. The Committee also makes a major commitment to retired workers by including an increase of \$1,000,000,000 for the Social Security Administration's operating expenses, which will restore federal capacity to provide earned benefits and services through Social Security, one of the cornerstones of the federal safety net.

Some of the most notable initiatives in fiscal year 2022 include:

Investing in Public Education

The Committee is committed to increasing investments in core Federal programs that support high-quality public education opportunities for all students. Our nation's public schools serve more than 50 million children, more than 50 percent of whom come from low-income families. Research shows that low-income students are more likely to struggle academically and often attend high-need schools with fewer resources, less experienced teachers, and more limited access to advanced coursework. At the same time, there is overwhelming empirical evidence on education spending and student outcomes that finds more funding in schools yields statistically significant positive results for students.

Overall, the Committee recommendation provides \$65,551,722,000 for Federal K-12 education programs, including Individuals with Disabilities Education Act (IDEA), an increase of \$24,998,971,000 over the fiscal year 2021 enacted level and the same as the Biden-Harris Administration's fiscal year 2022 budget request. The recommendation is a 62 percent increase over last year.

In particular, the Committee recommends an additional \$19,500,000,000 over the fiscal year 2021 enacted level for Title I Grants to Local Educational Agencies for a total of

\$36,036,802,000. Title I serves an estimated 25 million students in nearly 90 percent of school districts and nearly 60 percent of all public schools.

The Committee recommends \$1,000,000,000 for the English Language Acquisition program, which provides formula grants to States to serve English Learners (EL), an increase of \$202,600,000 over the fiscal year 2021 enacted level and \$82,600,000 above the fiscal year 2022 budget request. Federal data shows that significant achievement gaps exist between ELs and their peers. At the same time, many States and school districts have experienced rapid growth in their EL populations. Providing increased resources to improve educational quality for EL students is a top priority for the Committee.

The Committee recommends \$15,537,429,000 for IDEA Part B Grants to States, which is \$2,599,972,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The Committee is concerned that the Federal share of the excess cost of educating students with disabilities has declined and notes the critical role this increase will play in helping to reverse this trend and serve as a significant first step toward fully funding IDEA.

Public Health Infrastructure

The COVID–19 pandemic exposed the inadequacies of the current public health ecosystem. After the COVID–19 pandemic is over, public health agencies cannot go back to what they were and can no longer only get attention during a crisis. The Committee recognizes that State, local, territorial, and Federal public health partners need a long-term strategy and long-term investments, beginning at CDC. The bill includes more than \$10,500,000,000 for the CDC, an increase of nearly \$2,700,000,000.

The Committee provides a new, annual funding line to turn the tide on the nation’s public health infrastructure by providing a stable source of disease-agnostic funding so that nation’s State, local, territorial, and Federal public health agencies are better equipped to coordinate together to save lives. This bill includes \$1,000,000,000 for Public Health Infrastructure and Capacity to begin to address mission-critical gaps nationwide.

In addition, this bill includes increases of: \$50,000,000 for Public Health Workforce and Career Development to invest in essential public health workers who protect our communities and are empowered by science; \$100,000,000 for Public Health Data Modernization to advance the transformation of the collection and utilization of public health data from retrospective reporting to driving action in real time; \$15,000,000 for the National Center for Health Statistics to initiate investments in the next generation of surveys; and \$250,000,000 for Global Health to modernize and expand disease surveillance and response capabilities to strengthen global health security.

NIH Research

The unprecedented speed with which scientists were able to develop effective COVID–19 vaccines would not have been possible without years of sustained investments made by Congress in bio-

medical research supported by the National Institutes of Health (NIH). The Committee continues and accelerates this investment by providing \$46,434,000,000, an increase of \$6,500,000,000 above the fiscal year 2021 enacted level. The bill includes an increase of \$3,500,000,000 for traditional NIH research and activities, the largest annual appropriations increase for NIH since fiscal year 2003.

The Committee continues its ongoing support for key NIH initiatives, such as the Cancer Moonshot, BRAIN Initiative, and the All of Us Precision Medicine Initiative. The bill also includes sufficient funding to provide an across-the-board increase of no less than five percent for each Institute and Center. The Committee remains concerned that targeted funding for specific research initiatives in recent years has slowed the growth in other areas of basic research that may lead to unforeseeable scientific breakthroughs.

The Committee also includes \$3,000,000,000 to establish the Advanced Projects Research Agency for Health (ARPA-H), as proposed in the President's budget request. Modeled after the Defense Advanced Research Project Agency (DARPA), ARPA-H will invest in large high-risk, high-reward research projects that have the potential to achieve breakthroughs in the treatment of diseases such as cancer, Alzheimer's disease, diabetes, and amyotrophic lateral sclerosis (ALS).

Employment and Training

The economic recession resulting from the COVID-19 pandemic impacted American families and further exposed existing inequities in our society. For example, while the unemployment rate peaked at 14.8 percent in April 2020 and is now at 5.9 percent, the unemployment rate for Black workers peaked in May 2020 at 16.7 percent and is now at 9.2 percent and the unemployment rate for Hispanic workers peaked at 18.9 percent in April 2020 and is now at 7.4 percent. The unemployment rate for White workers peaked at 14.1 percent in April 2020 and is now at 5.2 percent. In addition, COVID-19 had devastating impacts on women's participation in the labor force, especially for women of color. As our nation emerges from the COVID-19 pandemic, unemployment assistance and workforce development opportunities will continue to play a critical role in our recovery.

As such, the Committee recommendation includes needed investments in workforce and training systems. Specifically, the recommendation includes \$6,237,181,000 for Workforce Innovation and Opportunity Act Programs, an increase of \$825,326,000 above the fiscal year 2021 enacted level and \$271,750,000 above the fiscal year 2022 budget request. The recommendation includes \$285,000,000 for registered apprenticeships, an increase of \$100,000,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The recommendation also includes \$100,000,000 for the Strengthening Community Colleges Training Grant program, an increase of \$55,000,000 above the fiscal year 2021 enacted level and the fiscal year 2022 budget request. This program helps community colleges build capacity for training workers. The recommendation includes \$100,000,000 for a new grant program to support communities suffering dislocations related to changes in fossil fuel and other energy industries.

The recommendation also includes \$2,866,214,000 for Unemployment Compensation State Operations, an increase of \$509,398,000 over the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. This funding will help support States in overcoming challenges associated with administering unemployment insurance programs. Altogether, these investments will continue to support families struggling with the economic consequences of COVID-19 and prepare workers for new employment opportunities.

Protecting America's Workers

The Committee recommends \$2,095,685,000 for Department of Labor agencies responsible for worker protection and worker rights. This is an increase of \$305,015,000 over the fiscal year 2021 enacted level and \$1,161,000 over the fiscal year 2022 budget request.

The Wage and Hour Division employs fewer investigators today than it did in 1948, despite the workforce having grown significantly in that time. To help make up for this lost ground, hold bad-acting employers accountable and defend working people so they receive the pay they earned and are legally entitled to, the Committee recommendation includes \$300,000,000, an increase of \$54,000,000 over the fiscal year 2021 enacted level and an increase of \$23,500,000 over the fiscal year 2022 budget request.

The Occupational Safety and Health Administration (OSHA) currently has the lowest number of health and safety inspectors in the agency's 48-year history. OSHA enforcement is critical to preventing workplace tragedies from occurring, which is why it is concerning that, under current staffing levels, the agency would need 165 years to inspect each workplace under its jurisdiction just once. To reverse the erosion of enforcement capacity at OSHA, the Committee includes \$691,787,000, an increase of \$100,000,000 over the fiscal year 2021 enacted level and \$27,163,000 over the fiscal year 2022 budget request for this critical worker protection agency.

The Committee also recommends \$316,925,000 for the National Labor Relations Board, an increase of \$42,701,000 over the fiscal year 2021 enacted level and \$15,000,000 over the fiscal year 2022 budget request. This increase will address decline in field staff the Board has seen over the past four years.

Early Childhood Education

The Committee includes over \$20,000,000,000 for early childhood education programs through the Child Care and Development Block Grant (CCDBG), Head Start, and Preschool Development Grants—an increase of \$3,075,000,000 over the fiscal year 2021 enacted level.

Child care is one of the most critical needs of families with young children—it is essential—and yet CCDBG currently reaches only 15 percent of children who are eligible to receive child care services. The increase included in this bill will provide CCDBG-funded child care for approximately 200,000 additional children, which will also enable more parents in low-income families to remain in the workforce. Women, particularly women of color, are disproportionately impacted by the child care crisis in this country, and the investment in this bill builds on the \$52,500,000,000 in supplemental

funding that Congress provided for child care during the coronavirus pandemic: \$3,500,000,000 in the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116–136), \$10,000,000,000 through the Coronavirus Response and Relief Supplemental Appropriations (CRRSA) Act, 2021 (P.L. 116–260), and \$39,000,000,000 through the American Rescue Plan (P.L. 117–2).

The bill includes an increase of \$1,434,000,000 for Head Start, including increases of \$250,000,000 for Quality Improvement Funding for Trauma-Informed Care and \$750,000,000 to expand Head Start, Early Head Start, and Early Head Start-Child Care Partnerships to over 40,000 additional infants and toddlers from low-income families. The bill also includes \$200,000,000 for Head Start programs to extend to full day services, to better support working parents and bring additional programs into compliance with the 2016 Head Start Program Performance Standards.

The Committee further recommends \$450,000,000, an increase of \$175,000,000, for Preschool Development Grants to build State and local capacity to provide early childhood care and education for children birth through five from low- and moderate-income families.

Higher Education

In the aftermath of the COVID–19 pandemic, college affordability and access are vital to our nation’s recovery efforts. Therefore, the Committee recommendation makes necessary investments in programs supporting student financial aid, student support services, and other programs supporting institutions of higher education and their students.

The recommendation includes sufficient funding to support an increase in the maximum Pell Grant by \$400 over the fiscal year 2021 enacted level, from \$6,495 to \$6,895, which is the same as the fiscal year 2022 discretionary budget request.

In addition, the Committee recommendation provides \$1,434,000,000 for Federal Work Study, an increase of \$244,000,000 over the fiscal year 2021 enacted level and the fiscal year 2022 budget request. The Committee recommendation also includes \$1,028,000,000 for the Federal Supplemental Educational Opportunity Grants, an increase of \$148,000,000 over the fiscal year 2021 enacted level and the fiscal year 2022 budget request.

The Committee recommendation includes \$1,297,761,000 for the TRIO programs, an increase of \$200,761,000 over the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The recommendation also includes \$408,000,000 for the Gaining Early Awareness and Readiness for Undergraduate Programs, which is \$40,000,000 more than the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request.

In an effort to assist postsecondary institutions in addressing barriers in completion and attainment, the Committee recommendation includes a total of \$1,134,054,000 for programs that serve high proportions of students of color (Historically Black Colleges and Universities, Hispanic-Serving Institutions, Tribal Colleges and Universities, and other Minority Serving Institutions), an increase of \$345,000,000 over the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request.

The Committee also includes robust funding to support teacher preparation. The recommendation includes \$20,000,000 in new funding for the Augustus F. Hawkins Centers of Excellence program, and the recommendation includes \$132,092,000 for the Teacher Quality Partnerships program, an increase of \$80,000,000 over the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request.

Maternal Health

The U.S. has the highest maternal mortality rate among developed nations, with a particularly high mortality rate for Black and American Indian/Alaska Native women. To help eliminate race-based disparities in outcomes among birthing people and drive down the rate of maternal mortality, the bill provides an increase of \$56,000,000 for CDC's Safe Motherhood and Infant Health programs. This funding allows for the expansion of Maternal Mortality Review Committees and Perinatal Quality Collaboratives to all 50 States and territories, and for increased support to current States and territories, as well as increased support for other programs including Sudden Unexplained Infant Death. The bill includes an increase of over \$178,000,000 at HRSA to support activities to improve maternal health, including an increase of \$30,000,000 for State Maternal Health Innovation Grants, an increase of \$5,300,000 to expand the Alliance for Maternal Health Safety Bundles to more States, an increase of \$2,000,000 to support and expand availability of the Maternal Mental Health Hotline, \$25,000,000 to conduct a demonstration program on pregnancy medical homes, an increase of \$5,000,000 to double funding for Screening and Treatment for Maternal Depression and Related Disorders, an increase of \$5,400,000 for Rural Maternity and Obstetrics Management Strategies. The bill also includes increased investments in research related to maternal health and health disparities at NIH and the Agency for Healthcare Research and Quality (AHRQ).

HIV Initiative

Advances in medications for the prevention and treatment of HIV, improved diagnostic tests, and new outbreak detection technology provide a unique opportunity to alter the trajectory of HIV infection rates in the U.S. with a goal of eliminating new HIV infections. This bill provides a total of \$688,000,000, which is an increase of \$245,000,000 for the third year of the Ending the HIV Epidemic Initiative, which began a new era of moving the U.S. from HIV prevention to HIV epidemic control.

Firearm Injury and Mortality Prevention Research

Firearm injury and mortality is among the leading causes of death for people aged 1–64 in the U.S. In 2019, there were nearly 40,000 firearm-related deaths in the U.S. Addressing the gaps in knowledge around this issue and identifying effective prevention strategies are needed steps toward keeping people, families, schools, and communities safe from firearm injury. In fiscal year 2020, the Committee provided the first funding in more than two decades to address the public health emergency of firearm violence

with a total of \$25,000,000 to CDC and NIH. This bill doubles the total funding to \$50,000,000 to support research to identify the most effective ways to prevent firearm related injuries and deaths, and to broaden firearm injury data collection. Building on these efforts to address firearm injury and death, this bill also includes \$100,000,000 for a new evidence-based community violence intervention initiative at CDC, which aims to prevent intentional violence, such as mass casualty violence or gang violence.

Mental and Behavioral Health

The existing mental health and substance use disorder crises were worsened by the COVID–19 pandemic, with Americans reporting increased levels of anxiety, depression, suicidal ideation, and substance use. Between September 2019 and August 2020, more than 85,000 people nationwide died from drug overdoses, and 47,000 people died from suicide in 2019.

The Committee recommendation includes \$9,160,277,000 for the Substance Abuse and Mental Health Services Administration (SAMHSA), making a range of investments across the behavioral health continuum to support prevention, screening, treatment, and other services. The Committee includes a total increase of \$1,366,020,000 for mental health activities. This includes an increase of \$825,000,000 for the Mental Health Block Grant and an increase of \$125,000,000 for Certified Community Behavioral Health Clinics. The bill increases the mental health crisis set-aside to ten percent, creates a new set-aside for prevention and early intervention, and makes investments to prepare for the launch of a new three digit National Suicide Prevention Lifeline.

The Committee includes \$100,000,000 to establish the Mental Health Crisis Response Partnership Pilot Program, to help communities create mobile crisis response teams that divert the response for mental health crises from law enforcement to behavioral health teams.

The bill supports children’s mental health with a \$28,113,000 increase to the National Child Traumatic Stress Initiative, a \$17,000,000 increase for Infant and Early Childhood Mental Health, and an additional \$25,000,000 for Children’s Mental Health services.

The Committee includes a total increase of \$1,657,187,000 for substance use treatment activities. This includes an increase of \$1,000,000,000 for the Substance Abuse Prevention and Treatment Block Grant and an increase of \$500,000,000 for State Opioid Response Grants. The bill creates a new set-aside within the block grant to support recovery services. The Committee recommendation also includes an increase of \$35,284,000 for substance misuse prevention activities.

OVERSIGHT OF THE EXECUTIVE BRANCH

The Committee has also fulfilled its responsibility to maintain oversight of the Executive Branch by holding seven oversight hearings—in addition to annual hearings on the fiscal year 2022 budget request. The Committee has focused on ongoing crises in health care, education, and labor, which have highlighted unjust racial disparities which were further exacerbated by the COVID–19 pan-

demic. These oversight hearings have informed many of the decisions in the fiscal year 2022 Labor-HHS Education bill.

COVID-19 and the Child Care Crisis

The Committee held a virtual hearing to discuss the devastating impacts that the COVID-19 pandemic had on a child care industry already in crisis. Affordable child care was already a significant and severe issue, but rising operating costs and decreased enrollment as a result of the pandemic were too much for the razor thin margins of many child care providers, and other providers were left grasping for financial assistance. The Committee heard from policy experts, a State administrator, and a program director, about the critical financial needs of child care providers struggling to stay afloat, the necessity of child care for parents and especially for women in the workforce, and the impact that the child care shortage has on job reports and unemployment statistics. The hearing highlighted how COVID-19 exacerbated the child care crisis, and exposed the necessity for a financially stable child care industry, to support women and communities of color, and for post-pandemic economic recovery. Soon after the Committee's hearing, House and Senate Democrats passed the American Rescue Plan (P.L. 117-2) which included \$39,000,000,000 for the Child Care and Development Block Grant program.

Ready or Not: U.S. Public Health Infrastructure

The Committee held a virtual hearing to examine the status and challenges of our nation's public health infrastructure, with a particular focus on public health data, laboratories, and workforce. The COVID-19 pandemic exposed the inadequacies of the current public health ecosystem, and the Committee heard from State and local public health officials about the importance of flexible, long-term investments in public health. As a result of this hearing, this bill includes a new funding line of \$1,000,000,000 for Public Health Infrastructure and Capacity. The Committee's action denotes that the tide has turned for public health funding, as it establishes a disease-agnostic source of funding to address mission-critical gaps in public health infrastructure nationwide.

Health and Safety Protections for Meatpacking, Poultry, and Agricultural Workers

The Committee held a virtual hearing to examine dangerous conditions faced by meat, poultry, and farm workers, especially during the COVID-19 pandemic, and to highlight the role strong federal enforcement from the Occupational Health and Safety Administration (OSHA) can play in addressing the problem. The Committee heard from a worker safety and health expert, a farmworker advocate, and the child of a Smithfield meatpacking worker about the concerning hazards workers faced during the pandemic and the need for urgent action from OSHA to hold these industries accountable to protect vulnerable workers. As a result of this hearing, this bill includes an increase of \$100,000,000 for OSHA above the fiscal year 2021 enacted level. The recommendation, a 17 percent increase over last year, will support additional OSHA inspectors and restore the agency's capacity to conduct more complex, labor-intensive inspections.

COVID-19 and the Mental Health and Substance Use Crises

The Committee held a virtual hearing to examine the impact of the COVID-19 pandemic on the mental health and substance use crises and the responses to this emergency, and heard recommendations on how to build a stronger behavioral health system capable of meeting the demand for services. The COVID-19 pandemic dramatically worsened these existing crises, creating new barriers to treatment while increasing numbers of Americans are reporting anxiety, depression, and substance use. People with existing vulnerabilities have been disproportionately affected—including communities of color, underserved communities, essential workers, people who were already struggling with a mental illness or substance use disorder or were otherwise in poor health, children, and families struggling economically. As a result of this hearing, the Committee is making substantial investments to strengthen the behavioral health continuum of care to increase access to prevention, screening, treatment and other critical services.

Addressing the Maternal Health Crisis

The Committee held a virtual hearing to identify the reasons why the U.S. lags behind other industrialized nations in maternal health outcomes; examine the disparities in maternal health outcomes by race, socioeconomic status, residence, and other factors; and identify opportunities to address these issues through investments in HHS programs. As a result of this hearing, the bill increases funding for programs across HRSA, CDC, NIH, and AHRQ to improve access to quality maternal and postpartum health care and reduce disparities in maternal health outcomes.

Building Capacity, Building Community: Increasing Investments in Community Colleges

The Committee held a virtual hearing that explored the importance of community colleges, as well as their strengths and challenges. Today, there are more than 1,000 community colleges. Community colleges touch upon the lives of individuals in every State and even the outlying areas. Community colleges are typically open access institutions, serving a diverse student body with unique challenges. While, typically, the associate's degree is the highest degree awarded at community colleges, these institutions also offer a wide variety of postsecondary credentials. In this way, community colleges are uniquely positioned to meet the workforce development and educational needs of our country simultaneously. As a result of this hearing, the recommendation includes robust increases for programs that help support community colleges and their students: the WIOA programs, the Strengthening Community Colleges Training Grant program, the Apprenticeship Grants program, the Strengthening Institutions program, and the Child Care Access Means Parents in School program.

Mental Health Emergencies: Building a Robust Crisis Response System

The Committee held a virtual hearing on how to create a robust mental health crisis care system with services available to anyone, anywhere, anytime, with a goal of diverting people experiencing a mental health crisis from the criminal justice system into mental

health treatment. The lack of sufficient mental health care resources in communities means mental illness often goes untreated, which can lead to law enforcement responding to mental health emergencies because there are no alternatives to respond to the crisis. As a result of this hearing, the bill increases funding for mental health crisis services and creates a Mental Health Crisis Response Partnership Pilot Program for communities to create, or enhance existing, mobile crisis response teams that divert the response for mental health crises from law enforcement to behavioral health teams.

NATIONAL INSTITUTES OF HEALTH

Appropriation, fiscal year 2021	\$42,934,000,000
Budget request, fiscal year 2022	51,732,713,000
Committee Recommendation	49,434,000,000
Change from enacted level	+6,500,000,000
Change from budget request	-2,298,713,000

The Committee recommendation for the National Institutes of Health (NIH) program level includes \$48,162,495,000 in discretionary appropriations and \$1,271,505,000 in Public Health Service Act section 241 evaluation set-aside transfers. Within the total appropriation, the Committee recommendation includes \$496,000,000 in budget authority authorized in the 21st Century Cures Act (P.L.114-255).

The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH conducts and supports research to understand the basic biology of human health and disease; apply this understanding towards designing new approaches for preventing, diagnosing, and treating disease and disability; and ensure that these approaches are widely available.

The recommendation includes funding for initiatives established in the 21st Century Cures Act, including a total of \$194,000,000 for the Cancer Moonshot Initiative; \$541,000,000 for the “All of Us” precision medicine initiative (including \$150,000,000 from the Cures Act); and \$612,000,000 for the Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative (including \$152,000,000 from the Cures Act).

The Committee includes specific funding allocations for several initiatives and activities detailed in the Institute- and Center-specific sections below.

NATIONAL CANCER INSTITUTE (NCI)

Appropriation, fiscal year 2021	\$6,559,852,000
Budget request, fiscal year 2022	6,733,302,000
Committee Recommendation	6,992,056,000
Change from enacted level	+432,204,000
Change from budget request	+258,754,000

Mission.—NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

Cancer Data Sharing.—The Committee applauds NIH for creating the National COVID Collaborative (N3C), a commercial solution leveraged to create a centralized and secure database that researchers in academic institutions can use to study COVID-19 and identify potential treatments. The Committee encourages NIH to continue pursuing similar approaches to other critical areas of research, including cancer, where data sharing continues to be a barrier to progress. The Committee commends NCI’s data sharing efforts through the Cancer Moonshot, the Childhood Cancer Data Initiative, and other programs, and requests an update in the fiscal year 2023 Congressional Budget Justification on NCI’s continued progress toward adopting a centralized, secure, national platform to share cancer research data to drive new insights and speed research efforts across the country.

Cancer Immunotherapy.—The Committee recognizes that NCI-supported research exploring cancer immunology, cancer immunotherapy, and cancer vaccines that started years before the emergence of COVID-19 contributed to the rapid development of COVID-19 treatments and vaccines. Applying lessons learned from COVID-19 therapeutic development to cancer immunotherapy clinical trials has the potential to greatly improve treatment options and outcomes for cancer patients. The Committee encourages NCI to accelerate the translation of discoveries in cancer immunotherapy by means of the same innovations used to develop COVID-19 treatments and vaccines. This should include expediting consideration and support for potential high-impact cancer immunotherapy clinical trials, and for correlative science based on planned and ongoing clinical trials.

Cancer Moonshot.—The Committee directs NIH to transfer \$194,000,000 from the NIH Innovation Account to NCI to support the Cancer Moonshot initiative. These funds were authorized in the 21st Century Cures Act (P.L. 114–255).

Cancer Vaccines.—The Committee recognizes that the success of the COVID-19 vaccines—which became available less than a year from the outset of the pandemic and now deliver up to 95 percent protection rates—is due to the fact that these vaccines were built on messenger RNA technology, or mRNA, an approach that had been initiated for cancer research. While most traditional vaccines use inactivated viruses to stimulate an immune response, a complicated process that can take several years, mRNA vaccines use the body's own genetic material, and can be developed much more quickly. The Committee understands that with further research, mRNA cancer vaccines could potentially be among the most cost-effective methods of preventing recurrences and the high costs of cancer care. The Committee commends the work of NCI, which is currently supporting multiple research projects focusing on the use of mRNA vaccines, and encourages its continued commitment to moving the field forward for mRNA vaccines as an approach for cancer immunotherapy treatment and prevention. To better understand NCI's progress to date and the potential of new breakthroughs with mRNA, the Committee requests an update in the fiscal year 2023 Congressional Budget Justification on NCI's work on mRNA vaccines, noting existing barriers or challenges, if any.

Childhood Cancer Data Initiative (CCDI).—The Committee includes \$50,000,000 for the second year of the CCDI, as proposed in the fiscal year 2022 budget request. The development of new therapies is important to finding a cure for childhood cancers, many of which have not seen new therapies in decades. The Committee commends NCI for its support of the establishment of the National Childhood Cancer Registry as a part of the Childhood Cancer Data Initiative. Data sets for childhood cancers are often small and spread out across institutions or aggregated into State-wide or Federal registries where the particulars of incidence rate by cancer are lost. Traditional disease registries such as the Federally-supported Surveillance Epidemiology and End Results Program (SEER) and the CDC's National Program for Cancer Registries (NPCR) aggregated into the U.S. Cancer Statistics (USCS) do not yet include all of the data relevant to cutting-edge pediatric cancer research, such as the molecular characteristics of each child's cancer. The Com-

mittee urges NCI to use available resources to ensure all relevant data needed to assist childhood cancer researchers in developing innovative treatments for childhood cancer are made available through the National Childhood Cancer Registry and other integrated CCDI programs. The Committee requests an update on the progress made to increase available childhood cancer data in the fiscal year 2023 Congressional Budget Justification.

Childhood Cancer STAR Act.—The Committee includes no less than \$30,000,000, the same as the fiscal year 2021 enacted level, for continued implementation of sections of the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act 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.

Colorectal Cancer Disparities.—Given the impact that screening can have on reducing mortality and morbidity in colorectal cancer, the Committee encourages NIH to study the impact of the COVID-19 pandemic on the incidence of colorectal cancer in minority communities. The Committee is hopeful that such information will provide policymakers with a better understanding of the effects on minority communities and help develop strategies to address barriers to screening and reduce health inequities and cancer deaths.

Deadliest Cancers.—The Recalcitrant Cancer Research Act (RCRA) of 2012 (P.L. 112-239) focuses on cancers with a five-year survival rate below 50 percent, which account for 44 percent of all U.S. cancer deaths. While advances in some cancers have made it possible to reduce the overall rate of cancer deaths over the last two decades, there has been limited progress reducing mortality for these diseases. For fiscal year 2020, Congress directed NCI to develop a scientific framework using the process outlined in the RCRA for stomach and esophageal cancers. The Committee notes that in addition to the ongoing framework development, NCI has also developed and received approval from its Board of Scientific Advisors to launch a Program in Origins of Gastroesophageal Cancers. Alongside the research and advocacy communities, the Committee appreciates NCI's efforts to keep the Committee apprised of continued research progress informed by the pancreatic, lung, glioblastoma, esophageal, and stomach cancer frameworks. The Committee encourages NCI to consider a similar process, as appropriate, for primary liver cancer, including cholangiocarcinoma. Given the toll all recalcitrant cancers exact on society and the lack of diagnostic and treatment resources currently available to help patients, the Committee also requests an update in the fiscal year 2023 Congressional Budget Justification on research goals to advance progress for the deadliest cancers (brain, esophagus, liver, lung, ovary, pancreas, stomach and mesothelioma).

Germline RUNX1 Mutations.—The Committee commends NCI for supporting NHGRI in running a natural history study of patients with germline RUNX1 mutations and their families. These mutations frequently lead to blood cancers, especially acute mye-

loid leukemia; more research on how this occurs could ultimately lead to treatments that would prevent malignancy. Interest in this field has grown significantly in recent years, and the Committee strongly urges NCI to initiate funding opportunities for NIH intramural and extramural researchers. Priority areas of research should include the role of inflammation and the immune system on cancer transformation, pharmacological approaches to regulating RUNX1 activity, gene editing strategies, and support for an extramural clinical consortium dedicated to national patient data collection, analysis and specimen storage for collaborative research.

Glioblastoma (GBM).—The Committee commends NCI for its establishment and initial implementation of the GBM Therapeutics Network (GTN). The GTN’s cross-cutting teams’ capability of pre-clinical and early-phase clinical trials necessary to rapidly evaluate potential treatments, including but not limited to 87 drugs, biologics, radiation, and devices, is what is needed to continue to advance toward cures and improved quality of life. The Committee urges NCI to continue to implement the GTN so that this program can rapidly launch clinical trials that speed access to promising qualified treatments to patients consistent with NCI’s Glioblastoma Working Group recommendations in 2019.

Gynecologic Cancers.—The Committee continues to be concerned about the growing racial, socioeconomic, and geographic disparities in gynecologic cancers. In contrast to most other common cancers in the U.S., relative survival for women with newly diagnosed advanced cervical or endometrial cancer has not significantly improved since the 1970s. Furthermore, historical data demonstrates that Black and Latina women with gynecologic cancers are not as likely to receive standard therapy and/or die more frequently. The current COVID–19 pandemic has only exacerbated the health care disparities that were already present in minority and underrepresented communities. Therefore, the Committee urges NCI to expand the number of programs, projects, clinical trials, research grants, and contract opportunities for investigators that focus on discoveries that will positively impact access to prevention, early detection, diagnosis, and treatment for gynecologic cancers and address these now well-documented disparities. The Committee requests an update on NCI’s research program for gynecologic cancers in the fiscal year 2023 Congressional Budget Justification, including specific grants and strategies where the intent is to overcome these racial disparities in gynecologic cancers outcomes, including the underrepresentation of minority women in gynecologic cancer clinical trials.

HPV-Associated Cancers.—The Committee encourages NCI to expand research related to HPV-associated cancers.

Liver Cancer.—The Committee notes that liver cancer is the second deadliest cancer, with a five-year survival rate of only 20 percent. The number of liver cancer cases in the U.S. has increased by over 250 percent since 2000 and continues to increase. Since early detection of cancer in general and liver cancer in particular is the most effective way to reduce cancer mortality, the Committee urges NCI to support the research needed to develop a liver cancer screening test using the blood and saliva samples from widespread national COVID testing. This extensive and growing inventory of saliva and blood samples offers a unique opportunity to develop a

liver cancer screening test that can soon reach over 100 million citizens, a number that will grow as COVID testing is expanded.

Melanoma.—As UV radiation is established as the primary carcinogen for melanoma, the Committee urges NCI to support research directed at genomic and mechanistic characteristics of mutagenesis; optimization of prevention strategies; and early detection and risk declassification strategies that leverage artificial intelligence, access to large databases, noninvasive technologies, and molecular markers that will support precision medicine.

Although SEER data show decline in mortality with the advent of new categories of treatment, some patients do not respond to initial treatment, and many of the responders have disease that will recur. The Committee encourages NCI to expand research on mechanisms of primary and secondary drug resistance and validation of predictive biomarkers that allow selection of optimal therapy and prediction of comprehensive longitudinal monitoring. Basic and translational goals should be facilitated through development and use of ever-improving models of human melanoma.

Building on the success of adjuvant therapies, and the promising results of neoadjuvant therapies, the Committee encourages NCI to continue support of research addressing tumor cell dormancy and metastases. The Committee encourages NCI to support multicenter trials that will determine whether shorter courses of therapy will decrease toxicity and costs while maintaining benefit, the role of adjuvant therapy and whether patients with earlier disease should receive adjuvant therapy and that further determine the role of adjuvant therapy in both treatment and drug development.

The Committee encourages NCI to support research on novel targets, especially for rare subtypes, and support development of registries where populations are not adequate for randomized trials. The Committee requests an update on these requests and a status of NCI-funded melanoma research in NCI's fiscal year 2023 Congressional Budget Justification.

Metastatic Breast Cancer.—The Committee is aware that clinical research is of utmost importance to those living with metastatic breast cancer (MBC), which is breast cancer that has spread to other organs and become incurable. An estimated 168,000 Americans live with MBC, and nearly all of the more than 43,000 deaths from breast cancer are attributed to this late stage of disease. Given the mortality associated with MBC and the lack of treatment options, research offers the best possibility of therapeutic advances and extended life for these patients. MBC is also associated with startling health disparities, since breast cancer mortality is about 40 percent higher for Black women in the U.S. than White women, and breast cancer is the second most common cause of death by cancer for Black women. The Committee believes that a renewed emphasis by NCI on research for MBC, especially in communities of color, is needed to discover better treatments and a cure for MBC and to address health disparities in this population. The Committee requests an update on NCI's activities regarding MBC in the fiscal year 2023 Congressional Budget Justification, including progress made with respect to inclusion of people of color in NCI-funded clinical trials in this area.

Metastatic Cancer Research.—While the early detection and treatment of early stage disease for many cancers results in cures,

for most tumors, metastatic cancer remains incurable. More than 90 percent of cancer deaths are due to metastatic disease. In addition to genetic alterations in the cancer itself, recent research has revealed that there is a genetic basis for susceptibility to metastatic cancer or resistance to metastasis. More research is required to develop a comprehensive understanding of this complex process involving tumor and host interactions. Clinical trials are an important aspect of that progress, and diverse representation of patients in clinical trials is integral to the development of medications and therapies that effectively treat metastatic disease. Ethnicity, gender, age, and genetics all play a role in the safety and efficacy of a treatment for an individual. The Committee commends NIH and the Department of Defense (DoD) for work already underway to support research needs and opportunities identified in the April 2018 Task Force Report to Congress on Metastatic Cancer. The Committee encourages NIH to maintain collaborative efforts with DoD and provide subject matter expertise as appropriate as DoD continues to implement recommendations from the report aimed at achieving representation of the demographics of the U.S. population in clinical trials.

NCI Paylines.—Grant applications to NCI have increased by approximately 50 percent since 2013, outpacing available funding, with requests for cancer research ten-fold greater than other Institutes and Centers. With such a high demand for NCI grants, only a fraction of highly meritorious research proposals can be funded. To support more awards and improve success rates, the Committee provides an increase of \$200,000,000 for NCI to prioritize competing grants and to sustain commitments to continuing grants.

Pancreatic Cancer.—Pancreatic cancer is the third leading cause of cancer-related death in the U.S. In 2020, over 60,000 Americans will be diagnosed with pancreatic cancer; more Americans than ever before. The five-year survival rate for pancreatic cancer remains at just over ten percent. The Committee appreciates that NCI has adhered to and completed all reporting requirements of the Recalcitrant Cancer Research Act of 2012 (RCRA) as it pertains to the Pancreatic Cancer Scientific Framework. The Committee looks forward to updates and progress made on the action items identified in the pancreatic cancer focus areas. The Committee is encouraged to hear that NCI is building upon the RCRA's Strategic Framework and taking steps to integrate research efforts across the NCI, and that several NCI-supported consortia focused on early detection have formed the Alliance of Pancreatic Cancer Consortia as a virtual network of researchers, clinicians, and advocacies to provide a platform and coordinate resources to discover and validate biomarkers and imaging methods for early detection. The Committee applauds this effort and requests an update in the fiscal year 2023 Congressional Budget Justification on progress made within the Alliance since its inaugural meeting in December 2016.

Pediatric Cancer Expertise.—The Committee recognizes that the Childhood Cancer STAR Act (P.L. 115–180) calls on NCI to ensure that all applicable study sections, committees, advisory groups, and panels at NCI include one or more qualified pediatric oncologists, as appropriate. The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on the actions NCI

has taken to ensure appropriate pediatric cancer expertise is included in such groups.

Prioritizing Underserved Populations in Cancer Clinical Trials.—The Committee remains concerned about the lack of equity and access to cancer clinical trials across the country. Groups that are generally underrepresented in clinical trials include racial and ethnic minorities and older and lower-income individuals as well as those from rural communities. To better identify and address these disparities, the Committee encourages NCI to continue to develop and prioritize trial recruitment strategies that consider socioeconomic status, race/ethnicity, or location and to prioritize grant applications that aim to recruit and enroll diverse patient cohorts when appropriate. The Committee urges NCI to continue collecting and publicly reporting research data on race/ethnicity, and to encourage the collection of data, when appropriate, on sexual orientation, gender identity, and other variables that are known to influence clinical outcomes.

Prostate Cancer.—The Committee remains concerned that prostate cancer lacks treatments for men with advanced disease as well as adequate diagnostic and imaging methodologies. To ensure Federal resources are leveraged to the greatest extent possible, the Committee encourages NCI to coordinate, when appropriate, its research efforts with other Federal agencies, including DoD, as well as private research foundations and advocacy groups.

Research on Cancer Disparities.—The Committee encourages NCI to continue its commitment to support the NCI Community Oncology Research Program and the activities of the Center to Reduce Cancer Health Disparities, two key efforts that contribute to building a cadre of community stakeholders and medical researchers prepared to engage in transdisciplinary approaches to address cancer, including its disparate impact on some communities nationwide. Although there have been significant advances in the prevention and treatment of cancer, evidence shows persistent differences in cancer incidence, late-stage diagnosis, and mortality in many States depending on socioeconomic status, geography, race, ethnicity, and other factors. The Committee encourages NCI to continue to prioritize research and training programs aimed at reducing health disparities in cancer, including through NCI's continued support of its integrated training, education, and outreach networks between communities and medical research centers. The Committee encourages NCI to prioritize partnerships with community groups and other stakeholders to explore the issues associated with cancer disparities as identified by local communities and include activities to develop curriculum to inform health professions education to reduce medical mistrust in targeted groups and to highlight relevant research questions to address cancer disparities. Additionally, NCI efforts should support the development of a cancer research infrastructure to identify relevant research questions related to disparities and to develop integrated and sustainable approaches to reducing cancer disparities, including examining social determinants of health and their impacts on such disparities.

Skin Cancer in Communities of Color.—Research has shown that skin cancer in patients with skin of color is often diagnosed in its later stages, making treatment more difficult and decreasing the chances for survival. The Committee requests an update in the fis-

cal year 2023 Congressional Budget Justification regarding research that assesses factors contributing to later diagnoses of skin cancer among patients with skin of color, as well as research focused on measures to raise awareness of risk factors for skin cancer and to encourage activities that promote prevention and early detection of skin cancers among patients with skin of color and other underserved populations.

Telehealth-Based Services for Vulnerable Patients.—The COVID-19 pandemic significantly exacerbated the physical, emotional, and mental toll on cancer patients and families. Providing clinical and psychosocial services to address these challenges is an essential component of comprehensive cancer care across a patient’s lifespan. Cancer centers across the U.S. quickly pivoted to providing patient support and related health services by telehealth, although the extent to which all patients and families had equitable access to these services and the impact for those who have attended them is unknown. For example, both rural and urban underserved areas disproportionately lack reliable home-based Internet service, creating barriers for patients to access telehealth-based clinical and psychosocial support services. To overcome this, many cancer centers provided technical assistance to patients during the pandemic to support their use of telehealth. The Committee urges NCI to increase its support of research on the delivery and evaluation of telehealth-based clinical and psychosocial services, particularly among vulnerable patients and disadvantaged communities. This enhanced research would lead to evidence-based best practices, so that all patients can benefit from the most effective cancer care at all stages of the disease.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

Appropriation, fiscal year 2021	\$3,664,811,000
Budget request, fiscal year 2022	3,845,681,000
Committee Recommendation	3,866,828,000
Change from enacted level	+202,017,000
Change from budget request	+21,147,000

Mission.—NHLBI provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood disorders and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Alzheimer’s Disease and Vascular Dementia.—Well-characterized, longitudinal, population-based cohort studies provide value 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; 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. The Committee urges NHLBI to fund research into next generation cohorts, with a focus on understanding the development and progression of risk factors and detection of early signs of cognitive decline. Funded cohorts should be racially and ethnically diverse with broad geographic representation.

Blood Donor Questionnaire Educational Materials.—The Committee is concerned that certain FDA guidance in the educational

materials provided in the blood donor questionnaire are inappropriate and misguided. The recommendations for deferral should not mention someone's sexual orientation, and rather focus on risk factors that might expose a potential donor to blood-borne illness. The Committee strongly recommends that NHLBI work with the FDA and remove or replace the recommended deferment of blood for men who have had sex with men in the last 12 months.

Community Engagement Alliance Against COVID-19 Disparities (CEAL) Initiative.—The Committee includes \$30,000,000 for the new CEAL initiative, the same as the fiscal year 2022 budget request. This initiative will connect researchers with community organizations and leaders to conduct outreach and increase participation of people from underrepresented communities in clinical trials for COVID-19 treatments and vaccines.

COVID-19-Associated Illnesses.—The Committee recognizes the growing burden of COVID-associated critical illnesses, including sepsis and pneumonia. The Committee encourages NHLBI to accelerate research into sepsis, pneumonia, and acute lung injury.

Duchenne Muscular Dystrophy.—In light of improvements in care leading to patients living into their third decade, the leading cause of death in Duchenne Muscular Dystrophy patients is heart failure. The Committee urges NHLBI to support research that characterizes cardiomyopathy in Duchenne and Becker Muscular Dystrophy. There is a gap in the ability to develop novel cardiac therapeutics for Duchenne Muscular Dystrophy due to a lack of accepted cardiac outcome measures. The Committee encourages NHLBI to convene a workshop with research, clinical, and patient organization leaders to work towards establishing viable cardiac outcome measures for the development of therapeutic agents to combat cardiomyopathy.

Health Disparities Research.—The COVID-19 pandemic has highlighted and exacerbated health disparities in the U.S. The Committee includes an increase of \$50,000,000 for NHLBI to support research related to identifying and reducing health disparities, the same as the fiscal year 2022 budget request.

Long-Term Impact of COVID-19.—The Committee notes with concern that an estimated ten percent of individuals who have recovered from COVID-19 are experiencing “long haul” health conditions, including serious respiratory diseases such as acute respiratory distress syndrome and pulmonary fibrosis. The Committee urges NHLBI to prioritize research into the understanding, treatment and prevention of “long haul” post-COVID respiratory conditions, particularly among minority populations disproportionately impacted by COVID-19.

Lymphedema (LE).—LE is a chronic, debilitating, and incurable swelling that can be a result of damage to the lymphatic system due to surgery, cancer treatment, or injury, and that can also be inherited. An estimated 10,000,000 Americans suffer from LE. Additional research is necessary to improve our understanding of this condition and expand the treatment options available. The Committee directs NHLBI to increase support for research on LE and to establish a Research Condition Disease Categorization category for research related to lymphedema.

Mitral Valve Prolapse (MVP) Workshop.—MVP is a common valve disease that has an estimated 2.4 percent prevalence. Though

most cases are thought to be benign, reported complications such as severe mitral regurgitation and arrhythmias can result in sudden cardiac death (SCD). Medical research has found an association between MVP and SCD. Predictors of this outcome, however, are not readily available, underlying mechanisms are poorly understood, and indicators of high-risk individuals are lacking. Despite several studies, there is not sufficient data to generate guidelines for care of patients with valvular heart disease, including MVP. The Committee encourages NHLBI to convene a workshop of subject matter experts to identify research needs and opportunities with the goal of informing guidelines for treatment of patients with MVP.

National Commission on Lymphatic Diseases.—The Committee directs NIH to establish a National Commission on Lymphatic Diseases and to engage with relevant Institutes, Centers, and external stakeholders in establishing this Commission. The Committee directs NIH to provide an update on progress to establish the Commission within 60 days of the enactment of this Act.

National Chronic Obstructive Pulmonary Disease (COPD) Action Plan.—The Committee notes NHLBI's role in crafting the National COPD Action Plan. NHLBI is encouraged to continue this important work by supporting additional research activities and collaborating with other Public Health Service agencies to facilitate implementation of the plan's recommendations.

Polycystic Kidney Disease.—The Committee commends NIDDK for its continued commitment to Polycystic Kidney Disease Research and Translation Centers and the Pediatric Centers of Excellence in Nephrology, which improve our understanding of the causes of autosomal dominant polycystic kidney disease and autosomal recessive polycystic kidney disease. The Committee encourages NIDDK to ensure that funds previously committed for polycystic kidney disease research centers remain dedicated to funding other PKD research efforts.

Pulmonary Fibrosis (PF).—The Committee recognizes that PF is a family of more than 200 different lung diseases that all look very much alike despite having a variety of causes. This heterogeneity presents significant challenges for diagnosis and treatment. The Committee commends NHLBI for its recent efforts to apply the principles of precision medicine to PF research, especially by funding a major new study that will evaluate a promising treatment for a subset of patients with a particular gene variant. This study, known as PRECISIONS, also aims to identify genetic variants that play a role in certain forms of PF. The Committee urges NHLBI to prioritize basic research on PF, particularly to better understand the causes and process of scarring and the varying impacts on patients.

Sickle Cell Disease (SCD) Research.—The Committee commends NIH for its ongoing support of clinical research for SCD, which imposes major morbidity on an estimated 90,000 to 100,000 individuals in the U.S., with three million Americans carrying the sickle cell trait. The Committee encourages NIH to support clinical trials for prenatal and postnatal treatment of SCD, which includes multiple promising approaches to eradicate this disease, save lives, and reduce dramatically the substantial health care costs associated with SCD for children and adults. The Committee encourages NIH to consider programs both domestically and globally to evaluate the

effectiveness of screening technologies for infants and children with the sickle cell trait and disease.

Support for The Heart Truth Program.—For over a decade, The Heart Truth program has worked to raise awareness about women's risk of heart disease. The program's goals are to increase awareness that heart disease is the leading cause of death among women and to increase the conversations between women, and their health care providers. Accordingly, the Committee encourages the NHLBI to robustly fund The Heart Truth program.

Thalassemia.—Recent studies have shown that the length of time between when blood is donated and transfused does not impact outcomes for patients in need of an emergency blood transfusion, such as in cases of trauma or acute events. However, these studies do not determine the impact on chronically transfused patients, such as those with thalassemia, in which an administration of older red cells may exacerbate iron loading in the heart and other internal organs and contribute to worse outcomes for patients. The Committee urges NHLBI to establish research initiatives to address current gaps in clinical understanding in this area.

Valvular Heart Disease Research.—Many people in the U.S. have heart valve defects or disease but do not have symptoms. For some, the condition remains the same throughout their lives and does not cause significant or life-threatening problems. Unfortunately, over 25,000 people die each year in the U.S. from heart valve disease, primarily due to underdiagnosis and undertreatment of the condition. The Committee strongly supports more research into valvular heart disease. Such research should focus on advances in technological imaging and precision medicine to generate data on individuals with valvular heart disease, identify individuals who are at high risk of sudden cardiac death, and develop prediction models for high-risk patients, enabling interventions and treatment plans to help keep these patients healthy throughout their lives. Additionally, the Committee supports efforts by NIH to convene a workshop of subject matter experts to identify research needs and opportunities with the goal of informing guidelines for treatment of patients with valvular heart disease.

Vascular Dementia.—A growing number of Americans are developing severe forms of vascular dementia, conditions resulting from many years of living with chronic diseases such as hypertension and cardiovascular disease. This prevalence is especially high in areas with high rates of hypertension, obesity, and lack of access to regular health care. Epidemiological studies and human pathology studies have demonstrated association of vascular risk factors, vascular diseases, and pathology with dementia. Research in animal models could further investigate causal relationships, understand mechanisms, and test novel interventions (including repurposing existing drugs). Study of the mechanisms of vascular dementia can help researchers to understand causation, develop new treatment therapies and study how to repurpose existing drugs to delay or halt disease progression. The Committee encourages NHLBI to continue its support for investigating potential relationship between vascular disease and risk factors for vascular dementia, leveraging the work of well-established longitudinal cohort studies of dementia and cardiovascular disease and experimental models well characterized phenotypes and mechanisms. The Com-

mittee encourages NHLBI to coordinate this research with NIA and NINDS to ensure that the continuum of research from basic science to observational cohort to clinical trial to implementation is maintained.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
(NIDCR)

Appropriation, fiscal year 2021	\$484,867,000
Budget request, fiscal year 2022	516,197,000
Committee Recommendation	519,010,000
Change from enacted level	+34,143,000
Change from budget request	+2,813,000

Mission.—The mission of NIDCR is to improve dental, oral, and craniofacial health through research, research training, and the dissemination of health information.

Dental Restorative Materials.—To help address one of the U.S. commitments under the Minamata Convention on Mercury, the Committee encourages NIDCR to conduct additional research on durable mercury-free dental restorative materials.

Opioids and Pain/Pain Management Research.—The Committee includes an increase of \$18,000,000 for NIDCR to support research related to opioids, pain, and pain management, as requested in the fiscal year 2022 budget.

Oral Microbiome.—The Committee appreciates NIDCR’s leadership in microbiome research, including its support of the Human Oral Microbiome Database. The Committee encourages NIDCR to build upon its microbiome research to discover and better understand the microbiome’s connection to overall health, including its influence on preventing and treating illness and disease.

SARS-CoV-2.—The Committee thanks NIDCR for its commitment to prioritizing research to answer critical research questions related to the novel coronavirus. The Institute’s research into high-impact areas such as transmission risk in dental environments is critical for the nation to continue fighting COVID-19 and to ensure everyone is as safe as possible.

Report on Oral Health in America.—The Committee greatly appreciates NIDCR’s leadership on the upcoming Report “Oral Health in America: Advances and Challenges”. The Committee anticipates the final release of the report and encourages NIDCR to utilize the findings of the 2021 Report to identify research gaps across dental, oral, and craniofacial research and to pursue research opportunities to fill those gaps.

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

Appropriation, fiscal year 2021	\$2,131,975,000
Budget request, fiscal year 2022	2,219,298,000
Committee Recommendation	2,237,625,000
Change from enacted level	+105,650,000
Change from budget request	+18,327,000

Mission.—The NIDDK mission is to conduct and support medical research and research training and disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people’s health and quality of life.

End-Stage Renal Disease (ESRD).—The Committee continues to note the important work in supporting critical kidney research that NIDDK has accomplished on ESRD. The Committee encourages NIDDK to work with stakeholders to facilitate new opportunities for research in related conditions.

Glomerular Disease.—The Committee continues to support the important work that the Cure Glomeruloneuropathy (CureGN) initiative has accomplished, which has led to breakthroughs for critical clinical trials. The Committee encourages NIDDK to continue supporting research on related conditions such as minimal change disease.

Inflammatory Bowel Diseases (IBD).—The Committee encourages NIDDK to continue pursuing bedside-to-bench research in IBD with a focus on biological and clinical drivers of patient remission and relapse in Crohn's disease and ulcerative colitis, including mucosal healing as well as environmental triggers such as nutrition and psychological stress. The Committee recognizes the importance of having common data elements (CDE), standardizing the clinical categorization of IBD patients, to facilitate the sharing, validation, and comparison of results across research studies, and commends the work many Institutes and Centers have done to support development of CDEs for a number of diseases and disorders. To effectively support bedside-to-bench research in IBD, the Committee encourages the Institute to support the development of CDEs and to collaborate with other IBD researchers and organizations.

Interstitial Cystitis.—The Committee notes the progress of interstitial cystitis research through the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Program and encourages NIDDK and stakeholders to continue collaboration on a comprehensive state of the science conference to examine mechanisms for scientific opportunity. The Committee requests an update on the progress of the conference in the fiscal year 2023 Congressional Budget Justification.

Liver Disease and Health Disparities.—The Committee notes the relationship between health disparities and a variety of conditions of the liver, such as nonalcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD). The Committee encourages NIDDK to continue to work with NIMHD and other Institutes and Centers to advance liver disease research in a comprehensive and impactful way.

Opioids and Pain/Pain Management Research.—The Committee includes an increase of \$20,000,000 for NIDDK to support research related to opioids, pain, and pain management, as requested in the fiscal year 2022 budget.

Pediatric Nephrology Workforce Diversification.—The Committee recognizes that the COVID-19 pandemic caused unprecedented disruption in biomedical research, delaying awards and dissuading applications for pediatric nephrology research. The Committee is concerned that these disruptions have disproportionately impacted researchers from traditionally underrepresented groups, resulting in even fewer researchers from communities of color. Pediatric nephrology studies continue to suffer from low enrollment, due in part to the disproportionate impact of kidney disease on children of color and longstanding challenges of clinical trial recruitment

within those communities. Because children and families of color are more likely to enroll in studies where the research team is from the same community, the diversity of pediatric nephrology biomedical workforce is paramount to the success of this research. The Committee requests that NIDDK consult with stakeholder groups to identify barriers to increasing the diversity of the pediatric nephrology workforce and identify ways to incentivize researchers from traditionally underrepresented groups to enter this field. The Committee requests that NIDDK include information in the fiscal year 2023 Congressional Budget Justification on the progress made to bolster the diversity of the pediatric nephrology biomedical research workforce.

Prostate Cancer Disparities.—Nearly 250,000 men will be diagnosed with and 34,000 men will die from prostate cancer in 2021. Incidence of prostate cancer is almost 80 percent higher in non-Hispanic Black men, and prostate cancer mortality among Black men is more than double that of men in every other racial or ethnic group, representing a stark example of health inequity in cancer outcomes. The Committee supports NCI and NIMHD research on Prostate Cancer in Men of African American Ancestry: Defining the Roles of Genetics Tumor Markers, and Social Stress (RESPOND) Study, intended to identify the underlying causes of disparities in prostate cancer incidence and mortality. The Committee requests an update on the study in the fiscal year 2023 Congressional Budget Justification.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
(NINDS)

Appropriation, fiscal year 2021	\$2,513,393,000
Budget request, fiscal year 2022	2,783,300,000
Committee Recommendation	2,799,515,000
Change from enacted level	+286,122,000
Change from budget request	+16,215,000

Mission.—The NINDS mission is to seek fundamental knowledge about the brain and nervous system and use that knowledge to reduce the burden of neurological disease.

BRAIN Initiative.—The Committee directs NIH to transfer \$76,000,000 from the NIH Innovation Account to NINDS to support the BRAIN Initiative. These funds were authorized in the 21st Century Cures Act (P.L. 114–255). This collaborative effort is revolutionizing the understanding of how neural components and their dynamic interactions result in complex behaviors, cognition, and disease, while accelerating the development of transformative tools to explore the brain in unprecedented ways, making information previously beyond reach accessible.

Cerebral Palsy (CP) Research.—The Committee commends NIH for supporting research on mechanisms leading to CP, health outcomes for those affected, biomarkers that may aid in diagnosis or treatment selection, and interventions for treatment and prevention of CP. The Committee strongly encourages NIH to strengthen, accelerate, and coordinate cerebral palsy research priorities across the lifespan identified in the 2017 NINDS/NICHHD Strategic Plan for CP Research, such as basic and translational discoveries, including neuroprotective, regenerative medicine and mechanisms of neuroplasticity, as well as implementation and clinical studies

aimed at early detection and intervention, comparative effectiveness, and functional outcomes. The Committee encourages that a follow-up workshop be held in 2022 in conjunction with key stakeholders to provide updates on promising research performed to date, with the goal to further refine or expand the opportunities that were identified in the five to 10 year NIH strategic plan, including early detection and intervention.

Duchenne Muscular Dystrophy.—While the expression of the dystrophin protein in the brain is recognized, our understanding of the link between the absence of dystrophin and related neurobehavioral/cognitive diagnosis is not well understood. The Committee urges NINDS to support research to characterize the role of dystrophin in the brain and to further define the relationships between mutation and neurobehavioral and cognitive diagnosis.

Dystonia.—The Committee continues to urge NINDS to implement the recommendations from the NINDS workshop “Defining Emergent Opportunities in Dystonia Research” and engage with other Institutes and stakeholders on advancing translational research that may lead to more treatment options for those affected by dystonia.

Expanded Access to ALS Treatments.—The Committee supports efforts to expand access for neurodegenerative diseases with no disease modifying treatments. The Committee encourages NINDS to collaborate with stakeholders to expand access for patients unable to access treatment through clinical trials.

Headache Disorders.—Migraine is a leading cause of disability, affecting more than 17 percent of people in the U.S. The statutory language providing authority for Helping End Addiction Long-Term (HEAL) Initiative cites the necessity of attending to disease burden in prioritizing HEAL research programs (42 U.S. Code § 284q 1). The Committee encourages NIH to consider HEAL Initiative support of fundamental, translational, clinical, and social science research on headache disorders, as appropriate to the mission of the HEAL initiative, to provide lasting scientific solutions to the opioid crisis. HEAL has invested in resources and infrastructure developed to support pain research across all pain conditions and should continue to encourage application submissions on headache disorders, as well as those on pain conditions for which opioid use and prescribing is highly prevalent. Headache disorders research supported through the HEAL initiative should supplement, not supplant, current funding for headache disorders research at NIH, which has contributed to many of the effective non-opioid treatments for headache.

Multiple Sclerosis (MS).—The Committee encourages NINDS to prioritize studies that develop the medical understanding of the progression of MS and advance research on prevention strategies, treatments, and cures for MS.

Opioid and Stimulant Research.—The Committee includes \$405,400,000 million within NINDS for the Helping to End Addiction Long-Term (HEAL) Initiative, \$135,105,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The HEAL Initiative is a trans-NIH effort to accelerate scientific discovery related to prevention and treatment of opioid use disorder and developing nonaddictive alternatives for pain

management. The Committee also includes an additional \$43,000,000 in NINDS to support basic research related to opioids and pain, as requested in the fiscal year 2022 budget.

Parkinson’s Disease (PD).—The Committee commends NINDS for taking critical steps in identifying priority recommendations to advance research on PD, which impacts between 500,000 and 1,500,000 people in the U.S. and is the second most prevalent neurodegenerative disease in this country. 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 PD. The Committee also encourages NINDS to submit an update of its progress on implementing these recommendations in the fiscal year 2023 Congressional Budget Justification.

Sleep Disorders.—The Committee notes the leadership of NINDS in advancing research into underrepresented sleep disorders, such as narcolepsy, restless legs syndrome, and Kleine Levin Syndrome. The Committee encourages NINDS to bolster these activities and review the state of the science around sleep disorders to better advance initiatives that advance scientific understanding of specific sleep disorders impacting patients.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Appropriation, fiscal year 2021	\$6,069,619,000
Budget request, fiscal year 2022	6,245,926,000
Committee Recommendation	6,557,803,000
Change from enacted level	+488,184,000
Change from budget request	+311,877,000

Mission.—The NIAID mission is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

Antiviral Drugs and Pandemic Preparedness.—The Committee strongly encourages NIAID efforts to establish a public-private partnership focused on global pandemic preparedness and antiviral drug discovery, in coordination with BARDA. Such a partnership could leverage the best of academia and pharmaceutical manufacturers to develop broad-spectrum antiviral drugs to address rapidly emerging public health threats, helping our nation be better prepared for the next global pandemic. The Committee directs NIAID to provide an update on this and any related efforts in the fiscal year 2023 Congressional Budget Justification.

Celiac Disease.—The Committee encourages NIH to devote focused research to the study of celiac disease, including the autoimmune causation underpinning the affliction. Today, the only known treatment for this disease is a gluten-free diet; however, recent public and private sector research confirms that such a treatment is insufficient for many who suffer from celiac disease. Therefore, the Committee urges NIAID to support new research on celiac disease, to better coordinate existing research, and to focus new research towards diagnosing and effectively treating this condition. The Committee also strongly encourages NIH to establish a Research Condition, Disease Categorization (RCDC) for celiac disease and a Notice of Special Interest to spur additional research.

Centers for AIDS Research.—As part of the Ending the HIV Epidemic initiative, the Committee includes \$71,000,000 for the Centers for AIDS Research, an increase of \$10,000,000 above the estimated fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. These Centers offer evidence-based practices on prevention and treatment to initiative partners and support for evaluating the initiative.

Combating Antibiotic-Resistant Bacteria.—The Committee supports NIAID's efforts related to combating antibiotic-resistant bacteria. These funds enable NIAID to support research on antimicrobial (drug) resistance, including basic research on how microbes develop resistance, new and faster diagnostics, and clinical trials designed to find new vaccines and treatments effective against drug-resistant microbes.

Consortium of Food Allergy Research (CoFAR).—The Committee recognizes the serious issue of food allergies which affect approximately eight percent of children and ten percent of adults in the U.S. The Committee commends the ongoing work of NIAID in supporting a total of 17 clinical sites for this critical research, including seven sites as part of the CoFAR. The Committee includes \$12,200,000, an increase of \$6,100,000, for CoFAR 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 proven expertise in food allergy research.

Emerging Diseases.—The Committee supports the work of NIAID in researching emerging coronaviruses, and urges NIAID to fund basic science on a host of deadly viruses, including SARS-CoV-2, Ebola, Marburg, and Nipah viruses. The Committee notes the importance of using high containment BSL-3 and BSL-4 labs in this effort. The Committee is aware of the success of non-animal approaches to identify how viral proteins interact with host proteins and their pathways. The Committee notes the success of these approaches with SARS-CoV-2 to identify new therapeutic approaches. The Committee encourages NIAID to support research into viruses, including Ebola, Marburg, and Nipah viruses, to help identify small molecule drugs to block infection by a host of deadly viruses.

Hereditary Angioedema (HAE).—The Committee recognizes NIAID for its ongoing stewardship of the HAE research portfolio, including advancements that have taken HAE from a debilitating and fatal condition to a manageable chronic disease. The Committee notes the potential of gene therapy and other cutting-edge research to further improve health outcomes for HAE patients and encourages NIAID to maintain the commitment to the HAE research at this critical time.

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 NIH to continue coordination with USAID, the State Department, and others to advance ARV-based microbicide development efforts, with the goal of enabling regulatory approvals 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.

Rapid Vaccine Development Platforms for Emerging Infectious Disease.—The Committee recognizes the importance of being able to quickly, efficiently, and safely develop and manufacture vaccines against emerging infectious diseases. Vaccines play a pivotal role in host protection against infectious diseases and have significantly reduced mortality worldwide. Older methods of developing vaccines are no match for a host of emerging and reemerging pathogens that call for a tailored and speedy response, such as the developing coronavirus variants. Today, innovations in how vaccines are developed enable faster production of platforms capable of making and initially testing a new vaccine in less than 120 days that then are tailored to specific pathogens as manufacturing begins, based on science and data, not speculation. Such rapid vaccine platform technologies can vastly decrease the time it takes to develop, manufacture and distribute vaccines. Therefore, the Committee includes \$50,000,000 to support research and development of rapid vaccine platform technologies and requests a briefing on these efforts within 180 days of enactment of this Act.

Regional Biocontainment Laboratories (RBLs).—The Committee commends NIAID for issuing a Request for Applications (RFA) to support the RBLs through the RFA for Facility and Building System Upgrades Support for the RBLs. The Committee encourages NIAID to continue supporting meritorious research applications from investigators conducting research through the RBLs on efforts to prevent, prepare for, and respond to infectious disease outbreaks, including, but not limited to: (1) conducting research on developing testing for antiviral compounds, new vaccines, and point of care tests; (2) conducting research on validating methods for identifying suitable prophylactic methods to prevent infections; and (3) training new researchers in biosafety level 3 practices.

Universal Influenza Vaccine.—The Committee includes no less than \$250,000,000, an increase of \$30,000,000 over the fiscal year 2021 level and the fiscal year 2022 budget request, to support basic, translational, and clinical research to develop a universal influenza vaccine that provides robust, long-lasting protection against multiple subtypes of flu, rather than a select few. Such a vaccine would eliminate the need to update and administer the seasonal flu vaccine each year and could provide protection against newly emerging flu strains, potentially including those that could cause a flu pandemic. The Committee requests an update on these efforts within 60 days of enactment of this Act.

Valley Fever.—The Committee is encouraged by NIAID's recent announcement to establish collaborative coccidioidomycosis (Valley Fever) research centers. To guide this continuing work, the Committee requests, within 180 days of enactment of this Act, a 10-year strategic plan from NIH with the objective of producing a Valley Fever vaccine by 2031. This plan should include, but not be limited to: (1) a statement of science on Valley Fever, including disease burden in the U.S.; (2) identifiable and achievable benchmarks for Valley Fever vaccine development, including vaccine market viability; (3) identifying or developing funding priorities and opportunities that actively support the development of a Valley Fever vaccine; and (4) any recommendations to Congress on policy reforms designed to help develop a Valley Fever vaccine. Furthermore, the Committee directs NIAID to convene a stakeholder and researchers

conference in an endemic region to help guide the strategic plan's development. The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on progress towards achieving goals in this strategic plan.

Viral Vector Platforms.—The Committee notes that viral vector platforms have a proven track record for successfully producing vaccines against infectious diseases for many decades and believes well-established viral vectors with a robust safety record for use in children, pregnant women, or other high-risk populations should be continuously developed and adjusted to potential emerging infections in the future. The Committee encourages investments in vaccine centers with long-term experience in the development of viral vectors covering multiple virus-based vaccine platforms, with particular emphasis on entities that have established collaborations with high-security facilities (BSL-4) for preclinical studies.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

Appropriation, fiscal year 2021	\$2,991,417,000
Budget request, fiscal year 2022	3,096,103,000
Committee Recommendation	3,139,656,000
Change from enacted level	+148,239,000
Change from budget request	+43,553,000

Mission.—NIGMS supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.

Increasing Diversity in Biomedical Research.—The Committee has long sought to promote opportunities for the Nation's next generation of researchers and enhance diversity in biomedical research. Early-stage researchers, particularly women and racial and ethnic minorities, spend longer periods of time in postdoctoral positions with lower salaries, receive inadequate mentorship, and are offered fewer opportunities for professional advancement, resulting in lower retention rates for these groups. Even with these obstacles, many early-stage researchers tackle riskier projects and have seen positive outcomes for the benefit of society. Grant programs offering support and opportunities for researchers at key career transition points requiring little or no preliminary data, are critical to ensuring innovative scientists from diverse backgrounds succeed in biomedical research. The Committee provides an increase of \$20,000,000 for NIGMS for programs, including but not limited to the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC), Minority Access to Research Careers (MARC), Bridges to the Baccalaureate, and Undergraduate Research Training Initiative for Student Enhancement (U RISE) programs, that train the next generation of scientists while enhancing the diversity of the biomedical research workforce and enabling promising scientists to pursue high-risk, high-reward research.

Institutional Development Awards (IDeA).—The Committee provides \$415,000,000 for IDeA, \$18,427,000 above the fiscal year 2021 enacted level. IDeA supports high-quality research and investigators throughout the country in States in which the success rate for NIH grants has been historically low.

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

Appropriation, fiscal year 2021	\$1,590,337,000
Budget request, fiscal year 2022	1,942,117,000
Committee Recommendation	1,689,786,000
Change from enacted level	+99,449,000
Change from budget request	-252,331,000

Mission.—NICHD investigates human development throughout the entire life process, with a focus on understanding disabilities and important events that occur during pregnancy.

The Committee commends the important role that NICHD has historically served to support research in the areas of behavioral health, cognition, development of young children, language, learning differences, and school readiness. The COVID pandemic has only increased the importance of research in these areas, such as the long-term consequences of social isolation or emotional development after a year of inconsistent in-person school attendance. Accordingly, the Committee encourages NICHD to prioritize ongoing investment in these areas.

Endometriosis Research.—The Committee urges NICHD to expand funding for basic, clinical, and translational research into the mechanics of endometriosis, identify early diagnostic markets, and develop new treatment methods.

Human Milk Research.—The Committee encourages NICHD to continue to support human milk research through peer-reviewed scientific research and graduate and postdoctoral fellowships. The Committee encourages NICHD to connect at least four, but not more than 10, centers for human milk research to establish a research center network to support shared resources and facilities for human milk research and any required infrastructure.

Impact of COVID-19 on Children.—The Committee includes an increase of \$15,000,000, as requested in the fiscal year 2022 budget, for NICHD to support additional research into multisystem inflammatory syndrome in children (MIS-C) and other ways in which COVID-19 affects children. The Committee looks forward to receiving NIH's SARS-CoV-2 pediatric research agenda and asks NIH to continue identifying research needs focused on the novel coronavirus impacts on children and adolescents, exploring how pediatric patients have been included in current NIH SARS-CoV-2 research and clinical trials, investigating any disparities that have emerged in how children of different communities have been affected, assessing the risk and protective factors children may produce against COVID-19 antigens, investigating longer-term impacts of SARS-CoV-2 on child health, and pursuing research focused on treatments and prevention methods for SARS-CoV-2 focused on children and adolescents when carrying out this agenda.

Learning Disabilities Research Centers and Learning Disabilities Innovation Hubs.—The Committee is increasingly concerned with the decline in achievement for students with disabilities and recognizes the need for continued research and improved interventions, particularly in light of the COVID-19 crisis, which has led to significant loss of in-person instruction for many students. The Committee recognizes the importance of NICHD's funding of Learning Disabilities Research Centers and Learning Disabilities Innovation Hubs, which are the only source of Federal funding available to re-

searchers interested in exploring child development and learning disabilities to conduct randomized control trials and explore the relationships between different variables at work. While learning disabilities do impact an individual's education and academic achievement, these disorders are brain-based, and so clinical research using the latest technology and advances in neuroscience is essential. To continue robust research into language, reading development, learning disabilities, and disorders that adversely affect the development of listening, speaking, reading, writing, and mathematics abilities, the Committee urges NICHD to continue its investment in its Learning Disabilities Research Centers and Learning Disabilities Innovation Hubs.

Male Reproductive Health.—The Committee urges NICHD to continue to support research on male mechanisms of infertility. There is a gap in the knowledge of how to diagnose and treat male infertility, often resulting in women undergoing unnecessary treatments due to undiagnosed or untreated male partner infertility. The Committee supports research to identify new proteins and sperm structures that are necessary for normal sperm function and, consequently, for fertility and healthy embryo development.

Maternal Health Research.—The Committee includes an increase of \$30,000,000 for the Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative, as requested in the fiscal year 2022 budget. Maternal mortality in the U.S. is higher than in other industrialized nations, and there are disparities in maternal outcomes across the country. For example, Black women experience maternal mortality at nearly four times the rate of White women. The IMPROVE Initiative advances research to reduce preventable causes of maternal deaths and improve health for pregnant and postpartum individuals before, during, and after delivery. The initiative uses an integrated approach to understand biological, behavioral, sociocultural, and structural factors that affect severe maternal mortality and maternal mortality (SMM/MM) by building an evidence base for improved care and outcomes in specific regions of the country. IMPROVE will target health disparities associated with SMM/MM by (1) implementing and evaluating community-based interventions for disproportionately affected women (e.g., African American, American Indian/Alaska Native, advanced maternal age, low socioeconomic status, and rural populations), and (2) identifying risk factors and the underlying biological mechanisms associated with leading causes of SMM/MM, including cardiovascular disease, infection and immunity, and mental health.

Population Research.—The Committee applauds NICHD for supporting many of the Nation's most used prospective, population-representative longitudinal studies, including the Fragile Families and Child Wellbeing Study, Panel Study of Income Dynamics Child Supplement Survey, and National Longitudinal Survey of Youth, and also for supporting research and research training through the NICHD Population Dynamics Centers Research Infrastructure Program. Given the dearth of data being collected regarding the short and long-term social, economic, developmental, and health effects of the COVID pandemic on children and families, the Committee urges NICHD to consider expanding data collection and research through these existing surveys and the Centers Program. Further,

the Committee encourages NICHD to explore the use of existing and new mechanisms to enhance research regarding the effect of COVID on fertility trends and reproductive health overall. Finally, the Committee urges NICHD to expand data collection and research regarding maternal, infant, child, and adolescent mortality. The Committee asks that NICHD report on its progress to enhance and expand these research and survey activities within 90 days of enactment of this Act.

Research in Pregnant and Lactating Women.—The Committee is pleased with the progress being made by the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) in identifying and developing strategies to address gaps in knowledge and research on safe and effective therapies for pregnant and lactating women. The Committee encourages NICHD, along with other relevant Institutes and Centers, CDC, and FDA, to continue to implement PRGLAC recommendations to the extent appropriate and feasible under the legal authorities available to the Secretary.

Additionally, The Committee includes \$1,500,000 within NICHD to contract with the National Academies of Science, Education, and Medicine (NASEM) to convene a panel with specific legal, ethical, regulatory, and policy expertise to develop a framework for addressing medicolegal and liability issues when planning or conducting research specific to pregnant people and lactating people. Specifically, this panel should include individuals with ethical and legal expertise in clinical trials and research; regulatory expertise; plaintiffs’ attorneys; pharmaceutical representatives with tort liability and research expertise; insurance industry representatives; Federally funded researchers who work with pregnant and lactating women; representatives of institutional review boards (IRBs); and health policy experts.

Uterine Fibroids.—Nationally, an estimated 26,000,000 individuals ages 15 to 50 have diagnosed uterine fibroids. Uterine fibroids are the most common gynecological condition, but individuals are frequently unaware that the symptoms of this condition, including heavy menstrual bleeding, pain, and frequent urination during periods, are abnormal. Fibroids contribute to significant negative health outcomes including chronic pain, iron deficiency and anemia, miscarriage, and/or infertility. The Committee strongly urges the NICHD to prioritize funding to expand basic, clinical, and translational research into the mechanics of fibroids, identification of early diagnostic methods, and fertility-preserving treatments. Research focusing on understanding the significant health disparities among individuals with fibroids should also be prioritized, given that Black women are at increased risk for fibroids, tend to develop symptoms at a younger age, and suffer more severe symptoms.

NATIONAL EYE INSTITUTE (NEI)

Appropriation, fiscal year 2021	\$835,714,000
Budget request, fiscal year 2022	858,535,000
Committee Recommendation	877,129,000
Change from enacted level	+41,415,000
Change from budget request	+18,594,000

Mission.—NEI conducts and supports basic and clinical research, research training, and other programs with respect to blinding eye diseases, visual disorders, and mechanisms of visual function, preservation of sight, and the special health problems and needs of individuals who are visually-impaired or blind.

Blepharospasm.—The Committee notes the work of NEI in expanding research into blepharospasm, a form of dystonia, and requests an update on collaboration amongst stakeholders and other Institutes and Centers.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

Appropriation, fiscal year 2021	\$814,675,000
Budget request, fiscal year 2022	937,107,000
Committee Recommendation	941,799,000
Change from enacted level	+127,124,000
Change from budget request	+4,692,000

Mission.—NIEHS’s mission is to discover how the environment affects people in order to promote healthier lives.

Climate Change Research.—The Committee includes an increase of \$100,000,000, the same as the fiscal year 2022 budget request, for NIEHS to support research on the impact of climate change on human health.

Harmful Algal Blooms Research.—The Committee recognizes the value of the NIEHS mission and the NIEHS NSF jointly-funded Oceans and Human Health Program as a means to increase scientific knowledge about short-term and long-term human health effects potentially associated with acute and chronic exposures to toxins produced by harmful algal blooms (HABs). The Committee recognizes the increasing relevance of this scientific research to communities directly affected by HABs, including Florida, where a 16-month bloom one of the longest documented HABs in the State’s history occurred from late 2017 through early 2019. The Committee encourages NIEHS to continue investing in this research area using its competitive, peer-reviewed grantmaking processes. In particular, the Committee notes growing scientific interest in the use of multidisciplinary approaches to investigate respiratory irritation or illness associated with inhalation of aerosolized HAB toxins and with neurotoxic shellfish poisoning arising from ingestion of contaminated seafood. The Committee commends NIEHS for its collaborations with other agencies, including NSF, NOAA, EPA, and CDC, to advance such research and translate key research findings for clinical and public health benefits.

Parkinson’s Disease.—Research suggests that Parkinson’s disease (PD) is caused by a combination of genetic and environmental factors. Agricultural exposure to pesticides, including herbicides, has been associated with an increased risk of developing the disease, yet other exposures common to soldiers, firefighters, first responders and others, such as burn pits, insecticides, solvents and heavy metals, need to be explored or should be considered. The Committee urges NIEHS to expand its research and collaborate with appropriate partners to understand effects of these chemicals on PD development and progression. Research should include fundamental approaches to identify other environmental triggers and to understand the expression of PD traits that result from the interplay of genes and environment to advance the development of indi-

vidualized precision environmental health strategies to prevent and treat PD. The Committee requests an update on these activities in the fiscal year 2023 Congressional Budget Justification.

NATIONAL INSTITUTE ON AGING (NIA)

Appropriation, fiscal year 2021	\$3,899,227,000
Budget request, fiscal year 2022	4,035,591,000
Committee Recommendation	4,258,049,000
Change from enacted level	+358,822,000
Change from budget request	+222,458,000

Mission.—NIA’s mission is to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life.

Alzheimer’s Disease and Related Dementias.—In recognition that Alzheimer’s disease poses a serious threat to the nation’s long-term health and economic stability, the Committee recommends a total of no less than \$3,394,000,000 for Alzheimer’s disease and related dementias research, \$200,000,000 above the estimated fiscal year 2021 level and the fiscal year 2022 budget request.

Center on Exposome Studies in Alzheimer’s Disease and Related Dementias (ADRD).—The Committee recognizes the importance of mechanistic research to address ADRD disparities, including the social and contextual factors that contribute to increased risk for disease. The Committee directs NIA to establish research infrastructure in the form of a Center(s) on Exposome Studies in ADRD, which would enable the linkage of community and health system-level factors to biological outcomes including cellular and molecular mechanisms that lead to disease. This includes linking social and biological factors via characterization of the exposome, the measure of all the exposures of an individual over the life course (e.g. physical, chemical, environmental, social), characterized through a mechanistic disparities lens. The Committee includes \$15,000,000 to facilitate these efforts to provide a cornerstone of health disparities operations to advance solutions, innovations, and cures.

Diversity in Alzheimer’s Disease Research.—The Committee commends NIA for its leadership in supporting longitudinal, population-based cohort studies into the causes of dementia. Since rural, poor, and minority populations may be at greater risk for dementia, the value and application of these studies are enhanced when they include individuals from various geographic, ethnic, socioeconomic, and generational backgrounds. The Committee urges NIA to continue to support diversity in its cohort studies, with the specific goal of better understanding disease burden and biomarkers by race and geographic region, as well as the underlying pathologies which may differ by race.

Elder Abuse.—The Committee commends NIA for its research on developing linguistically and culturally appropriate tools to combat elder abuse and financial exploitation and improve the identification and reporting of elder abuse. The Committee is pleased by efforts to facilitate cross-Institute collaborations, such as the 2015 Workshop on Multiple Approaches to Understanding and Preventing Elder Abuse and Mistreatment. The Committee urges NIH to utilize innovative means such as inter-institute workshops, improved cross-agency coordination, or the Project ECHO telementoring model with aging professionals and housing providers to

translate and disseminate information to combat elder abuse in diverse populations.

Opioids and Pain/Pain Management Research.—The Committee includes an increase of \$29,000,000 for NIA to support research related to opioids, pain, and pain management, as requested in the fiscal year 2022 budget.

Overactive Bladder and Cognitive Impairment Treatment.—The Committee is concerned that anticholinergic medications commonly prescribed to treat overactive bladder, a condition that affects one in three older Americans, have been shown in recent studies to increase the risk of developing ADRD. The Committee believes that further research of anticholinergic medications as well as on alternatives to these treatments is urgently needed to establish certainty regarding the safety of these medications as a treatment option for overactive bladder in older adults. The Committee urges NIA to prioritize research grants and contracts that study the long-term use of anticholinergic medications and the risk of cognitive impairment and ADRD. The Committee requests an update on this issue and on research activities to advance safe and effective alternative treatments for overactive bladder in the fiscal year 2023 Congressional Budget Justification.

Population Research.—The Committee praises NIA for supporting a scientifically innovative population aging research portfolio that reflects some of the Institute's, and Nation's, highest scientific priorities, including Alzheimer's disease and social inequality in health and the aging process. More research, however, is needed to understand the short and long-term social, behavioral, and economic health consequences of COVID-19 on older people and their families, which NIA is uniquely positioned to foster and support. Existing large-scale, longitudinal and panel surveys, such as the Health and Retirement Study, the National Health and Aging Trends Study, and Understanding America Study, should be enhanced to facilitate scientific research on the complex, multifaceted effects of the pandemic on older, diverse populations. Further, the Committee encourages NIA to support the further development of data infrastructure to promote research on racial, ethnic, gender, and socioeconomic disparities in health and well-being in later life and the long-term effects of early life experiences. The Committee asks that NIA to report on its progress to enhance and expand these research and survey activities within 90 days of enactment of this Act.

Prion Diseases.—The Committee encourages NIH to continue funding research proposals on prion diseases that could be relevant for ADRD. The disease mechanism and clinical presentation of prion diseases closely resemble AD/ADRDs. Advances in prion disease science have been valuable to the study of other ADRDs and vice versa, and further integration of the fields will benefit scientific pursuits in both fields.

Thalassemia.—Thanks to significant advances in medical science, thalassemia patients and others dealing with chronic diseases are now living well into adulthood, some even into their 60s. While this is a tremendous victory for research, it has opened new questions. Among these are female and male reproductive issues, the impact of non-disease related medicines, the relationship to diseases of aging such as ADRD, Parkinson's, arthritis, osteoporosis, and more.

The Committee requests that NIA develop a plan to research comorbidities in thalassemia and other rare disease patient populations as they continue to age.

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

Appropriation, fiscal year 2021	\$634,292,000
Budget request, fiscal year 2022	680,186,000
Committee Recommendation	679,410,000
Change from enacted level	+45,118,000
Change from budget request	- 776,000

Mission.—NIAMS’s mission is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases.

Opioids and Pain/Pain Management Research.—The Committee includes an increase of \$24,000,000 for NIAMS to support research related to opioids, pain, and pain management, as requested in the fiscal year 2022 budget.

Skin Disease Research Core Centers.—The Committee recognizes the important work at the Core Centers funded by NIAMS to conduct basic and clinical research on a variety of skin diseases, including inflammatory and infectious skin diseases. The Committee urges NIAMS to fund Centers with diverse geographic locations, and to encourage proposals that incorporate pediatric skin diseases and collaboration with diverse stakeholders, such as States or patient and provider groups.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

Appropriation, fiscal year 2021	\$498,076,000
Budget request, fiscal year 2022	511,792,000
Committee Recommendation	522,758,000
Change from enacted level	+24,682,000
Change from budget request	+10,966,000

Mission.—NIDCD conducts and supports biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. NIDCD also conducts and supports research and research training related to disease prevention and health promotion; addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders; and supports efforts to create devices which substitute for lost and impaired sensory and communication function.

Spasmodic Dysphonia.—The Committee notes the research NIDCD continues to facilitate on spasmodic dysphonia. The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on collaborative efforts with related Institutes, Centers, and stakeholders to advance critical research into all forms of dystonia, including spasmodic dysphonia.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

Appropriation, fiscal year 2021	\$174,957,000
Budget request, fiscal year 2022	199,755,000
Committee Recommendation	200,782,000
Change from enacted level	+25,825,000
Change from budget request	+1,027,000

Mission.—The mission of NINR is to promote and improve the health of individuals, families, and communities. To achieve this mission, NINR supports and conducts clinical and basic research and research training on health and illness, research that spans and integrates the behavioral and biological sciences, and develops the scientific basis for clinical practice.

Health Disparities Research.—The Committee includes an increase of \$20,000,000 for NINR to support research related to identifying and reducing health disparities, the same as the fiscal year 2022 budget request.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

Appropriation, fiscal year 2021	\$554,923,000
Budget request, fiscal year 2022	570,165,000
Committee Recommendation	582,422,000
Change from enacted level	+27,499,000
Change from budget request	+12,257,000

Mission.—NIAAA’s mission is to generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being, and apply that knowledge to improve diagnosis, prevention, and treatment of alcohol-related problems, including alcohol use disorder, across the lifespan.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

Appropriation, fiscal year 2021	\$1,479,660,000
Budget request, fiscal year 2022	1,852,503,000
Committee Recommendation	1,860,329,000
Change from enacted level	+380,669,000
Change from budget request	+7,826,000

Mission.—NIDA’s mission is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health.

Addiction Intervention.—The Committee is deeply concerned by alarming trends related to the addiction in the U.S. The number of alcohol-related deaths doubled in the US from 1999 to 2017, the age-adjusted rate of deaths involving synthetic opioids other than methadone increased 1,040 percent from 2013 to 2019, and the use of psychostimulants increased 317 percent. One trait that is evident in every form of addiction is the excessive discounting of the future by the addicted person, who will value the immediate over benefits of the future. Episodic Future Thinking is a promising intervention that helps individuals who are predisposed to addiction consider the positive consequences of remaining sober through a mental simulation of positive events that might occur in the future. The Committee encourages NIDA to support transdisciplinary research that incorporates neuroscience, behavioral research, neuroeconomics, brain imaging, decision-science, engineering, and computer science to deploy Episodic Future Thinking intervention strategies across a range of addictions.

Cannabis Research.—The Committee encourages NIDA to support coordinated, multidisciplinary cannabis research, including basic, clinical, and translational cannabis research and research on the health effects of cannabis use, potential therapeutic effects of cannabis use, and effects of cannabis legalization. NIDA is encouraged to support peer-reviewed scientific research, graduate and postdoctoral fellowships, and any required infrastructure, with priority given to research programs in States where State co-funding is available.

Cannabidiol Research.—The Committee strongly believes that cannabidiol (CBD), cannabigerol (CBG), cannabichromene (CBC), minor cannabinoids, and terpenes—compounds found in cannabis—may provide beneficial medicinal effects. However, there is insufficient scientific information about the short- and long-term effects of these compounds. The Committee is also concerned that marijuana policies on the Federal level and in the States are being changed without the benefit of scientific research to help guide those decisions. Additional, coordinated research on a national scale is necessary to determine the toxicology and medicinal effects of these compounds. The Committee believes that NIH should consider significantly expanding funds to study the medicinal effects and toxicology of CBD, CBG, CBC, minor cannabinoids, and terpenes. This expanded effort should include funding of clinical trials with academic health centers to study the long-term medicinal benefits and toxicology of CBD, CBG, CBC, minor cannabinoids, and terpenes. The Committee encourages NIH to continue supporting a full range of research on the health effects of marijuana and its components, including research to understand how marijuana policies affect public health.

Drug Impairment Standards for Marijuana.—The Committee is concerned that development of a drug impairment standard for marijuana remains unlikely in the near term and encourages NIH to continue supporting a full range of research on the health effects of marijuana and its components, including research to understand how marijuana policies affect behaviors that impact public health, such as drug-impaired driving. The Committee is aware that due to Drug Enforcement Administration restrictions on registered growers, the majority of Federal research using marijuana has been limited to marijuana produced by a single grower and encourages NIH, when possible, to undertake research that encompasses the diversity, quality, and potency of commonly available cannabis products.

Kratom.—The Committee recognizes that NIDA-funded research has contributed to the continued understanding of the health impacts of kratom, including its constituent compounds, mitragynine and 7-hydroxymitragynine. The Committee is aware of the potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids and of research investigating the use of kratom's constituent compounds for opioid use disorder. The Committee directs NIDA to continue to invest in this important research, especially considering the increase in overdose deaths during the COVID-19 pandemic.

Methamphetamine and Other Stimulants.—The Committee is concerned that, according to CDC, over 30,000 overdose deaths in-

volved drugs in the drug categories that include methamphetamine and cocaine in 2019, an increase of over threefold since 2014. The sharp increase has led some to refer to stimulant overdoses as the “fourth wave” of the current drug addiction crisis in America following the rise of opioid-related deaths involving prescription opioids, heroin, and fentanyl-related substances. Methamphetamine is highly addictive and there are no FDA-approved treatments for methamphetamine and other stimulant use disorders. The Committee continues to support NIDA’s efforts to address the opioid crisis, has provided continued funding for the HEAL Initiative, and supports NIDA’s efforts to combat the growing problem of methamphetamine and other stimulant use and related deaths.

Opioid and Stimulant Research.—The Committee continues to be concerned about the opioid overdose epidemic and appreciates the important role that research plays in the various Federal initiatives aimed at this crisis. The Committee is also aware of the most recent data from CDC that shows opioid overdose fatalities increasing from 2018 to 2019, with the primary driver being the increased overdose deaths involving synthetic opioids, primarily illicitly manufactured fentanyls. To combat this crisis, the Committee includes \$405,400,000 within NIDA for the HEAL Initiative, \$135,105,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The HEAL Initiative is a trans-NIH effort to accelerate scientific discovery related to prevention and treatment of opioid use disorder and developing nonaddictive alternatives for pain management. In response to rising rates of stimulant use and overdose, the Committee has included language expanding the allowable use of these funds to include research related to stimulant use and addiction. The Committee also includes an additional \$196,300,000 in NIDA to support basic research related to opioids and other stimulants, as requested in the fiscal year 2022 budget.

Overdose Prevention Centers.—The Committee recognizes that overdose prevention centers, or supervised consumption sites, are part of a larger effort of harm reduction interventions intended to reduce the risk of drug overdose death and reduce the spread of infectious disease. The Committee directs NIH, in consultation with CDC, to provide a report to the Committee no later than 180 days after the enactment of this Act that provides an updated literature review and evaluation on the potential public health impact of overdose prevention centers in the U.S.

Pain Prescribing Education.—The Committee encourages NIDA to continue and expand efforts to educate physicians and other medical professionals on safe prescribing for pain and managing patients who abuse prescription opioids, as well as best practices for incorporating substance misuse and addiction screening and treatment into their clinical practices.

Raising Awareness and Engaging the Medical Community in Drug Use 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 health care 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 area, 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. The Committee recommends that NIDA continue to support the education of scientists and practitioners to find improved prevention and treatments for substance use disorders.

Schedule I Drug Research.—The Committee recognizes that, despite marijuana being legalized in some form in 35 States and nearly 45,000,000 American adults reporting having used marijuana in the past year, research on marijuana and other Schedule I substances is extremely limited. The Committee directs NIH, in collaboration with FDA, DEA, ONDCP, and any other relevant agencies, to develop an approach to facilitate access to Schedule I drugs for research.

Sleep and Circadian-Dependent Mechanisms Contributing to Opioid Use Disorder.—The Committee notes NIDA's continued support in research to better understand opioid use disorder and urges engagement with stakeholders to examine contributing factors, including sleep and circadian-dependent mechanisms.

Tobacco Regulatory Science Program.—The Committee supports the Tobacco Regulatory Science Program and encourages NIH to increase funding for research into the understanding of nicotine addiction and to spur the development of better prevention and treatment strategies. Of particular importance is funding for research for effective interventions to help youth and young adults to quit tobacco use or vaping, and to understand the interrelationship between the vaping of tobacco and marijuana. The Committee directs NIDA to conduct interdisciplinary research on this topic with an emphasis on risk perceptions, decision-making and neuroscience.

Underage and Perinatal Marijuana Use.—The Committee includes \$2,000,000 for NIDA to enter into a contract with NASEM to commission a study to determine the scope of the problem of underage and perinatal marijuana use and effective ways of reducing it. Topics explored should include but not be limited to the demographics of underage and perinatal marijuana use; its economic and social costs; adolescent and perinatal decision making and risk and protective factors; and the effectiveness of various prevention programs and approaches, including media campaigns, school-based education, pricing, and access. The NAS will develop a strategy for reducing and preventing underage and perinatal consumption of today's marijuana and THC products, specifically focused on the impacts of THC on the developing brain.

To help develop an effective strategy, the NAS shall review existing Federal, State, and non-governmental programs, including media-based programs, that have been shown to be effective with other substances that can be harmful to youth, including any done on marijuana, that are designed to change the attitudes and health behaviors of youth (those under the age of 21).

In addition, the NAS shall review existing Federal, State, and non-governmental programs including media-based programs, that have been shown to be effective with other substances that can be harmful to babies of pregnant and breast-feeding women, including

any completed on marijuana, that are designed to change the attitudes and health behaviors of pregnant and breast-feeding women.

Based on its reviews, the NAS shall produce a strategy designed to prevent and reduce underage consumption of today's marijuana and THC products in addition to a strategy designed to prevent and reduce consumption of today's marijuana and THC products by pregnant and breast-feeding women. This shall include but not be limited to: an outline and implementation strategy, message points that will be effective in changing the attitudes and health behaviors of youth concerning underage marijuana consumption and an outline and implementation strategy, message points that will be effective in changing the attitudes and health behaviors of pregnant and breast-feeding women, target audience identification, goals and objectives of both campaigns, and the estimated costs of development and implementation.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

Appropriation, fiscal year 2021	\$2,103,708,000
Budget request, fiscal year 2022	2,213,574,000
Committee Recommendation	2,223,085,000
Change from enacted level	+119,377,000
Change from budget request	+9,511,000

Mission.—NIMH's mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.

Autism.—The Committee encourages NIH to continue to prioritize and invest in research on autism consistent with the recommendations included in the Interagency Autism Coordinating Committee's (IACC) Strategic Plan for Autism Spectrum Disorder. However, while significant progress has been made in our understanding of autism because of Federally-funded research, large gaps remain that must be addressed to improve outcomes and access to services for autistic individuals and their families. Research has shown that autistic individuals have higher rates of some co-occurring physical and mental health conditions, which not only lead to quality of life issues, but also increased medical utilization and costs. Similarly, to address the racial, ethnic, and socioeconomic health equity challenges experienced by autistic individuals and their families, it is imperative that greater investment is made to address disparities in access to services and interventions. The Committee encourages NIH to support greater investment in research focused on particular areas in need of growth, outlined in the strategic plan, including research on lifespan issues to address the needs of transition-age youth and adults on the spectrum, research to enable development of evidence-based services, and research to support the development and delivery of new and improved screening tools, treatments and interventions. The Committee further encourages NIMH to work collaboratively with NIMHD to support research on the socioeconomic, racial, and ethnic health disparities associated with autism spectrum disorder.

BRAIN Initiative.—The Committee directs NIH to transfer \$76,000,000 from the NIH Innovation Account to NIMH to support the BRAIN Initiative. These funds are authorized by the 21st Century Cures Act (P.L. 114-255). This collaborative effort is revolutionizing our understanding of how neural components and their

dynamic interactions result in complex behaviors, cognition, and disease, while accelerating the development of transformative tools to explore the brain in unprecedented ways making information previously beyond reach accessible.

Impact of COVID on Mental Health.—The Committee includes an increase of \$25,000,000 for NIMH to expand research on the impact of the COVID–19 pandemic on mental health, as requested in the fiscal year 2022 budget.

Suicide Prevention.—The Committee is encouraged that 2019 was the first year in two decades in which the suicide rate decreased. However, death by suicide remains the tenth leading cause of death in the U.S., and the Committee remains committed to providing the resources necessary to address this alarming crisis. The Committee commends NIMH for consistently expanding resources for suicide screening and prevention research over the last four fiscal years and strongly encourages the Institute to continue to prioritize suicide research in fiscal year 2022, with special emphasis on producing models that are interpretable, scalable, and practical for clinical implementation, including utilization of health care, education, and criminal justice systems that serve populations at risk. In addition, the Committee encourages NIMH to prioritize research efforts related to primary care settings to evaluate suicide prevention interventions, strategies, and programs, including assessments of the effects of the COVID–19 pandemic. The Committee requests that NIMH provide an update on these efforts in the fiscal year 2023 Congressional Budget Justification.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

Appropriation, fiscal year 2021	\$615,780,000
Budget request, fiscal year 2022	632,973,000
Committee Recommendation	646,295,000
Change from enacted level	+30,515,000
Change from budget request	+13,322,000

Mission.—NHGRI’s mission is to accelerate scientific and medical breakthroughs that improve human health by driving cutting-edge research, developing new technologies, and studying the impact of genomics on society.

Computational Medicine and RNA Molecules.—The Committee is encouraged by recent discoveries in the computational medicine field that are helping uncover more of the causes behind disease onset and disease progression. Multiple reports, in many human diseases and conditions, provide compelling evidence that an individual’s sex, ancestry, and age differentially affect the individual’s regulatory RNA molecules and their impacts. The Committee recognizes that more research in this area could lead to new and important biological discoveries, improve our understanding of disease processes, and herald highly personalized approaches to diagnosis, prognosis, and therapy. The Committee urges NHGRI to continue to support computational and experimental 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 provides no less than \$15,000,000 to sustain and grow the Emerging Centers of Excellence in Genomic Sciences competitive grant program, an increase of \$2,500,000 above the fiscal year 2021

enacted level. The Committee maintains prior direction that present awardees of the Centers for Excellence in Genomic Sciences program shall not be eligible to receive these grants.

Germline RUNX1 Mutations.—The Committee commends NHGRI for collaborating with NCI to launch and maintain the RUNX1–FPD Clinical Research Study, the only longitudinal natural history study of patients with germline RUNX1 mutations and their families. This study has broad implications for the fields of hematology and oncology because it offers researchers the rare opportunity to monitor the genomic evolution of cancer within a precancerous population in real time. Currently, the study tracks only 50 of the approximately 20,000 people in the U.S. with these mutations. The Committee encourages NHGRI to continue supporting this study. In addition, the Committee encourages NHGRI to continue to work towards the implementation of an open source database to share data in real-time for the benefit of the entire research community and the patients and their families searching for answers.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING
(NIBIB)

Appropriation, fiscal year 2021	\$410,728,000
Budget request, fiscal year 2022	422,039,000
Committee Recommendation	431,081,000
Change from enacted level	+20,353,000
Change from budget request	+9,042,000

Mission.—The NIBIB mission is to improve health by leading the development and accelerating the application of biomedical technologies.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
(NIMHD)

Appropriation, fiscal year 2021	\$390,865,000
Budget request, fiscal year 2022	652,244,000
Committee Recommendation	661,879,000
Change from enacted level	+271,014,000
Change from budget request	+9,635,000

Mission.—NIMHD’s mission is to lead scientific research to improve minority health and reduce health disparities.

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

Mercury in Beauty Products.—The Committee is concerned about the prevalence of cosmetics containing dangerous levels of mercury made available through online sales and increased global travel. Evidence suggests that these harmful unregulated cosmetics, such as skin lightening creams, are disproportionately used by women of color. The Committee encourages NIMHD to collaborate with FDA to identify research gaps in the understanding of the health effects of these products.

Research Centers at Minority Institutions.—The Committee includes \$88,000,000, an increase of \$8,000,000 above the fiscal year 2021 enacted level and the fiscal year 2022 budget request, for RCMI to ensure that infrastructure development in historically

minority graduate and health professional schools continue to enhance to meet these critical needs. The Committee also recognizes the importance of the RCMI Coordinating Center in ensuring that collectively, institutions can engage in multi-site collaborative research, especially as the U.S. and NIH positioned themselves to address the challenges imposed by the COVID-19 pandemic to our health system and underserved populations.

The Committee encourages the NIMHD to continue following Congressional intent for the RCMI program and follow the spirit of the original instructions provided to NIH by Congress. The Committee notes the original intent of the RCMI program is to provide equitable means for health professions institutions with historical missions and precedence of serving minorities and building research infrastructure.

Health Disparities Research.—The Committee includes an increase of \$250,000,000 for NIMHD to support additional research related to identifying and reducing health disparities, as requested in the fiscal year 2022 budget.

Rural Health.—Rural Americans are a population group that experiences significant health disparities. Health disparities are differences in health status when compared to the population overall, often characterized by indicators such as higher incidence of disease and/or disability, increased mortality rates, lower life expectancies, and higher rates of pain and suffering. Rural risk factors for health disparities include geographic isolation, lower socioeconomic status, higher rates of health risk behaviors, limited access to healthcare specialists and subspecialists, and limited job opportunities. The Committee encourages NIMHD to continue research to address the health disparities found in rural communities.

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH
(NCCIH)

Appropriation, fiscal year 2021	\$154,162,000
Budget request, fiscal year 2022	184,323,000
Committee Recommendation	185,295,000
Change from enacted level	+31,133,000
Change from budget request	+972,000

Mission.—The mission of NCCIH is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care.

Integrative Health.—The Committee commends NCCIH as the lead Federal scientific agency supporting research to determine the usefulness and safety of complementary and integrative health approaches and their roles in improving health and health care. The Committee supports the Center's continued leadership of several trans-NIH and inter-agency initiatives, including the NIH-DoD-VA Pain Management Collaboratory (PMC) and the Health Care Systems Research Collaboratory, both of which are investigating best practices for implementing complementary health approaches in clinical health care settings. Consistent with goals that NCCIH identified in its fiscal year 2021-2025 strategic plan, the Center is encouraged to maintain its focus on whole person health, pro-

moting research on multimodal approaches in treating pain and emphasize improving individual health.

Pain and Pain Management Research.—The Committee includes an increase of \$26,000,000 for NCCIH to support research related to pain and pain management, as requested in the fiscal year 2022 budget.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

Appropriation, fiscal year 2021	\$855,421,000
Budget request, fiscal year 2022	878,957,000
Committee Recommendation	897,812,000
Change from enacted level	+42,391,000
Change from budget request	+18,855,000

Mission.—NCATS was established to transform the translational process so that new treatments and cures for disease can be delivered to patients faster.

Clinical and Translational Science Awards (CTSA) Program.—The Committee includes \$616,183,000 for the CTSA Program, an increase of \$29,342,000 above the fiscal year 2021 enacted level and \$14,683,000 above the fiscal year 2022 budget request. The Committee notes that while the CTSA program works to advance the full spectrum of medical research and modernize our research enterprise, as demonstrated by the CTSA hubs being a driving force behind the Federal effort to rapidly develop COVID–19 treatments, diagnostic tools, and vaccines. Central to the ongoing success of the CTSA consortium are individual CTSA hubs that form a nationwide network. The Committee directs NCATS to maintain the current size of the core awards supporting CTSA hubs, including the institutional partners that are part of the hubs, and historic structure of the CTSA program. This ongoing approach reflects the central role of the hubs, including each hub’s partners, as critical national research infrastructure and the core of the CTSA Consortium. The Committee reiterates previous guidance that NCATS duly inform the Committee of any planned changes to the size of awards, scope of the program, or strategic direction of emerging or ongoing CTSA initiatives. Further, NIH is encouraged to further integrate the CTSA program into cross-agency initiatives that can leverage the full spectrum of medical research for progress on a variety of contemporary topics.

CTSA Diversity Supplements.—The Committee supports efforts by NCATS to promote diversity in the workforce, especially through its research supplements. The Committee encourages NCATS to ensure funding is available for its diversity research supplements for the CTSA program, and distributed equitability across CTSA hubs. Furthermore, the Committee encourages NCATS to continue funding, through the existing CTSA hubs, expanded programs that address the health inequities and significant burden of diseases and other conditions that disproportionately affect minority and special populations at both the community health and individual levels through a variety of funding mechanisms. Enhancing this capacity will contribute to reducing health disparities and promote health equity. The Committee also encourages continued support for CTSA efforts to engage communities for the purposes of educating community stakeholders and implementing proven clinical programs and treatments, including vaccines. Applying the CTSA

model to address longstanding regional health disparities can provide innovative, multi-disciplinary approaches to reducing the burden of disease among vulnerable populations.

Collaboration with Business Incubators.—The Committee urges NCATS to explore ways to increase the success in meeting its mission by exploring funding opportunities or potential collaborations with business incubators that host small to midsize science, research, and pharmaceutical companies that use services-based approaches to nurture and guide the member companies to success. Collaborations with such business incubators may offer the most effective way to advance translational science. Priority consideration should be given to nonprofit life science incubators that seek to advance biotechnology, maximize synergies between nonprofit scientists and their commercial colleagues, and launch new ideas and discoveries that will make a difference including drug discovery, biomarker discovery and translational biotechnology around common research themes in an environment conducive to interaction, collaboration, and focus.

Rare Disease Research.—The Committee recognizes the incredible unmet need in the rare disease research community and encourages NCATS to expand rare disease funding opportunities, including, but not limited to, the Rare Diseases Clinical Research Network. Accelerating rare disease research will allow society to capitalize on the evolution of science in rare diseases, leading to new treatments for the more than 95 percent of rare diseases without approved therapies and lowering the nearly \$1 trillion annual economic burden of rare diseases.

Cures Acceleration Network.—The Committee includes \$60,000,000 for the Cures Acceleration Network, the same as the fiscal year 2021 enacted level. The Committee does not include bill language proposed in the budget that would establish this program as a percentage of the NCATS appropriation.

JOHN E. FOGARTY INTERNATIONAL CENTER (FIC)

Appropriation, fiscal year 2021	\$84,044,000
Budget request, fiscal year 2022	96,322,000
Committee Recommendation	96,842,000
Change from enacted level	+12,798,000
Change from budget request	+520,000

Mission.—FIC’s mission is to support and facilitate global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

COVID–19 has shown the importance of FIC’s essential role in global infectious disease health research training, pandemic preparedness, and global health security by assisting low- and middle-income countries (LMICs) in advancing their own research and health solutions and tools. The FIC has developed important partnerships in countries to not only fight infectious diseases, but also to build their capabilities to detect and treat infectious diseases. The COVID–19 pandemic illustrates the importance of FIC’s efforts to strengthen country capacity to enable cutting edge research at the origin of outbreaks, improving the likelihood that emerging diseases can be addressed at their source—ultimately protecting

American health security. The Committee believes these long-standing relationships and unique capabilities position FIC to play an important and expanded role in pandemic preparedness, including developing a network of modeling hubs and joint research programs to engage LMIC investigators to collaboratively train for pandemic preparedness. The Committee requests information from FIC in the fiscal year 2023 Congressional Budget Justification about how FIC training programs and research collaborations have, and with additional resources can, increase efforts to advance global health security and pandemic preparedness. The Committee is particularly interested in understanding FIC’s unique capabilities and capacities as well as coordination with other Federal government agencies engaged in these efforts.

Health Disparities Research.—The Committee includes an increase of \$10,000,000 for FIC to support additional research related to identifying and reducing health disparities, as requested in the fiscal year 2022 budget.

NATIONAL LIBRARY OF MEDICINE (NLM)

Appropriation, fiscal year 2021	\$463,787,000
Budget request, fiscal year 2022	474,864,000
Committee Recommendation	486,769,000
Change from enacted level	+22,982,000
Change from budget request	+11,905,000

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

OFFICE OF THE DIRECTOR (OD)

Appropriation, fiscal year 2021	\$2,411,110,000
Budget request, fiscal year 2022	2,237,259,000
Committee Recommendation	2,667,385,000
Change from enacted level	+256,275,000
Change from budget request	+430,126,000

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

The items below include issues and programs specific to the Office of the Director as well as those that involve multiple Institutes and Centers.

Addressing Maternal Mental Health Gaps.—The Committee recognizes growing evidence that maternal mental health has long-

reaching effects on the physical, intellectual, and emotional development of a woman's children. Pregnancy-related mortality in the U.S. has steadily increased from 7.2 deaths per 100,000 in 1987 to 17.3 deaths per 100,000 in 2017. Black mothers are three to four times more likely than White mothers to die from complications related to pregnancy or childbirth. Maternal mental health disorders and associated symptoms are common, and cases often go unreported and untreated. The societal cost of untreated perinatal mood and anxiety disorders (PMADs) can reach \$14.2 billion, and those with PMADs have a higher risk of suicide, cesarean deliveries, and work absenteeism and presenteeism. The COVID-19 pandemic has exacerbated the mental and physical toll on pregnant and postpartum mothers. The Committee directs NIH to provide a report within 180 days of enactment of this Act with the number and description of research grants awarded over the past three fiscal years that address maternal mental health outcomes for women who are pregnant and one year postpartum. Further, the Committee encourages the Department to ensure mental health is incorporated in any efforts to reduce maternal mortality rates.

Adult Cellular Therapies.—To support collaborative evidence development, the Committee encourages NIH, in coordination with FDA and HRSA, to continue efforts to enhance transparency regarding outcomes from adult cellular therapies that are FDA-approved or being administered under FDA Investigational New Drug or Investigational Device Exemption protocols by ensuring that results are submitted to appropriate databases, such as the Stem Cell Therapeutic Outcomes Database and ClinicalTrials.gov.

Advancing Cell-Based Therapies.—The Committee recognizes that adult cell-based therapies hold promise for a broad range of conditions, including neurological conditions, musculoskeletal conditions, cancer, radiation damage, cardiovascular disease, diabetes, wound healing, and immunological disease, including COVID-19. While results of early clinical studies are promising, the primary barrier to advancing such therapies is the significant cost of conducting large-scale, randomized clinical trials—especially among academic and research institutions and small biotechnology companies—which are a precursor to bringing safe and effective therapies to patients.

Therefore, the Committee directs NIH to develop and submit a report within 180 days of enactment of this Act that describes current NIH funding for adult cell-based therapies, disaggregated by Institute and Center, and plans to support and expand investments in such therapies. Such report shall describe plans to support clinical trials; the characterization, optimization, and scaling of manufacturing of cell-based therapies; and collaborative evidence development, including the development and operation of an outcomes database. The Committee encourages NIH to consult outside experts, including researchers who have conducted clinical trials involving adult cell-based therapies, to inform its activities related to cell-based therapies.

All of Us Program.—The Committee provides a total of \$541,000,000 for the All of Us precision medicine initiative, \$41,000,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The total includes

\$150,000,000 authorized in the 21st Century Cures Act (P.L. 114–255) to be transferred from the NIH Innovation Account.

The All of Us initiative is a historic effort to collect data from over one million people living in the U.S. to accelerate research and improve health and serves as a national research resource to support thousands of studies, spanning various health conditions including COVID–19. More than 75 percent of these participants are from communities historically underrepresented in biomedical research, and more than 50 percent are from racial and ethnic minority groups. The Committee encourages NIH to increase its outreach through a network of trusted community engagement partners to continue enrollment of participants from diverse and underserved populations.

ALS Research Coordination and Acceleration.—The Committee is aware of the significant need to expand scientific understanding of amyotrophic lateral sclerosis (ALS) and to translate ALS science more rapidly into effective treatments that can make ALS a livable disease. To achieve these outcomes as soon as possible, the Committee directs NIH to organize a trans-agency initiative to develop an ALS research strategic plan. The plan, which should be developed in collaboration with the nation’s leading ALS patient and biomedical research organizations, should: identify the most promising areas of research and the specific NIH activities where additional funding could lead to more rapid translation of discoveries for treatments, prevention, and interventions or technologies that can reduce the burden of ALS; identify which Institutes and Centers are undertaking ALS and ALS-related research and which are not but have a role to play; and uncover any impediments to ALS research. As part of this effort, NIH should hold at least one public meeting at which stakeholders can provide testimony. This effort should include, but not be limited to: NINDS, NIA, NIEHS, NIMH, NHGRI, NIAMS, and NCATS.

Additionally, The Committee strongly supports the Transformative Research Award program for ALS and directs the Director to continue to fund this critical initiative in fiscal year 2022.

Finally, the Committee includes \$1,000,000 to commission a study by NASEM to identify and recommend actions for the public, private, and nonprofit sectors to undertake to make ALS a livable disease within a decade. Given the significant adverse physical, financial, psychological impact this progressive neurodegenerative disease has on the individuals and families affected by it, a comprehensive assessment of what is necessary to address its effects is warranted. The study should include, but not be limited to: how to develop more effective and meaningful treatments and a cure; interventions to reduce and prevent the progression and complications of ALS; the type and range of care and services people and families with ALS need and how to ensure they receive comprehensive, quality care; what care, services, and preventive measures people at-risk of ALS need; and how to improve the quality of life, health, and well-being of affected individuals and families. The Committee directs NIH to submit this study to the Committee no later than October 2024 and requests an update on the status of this study in the fiscal year 2023 Congressional Budget Justification.

Amyloidosis.—The Committee directs NIH to continue its expansion of research efforts in amyloidosis, a group of rare diseases characterized by abnormally folded protein deposits in tissues. Amyloidosis is often fatal, and there is no known cure. Current methods of treatment are risky and unsuitable for many patients. Average survival without treatment is in months. The Committee directs NIH to provide an update in the fiscal year 2023 Congressional Budget Justification on the steps NIH has taken to expand research into the causes of amyloidosis and the measures taken to improve the diagnosis and treatment of this devastating group of diseases.

Autoimmune Neuropathies.—The Committee notes the effect that the pandemic had on the progress of a state-of-the-science conference on autoimmune neuropathies research into conditions like Guillain-Barre syndrome and chronic inflammatory demyelinating polyneuropathy. The Committee supports continued efforts on establishing this critical conference.

Biomedical Research Facilities.—The Committee includes \$50,000,000, the same as the fiscal year 2021 enacted level and \$50,000,000 above the fiscal year 2022 budget request, for grants to public and/or nonprofit 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 make awards that are large enough to underwrite the cost of a significant portion of newly constructed or renovated facilities.

Biomedical Research Workforce Diversity.—The Committee is concerned with the impact of COVID-19 on the diversity of the biomedical research workforce, particularly women and women of color at risk across career stages. The Committee strongly encourages NIH to study the race and gender breakdown of the impact of COVID on participation in the workforce by monitoring the types of awards applied for and granted by gender, race, and ethnicity for two years. If the data demonstrate that fewer women are applying for grants, then it is imperative that NIH take steps to address this disparity. The Committee requests a status update from NIH on this research in the fiscal year 2023 Congressional Budget Justification as well as the steps being taken to maintain and stabilize the diversity of the biomedical research workforce.

Biosafety Labs.—The Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends as a special practice the reporting of all laboratory incidents and near misses in Biosafety Lab (BSL) BSL-3 and BSL-4 laboratories. The Committee directs NIH to ensure all funding for BSL-3, BSL-4, high containment laboratory, or any entity involved in managing Hazardous Biological Agents both foreign or domestic maintains up to date, comprehensive policies, to promote optimal Biosafety and Biosecurity practices. Such policies must reference (1) incident reporting, (2) roles and responsibilities, (3) training, (4) inventory control, and (5) inspections and must be reported to NIH and/or related agencies.

Black Men and Women Pursuing Medicine and Science.—The Committee supports the efforts of the National Academies Roundtable on Black Men and Black Women in Science, Engineering, and Medicine and its efforts to develop specific programs to increase numbers and effectiveness of Black Men and Women pursuing medicine and science. The Committee directs the Director to allo-

cate increased resources from the Common Fund of the diversity program consortium to the National Academies Roundtable on Black Men and Black Women in Science, Engineering, and Medicine to address the increasing underrepresentation of Black men in medical schools and in the biomedical research profession. In addition, the Committee recognizes the need to increase the number of biomedical research professionals as leaders in critical areas of national need. The Committee directs NIH to establish a scholarship program that encourages African American students to pursue a career in medicine, science, and biomedical research to combat the persistent decline of Black male physicians over the last decade.

Brain Cancer.—The Committee recognizes that certain types of brain cancers are associated with high mortality and morbidity rates. Primary brain tumors, such as glioblastoma multiforme, have a five-year survival rate of five percent in adults and less than 20 percent in children. Certain brain tumors that occur in humans also occur spontaneously and naturally in dogs. These brain cancers in dogs share many of the same molecular underpinnings of their human counterparts. There is great potential for developing treatments for brain cancers that will benefit dogs and humans and provide an intermediate step to evaluate human treatments in a more meaningful and related species. The Committee encourages NIH to continue to support research that brings together researchers and clinicians from pediatrics, adult oncology, veterinary medicine, and biomedical engineering to leverage the linkage between brain cancers in dogs and humans in order to evaluate and develop treatments and safe delivery systems to benefit both species.

Center for Alternatives to Animals in Research and Testing.—The Committee directs NIH to submit a plan not later than 180 days after enactment of the Act for the establishment of a Center for Alternatives to Animals in Research and Testing within NIH, for the purposes of (1) developing, promoting, and funding alternatives to animal research and testing, and (2) developing a plan for reducing the number of animals used in Federally funded research and testing.

Childhood Post-Infectious Neuroimmune Disorders.—The Committee continues to be concerned that some children, following streptococcal and other infections, may experience the onset of neuropsychiatric and behavioral disorders. These auto-inflammatory encephalopathic conditions include Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-onset Neuropsychiatric Syndrome (PANS). Due to a paucity of research and limited avenues of treatment, children continue to encounter significant delays in identification and treatment, resulting in escalation of mental health symptoms and associated costs. The incidence of neurological and psychiatric symptoms associated with SARS-CoV-2 underscores the need for research that expands our understanding of neuropsychiatric illness following infection. Because these complications lie at the nexus of medical and mental health, investigations into their mechanisms have far-reaching implications. The Committee encourages NIH to explore cross-disciplinary research in this area, including neurobiology, neurology, immunology, rheumatology, infectious disease, and mental health, and report to

the Committee in the fiscal year 2023 Congressional Budget Justification on the understanding of the incidence, causes, diagnostic criteria, and treatment of these conditions.

Chronic Fatigue Syndrome.—The Committee encourages NIH to expand ME/CFS efforts such as new ME/CFS disease specific funding announcements to deliver needed diagnostics and treatments as quickly as possible and mechanisms to incentivize researchers to enter the field.

Cockayne Syndrome.—The Committee recognizes that Cockayne Syndrome is a rare hereditary autosomal recessive disorder that disproportionately impacts children. It has no known treatments, therapies, or cures. Cockayne Syndrome presents unique research challenges for many reasons, including difficulty in accruing enough patients to participate in clinical trials and a lack of industry focus on such rare genetic diseases due to the relatively small number of patients diagnosed with this disease. The Committee strongly encourages NIH to expand funding on research on Cockayne Syndrome, including but not limited to gene replacement therapy.

Collection and Reporting of Animal Research Numbers and Agency Funding.—The Committee recognizes that Congress has long expressed an interest in reducing the use of nonhuman animals in NIH-funded research and replacing animals with valid, reliable alternatives. In the National Institutes of Health Revitalization Act of 1993, Congress first requested that the agency create a plan for doing so. The Committee also recognizes the scientific community’s Stated commitment to the “three Rs” of replacement, reduction, and refinement. Integral to that commitment are the accurate counting of animals used in research and testing and the accurate reporting of NIH funding dedicated to projects involving animals. The Committee recognizes that it has been NIH’s policy since 1985 to collect an “average daily inventory” of vertebrate animals housed in research facilities that wish to receive agency funding. The Committee understands that domestic facilities are required to file such documentation every four years as part of an Animal Welfare Assurance and that copies of the documents are available to the public only through Freedom of Information Act requests. The Committee requests a report from NIH within 120 days of enactment of this Act outlining a plan for increasing the accuracy and transparency of collecting and publicly disseminating research animal numbers. The plan should explain how NIH will collect the information annually and include a draft form that requires the total number of animals per species bred and used in the previous year and assigns all animals to a pain and distress category. The plan should also include details on how NIH will create a publicly accessible online database for dissemination of this information. Secondly, the Committee requests that NIH include in its report a plan for implementing a system that tracks which agency-funded projects involve the use of animals and makes the information publicly accessible. The Committee recognizes that NIH currently collects such information with every grant application using the Research & Related Other Project Information form, which asks applicants to answer “Yes” or “No” to the question “Are Vertebrate Animals Used?” NIH’s plan should ensure that the answer to that question for each funded project is searchable via the Expenditures

and Results module of NIH's Research Portfolio Online Reporting Tools website as many other categories of information are.

Common Fund.—The Committee recommends \$657,112,000 for the Common Fund (CF), and an additional \$12,600,000 provided to support the Gabriella Miller Kids First Research Act for the seventh year of the ten-year Pediatric Research Initiative. This is \$21,173,000 above the fiscal year 2021 enacted level and \$11,173,000 above the fiscal year 2022 budget request.

COVID-19 Technology Access Pool.—The Committee understands that the World Health Organization has developed a COVID-19 Technology Access Pool (C-TAP), which aims to facilitate access to COVID-19 health products by sharing intellectual property through pooling and voluntary agreements. The Committee strongly urges the Secretary, in partnership with NIH, to consider what contributions NIH could make to C-TAP.

Cybersecurity.—The Committee includes an increase of \$100,000,000 to support expanded cybersecurity efforts at NIH, as requested in the fiscal year 2022 budget. Funding will enhance Security Operations Center functions, expand threat mitigation and incident response capabilities, implement important architectural improvements to the NIH network, and implement tools and technologies to allow real time monitoring of activity across a variety of sources.

Diversity at NIH Working Group and Strategic Plan.—The Committee is encouraged by NIH's demonstrated commitment to diversity and thanks the NIH for acting on the fiscal year 2021 request to develop a strategic plan that includes long- and short-term goals to address disparities at NIH. The Committee understands that NIH is beginning robust outreach to traditionally marginalized communities to lay the foundation for a comprehensive strategic plan and encourages NIH to continue this line of work in order to fully understand the scope of need in this area, properly make recommendations, then develop and implement strategies to increase inclusivity and diversity in biomedical science while aligning with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. The Committee directs NIH to provide quarterly briefings to the Committee on the progress of the development of the strategic plan.

Diversity in NIH Clinical Trials.—While 40 percent of Americans belong to a racial or ethnic minority, 80 to 90 percent of participants in clinical trials are White. Patients in underserved communities are often less comfortable enrolling in clinical trials or are unaware of how to do so, excluding them from the opportunity to access potentially lifesaving treatment. Further, it is essential that NIH researchers develop a comprehensive understanding of how treatments impact various populations. The Committee encourages NIH to increase proactive outreach efforts to patients in minority and underrepresented communities and providers serving these populations, to improve awareness of clinical trials and understanding of how patients can participate.

Duchenne Muscular Dystrophy.—Duchenne muscular dystrophy is a severe form of muscular dystrophy for which there is no cure and for which life expectancy is in the second or third decade. The Committee urges NIH to establish a framework for data sharing

and sharing of specimens generated or collected within six months of completion of any NIH-funded clinical study. The Committee also urges NIH to support methodological research on challenges related to gene therapies, such as enabling delivery to individuals with neutralizing antibodies to viral vectors, manufacturing supply to ensure all patients can receive treatment, and minimizing potential life-threatening immune response to high viral doses.

Early Career Researchers.—The Committee recognizes the importance of awards intended to support training of early-stage researchers, including physician scientists. The Committee is also aware of the negative impact the ongoing COVID-19 pandemic has had on research career trajectories and that these challenges are particularly burdensome on early-career researchers who have yet to achieve research independence. The Committee commends NIH for allowing holders of fellowship and career development awards to apply for funded and no-cost extensions but is concerned about the possibility of uneven levels of support between Institutes and Centers, unclear qualifying standards, and demand that may exceed resources. To address these concerns, the Committee encourages NIH to develop and disseminate a standardized approach to support eligible investigators across Institutes and Centers.

The Committee also encourages NIH to develop a funding opportunity for a trans-NIH early career development award targeted to investigators working in pediatrics that would build upon the Next Generation Researchers Initiative and other initiatives and to provide an update on these efforts to Congress within 180 days of enactment of this Act.

Eating Disorders.—The Committee commends NIH for supporting multi-Institute research on the chronic, fatal, and serious mental illnesses encompassing eating disorders that affect 30,000,000 Americans during their lifetimes, and its association with other conditions such as diabetes, infertility, heart disease, PTSD, substance use, co-morbid mental illnesses, and tooth decay. The Committee encourages NIH to increase support for eating disorders research and encourages the relevant Institutes and Centers, including NIMH, NIMHD, NICHD, and NIDA, to collaborate to address research gaps in genetics, prevention, diagnosis, and treatment of eating disorders.

Ehlers-Danlos Syndrome.—The Committee encourages NIH to support research and activities with respect to Ehlers-Danlos Syndrome and related connective tissue disorders.

Environmental Influences on Child Health Outcomes (ECHO).—The Committee includes \$180,000,000, the same as the fiscal year 2021 enacted level and the fiscal year 2022 budget request, for the ECHO Project, which has the potential to greatly increase understanding of critical determinants of health across the lifespan, through its observational cohorts and the IDeA States Pediatric Clinical Trials Network. The Committee encourages continued communication about to the program's progress toward goals, milestones, and projected funding estimates with both external stakeholders and Congress. The Committee includes funding for ECHO in the Office of the Director, consistent with previous years.

Federal Advisory Committees Transparency Initiative.—The Committee recognizes that Federal advisory committees established pursuant to 42 U.S.C. 282(b)(6) fill an important role in advising

NIH on major decisions on plans and policies. However, to guarantee due process, it is vital that all NIH Federal advisory committees operate in a transparent way. The Committee recognizes that one particular NIH Federal advisory committee, the Literature Selection Technical Review Committee (LSTRC), has not made its review process clear or transparent. As such, the Committee directs the LSTRC, within 60 days of enactment of this Act, to make public all documents and any other relevant information related to its: (1) processes for and standards of review, including the scope of the review, a timeline and detailed steps of the review, and any other guidelines used to ensure objective reviews; and (2) decision-making processes and methodologies, including scoring rubrics, metrics, and any other guidelines used to ensure objective decisions. The Committee further directs the LSTRC, within 60 days of enactment of this Act, to make available detailed instructions regarding how to appeal its decisions. Moreover, the Director of NLM shall ensure and certify to the Committee that the LSTRC is operating in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., Appendix 2).

Firearm Injury and Mortality Prevention Research.—The Committee includes \$25,000,000 to support research on the prevention of gun violence, \$12,500,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request. The Committee also requires NIH and CDC to collaborate with the National Institute of Justice to compile, share, and improve firearm violence data. Such data must include the Uniform Crime Report (UCR) and include data from hospitals treating victims of nonfatal gunshot wounds.

Foreign Animal Research.—The Committee requests additional information in the fiscal year 2023 Congressional Budget Justification about how NIH monitors and ensures foreign institutions' compliance with applicable laws, regulations, and policies governing NIH-funded animal research.

Foreign Threats to Research.—Foreign actors continue to engage in the theft of intellectual property from NIH and its grantees, posing threats to national security. The Committee directs NIH to provide quarterly briefings on the progress of investigations into these efforts, as well as the institutions, scientists, and research affected. The Committee continues to direct NIH to provide \$5,000,000 to the Inspector General to continue additional investigations into this issue. The Committee also includes an increase of \$2,500,000 for the Office of Extramural Research to expand its resources dedicated to reviewing potential cases of fraud.

Fragile X.—The Committee commends NIH for funding three Fragile X Centers within the guidelines established in the Strategic Plan for Research on FMR1-Related Conditions. The Committee notes the importance of expanding the base of researchers and clinicians who are familiar with and trained in the Fragile X-associated disorders and promoting collaboration between basic scientists and clinicians to enable researchers to better understand phenotypes, document variations in how the disorder presents itself, identify potential biomarkers and outcome measures, and develop new interventions. The Committee also commends NIH for recognizing the ethical, legal, and social issues in premutation screening and testing and encourages NIH to look at existing pilot

studies that are exploring innovative ways to screen newborns, and to coordinate efforts and research with the CDC as they consider screening solutions for FMR1-related conditions.

Gabriella Miller Kids First Pediatric Research Program.—The Committee recognizes that pediatric cancer is a leading cause of death among children and is still poorly understood. Childhood cancer also has lasting negative health effects on children who do survive due to the high levels of toxicity associated with treatment. The Committee acknowledges that the Gabriella Miller Kids First Pediatric Research Program enables researchers to uncover new insights into the biology of childhood disease. Since its inception, Kids First has initiated the Gabriella Miller Kids First Data Resource Center, which is a comprehensive data resource for research and patient communities meant to advance discoveries. The Committee recognizes the progress that the Program has made towards understanding childhood cancer and disease and provides \$12,600,000 to support pediatric research as authorized by the Gabriella Miller Kids First Research Act (P.L. 113–94).

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 recognizes the need to better understand the interactions between genetics and environmental factors, in particular with older and diverse populations of African Americans and Latinos. The Committee encourages NIH to accelerate collaborative research across relevant Institutes and Centers 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.

Harassment Policies.—The Committee is deeply frustrated by NIH’s failure to implement its direction to address harassment in extramural research settings. Both the Statement of managers accompanying the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) and the Consolidated Appropriations Act, 2021 (Public Law 116–260) directed NIH to revise its guidance to make clear that grantees must identify any changes to key personnel on an award that are related to concerns about harassment. The Committee has included a new general provision to require institutions that receive NIH funding to notify the agency when key personnel are removed from their position for harassment.

Health Disparities for Persons with Disabilities.—Despite being uniquely affected by COVID–19, people with disabilities experienced gaps and inequities in health care in the response to the COVID–19 pandemic. This illustrates that there is a need for increased data collection to provide policymakers with necessary information to improve pandemic planning and outcomes. The Committee strongly encourages NIH to examine health and health care inequities more broadly for people with disabilities, including those with physical, sensory, cognitive, intellectual and developmental, and psychological disabilities. The Committee strongly encourages

NIH to fund research on identifying inequities in health and health care for people with disabilities and to support research that develops and evaluates interventions to reduce these disparities, including approaches that focus on addressing systemic and community-level barriers.

HEALthy Brain and Child Development (HBCD) Study.—The Committee recognizes and supports the HEALthy Brain and Child Development Study, which will establish a large cohort of pregnant women from regions of the country significantly affected by the opioid crisis and follow them and their children for at least 10 years. This knowledge will be critical to understanding typical brain development and how pre- and postnatal exposure to opioids and other substances or adverse environments affect brain development and other outcomes, including risk for future substance use, mental health disorders, and other behavioral and emotional difficulties and disorders. The Committee recognizes that the HBCD Study is supported in part by the HEAL Initiative, and NIH Institutes, Centers, and Offices, including OBSSR, ORWH, NIMHD, NIBIB, NIEHS, NICHD, NINDS, NIAAA, NIMH, and NIDA, and encourages other Institutes and Centers to support this important study.

Hearing Health Screening for Older Americans.—The Committee recognizes the associated comorbidities and costs of untreated hearing loss and, with the growing aging population, the importance of hearing screening for older Americans. The Committee urges NIH to provide an update in the fiscal year 2023 Congressional Budget Justification on hearing screening research for older adults across the NIH. The Committee encourages NIDCD and NIA to support studies that address the research needs and gaps identified by the U.S. Preventive Services Task Force (USPSTF) review of hearing screening recommendations for older Americans.

Hepatitis B.—The Committee recognizes the estimated \$4 billion of annual medical costs associated with the care and treatment of those infected with the hepatitis B virus and urges NIH to redouble its efforts to identify more effective treatments for the disease. While there are treatments available to control HBV, they must be taken for years if not for life. Without treatment, one in four of those infected will die prematurely from cirrhosis, liver failure, and/or liver cancer. This serious public health threat results in over 800,000 worldwide deaths each year, making it the tenth leading cause of death in the world. The Committee commends NIH for its support in the development of the 2019 Strategic Plan for Trans-NIH Research to Cure Hepatitis B and urges NIH to help implement the plan by issuing new targeted calls for research. The Committee requests that NIH support an update of the Strategic Plan for Trans-NIH Research to Cure Hepatitis B and that it submit it to the Committee, within 180 days of enactment of this Act, a specific plan to pursue a cure for hepatitis B in coordination with the Trans-NIH Hepatitis B Working Group.

Humane Research Alternatives.—Recognizing that humane, cost-effective, and scientifically suitable non-animal methods are available but underutilized, the Committee requests that NIH assemble a panel to investigate and make recommendations regarding incentives for more quickly and effectively moving NIH intramural and external research away from methods that rely on animals to meth-

ods that rely on non-animal methods including epidemiological and clinical studies, cell-based methods, computer modeling and simulation, and human tissue studies. The panel should review and recommend means of encouraging greater reliance on human-relevant non-animal methods/approaches. Panel membership should include individuals with proven knowledge of/experience with non-animal research methods; with expertise in evaluating the adequacy of searches for non-animal methods/approaches described in research proposals; and with knowledge of the welfare concerns and scientific limitations of animal-based studies. The Committee asks that NIH provide a report of the panel's findings within 60 days of enactment of this Act.

Impact of Technology and Digital Media Use Among Infants, Children, and Teens.—The Committee remains concerned about the impacts of technology use and media consumption on infants, children, and adolescents, especially during the COVID-19 pandemic. COVID-19 has resulted in closures of schools, sports, and extracurricular activities giving children less access to offline social opportunities and resulting in increased time children spend on screens and digital media. The Committee appreciates NIH's ongoing engagement on this important topic and encourages NIH to prioritize research into the cognitive, physical, and socioemotional impacts of young people's use of technologies as well as long-term developmental effects on children's social, communication and creative skills. The Committee also encourages NIH to study the repercussions of increased use of digital media and technologies on suicidal thoughts and ideation among children. The Committee encourages NIH to consider different forms of digital media and technologies including mobile devices, smart phones, tablets, computers, and virtual reality tools, as well as social-media content, video games, and television programming.

INCLUDE Initiative.—The Committee includes no less than \$80,000,000, an increase of \$15,000,000 above the fiscal year 2021 enacted level, within OD for the INCLUDE Initiative. The Committee is pleased that this multi-year, trans-NIH research initiative has enabled significant advances in understanding immune system dysregulation, new research into the connection with Alzheimer's disease, and the creation of national Data Coordinating Center, all of which may dramatically improve the health and quality of life of individuals with Down syndrome as well as millions of typical individuals. The Committee encourages NIH to pursue some of the most neglected areas of research and care such as health disparities for African Americans with Down syndrome, mosaic Down syndrome, those with the dual diagnosis of Down syndrome and autism, and new studies on metabolic dysregulation. The Committee requests the Director provide an updated plan within 60 days of enactment of this Act 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 and increase pipeline research initiatives specific to Down syndrome.

Indoor Amplified Microbial Growth Research.—The Committee believes that a more robust and focused NIH commitment to research relating to mold and amplified microbial growth in damp

and water-damaged buildings would yield significant advancements of knowledge and insight regarding how fungi, mycotoxins, actinobacteria, and endotoxins within indoor environments affect public health. The Committee urges NIH to expedite planned and ongoing studies already nominated and established through the National Toxicology Program (NTP). The Committee is concerned that some of these studies were nominated in 2001 but have yet to be conducted. The Committee also urges NIH to prioritize new research, explore the causal links, and interventions to the potential neurotoxic, immunosuppressive, immunoreactive, autoimmune, nephrotoxic, carcinogenic, and inflammatory responses due to inhalation of indoor amplified microbial growth in damp and water-damaged indoor environments. The Committee encourages NIH to improve applied research, communication and education, and coordination with other Federal, State and local health and environmental agencies regarding mold and microbial growth in damp and water-damaged indoor environments. The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on its efforts.

Inflammation.—Inflammation is one of the body’s major defense mechanisms in response to infection or injury, but when it is uncontrolled, it causes inflammatory diseases such as cardiometabolic diseases (such as hypertension, obesity, and diabetes), neurodegenerative diseases (such as Alzheimer’s disease and dementia), and mood disorders (such as depression). The Committee supports and encourages NIH to fund research into how inflammation may contribute to these various disorders.

Inflammatory Bowel Disease (IBD).—The Committee is aware of current and emerging NIH priorities focused on nutrition, including the recently finalized Strategic Plan for NIH Nutrition Research and the Common Fund’s Nutrition for Precision Health initiative. Given these priorities, the Committee encourages NIH to coordinate across Institutes and Centers focused on nutrition research to support research to understand the relationship between food and immune-mediated conditions, including IBD. This may include research on the development of evidence-based anti-inflammatory diets and the roles such diets can play in managing IBD and other immune-mediated conditions.

Lung Cancer Research.—The recent decline in cancer mortality that has been fueled by progress in lung cancer is directly attributable to NIH-funded research. Advances in the understanding of the molecular underpinnings of lung cancer and the identification of additional oncogene driver subsets has led to rapid development of new targeted therapies, which together with efforts to broaden uptake of comprehensive biomarker testing, has the potential to deliver the promise of precision medicine to more patients than ever before. The Committee therefore encourages the NIH to continue supporting important research across these areas, to broaden the base of lung cancer survivors across different disease types, including small cell lung cancer.

Lyme and Other Tick-Borne Diseases.—The Committee encourages NIH to support research on early diagnosis and treatment of Lyme and other tick-borne diseases (TBD) to prevent the development of late stage disease and more serious and longer-term disability, but also to intensify research on diagnosis and treatment

of late stage and chronic disease. Priority should be based on disease burden, which CDC has indicated for Lyme disease to be approximately 476,000 people diagnosed and treated annually in the U.S. Lyme has a significant patient population who are not diagnosed until late stage, when treatment is more difficult, and a significant percentage of patients who relapse and go on to develop chronic symptoms. Along with development of highly sensitive and specific diagnostics for all stages of disease, a goal should be to develop diagnostics with appropriate sensitivity and specificity for the detection of subclinical or low-level infection for use in disease eradication. Treatments for all stages of Lyme and other TBD, determining optimal combinations of new candidate or older drugs and exploring novel combinations should be developed. Although a cure may be defined to include sustained remission, a goal of treatment should be eradication of the pathogen, in which case resurgence is not possible.

The Committee is gratified that NIH officials have recognized the need for further exploration of maternal-fetal or vertical transmission of Lyme disease and the occurrence of adverse outcomes among women with untreated and disseminated Lyme disease during pregnancy. The Committee encourages NIH to intensify research on adverse outcomes related to Lyme disease during pregnancy and to continue to participate with Lyme advocacy organizations on these issues.

Maintenance of Chimpanzees on U.S. Air Force Bases.—The Committee remains concerned about NIH's intention to retain government-owned chimpanzees at the Alamogordo Primate Facility (APF), a laboratory facility, instead of retiring them to the national chimpanzee sanctuary, Chimp Haven. While NIH cites the health condition of the chimpanzees as a reason to warehouse them at APF, the health condition of the chimpanzees and their long history of laboratory use makes it urgent that they be provided an opportunity to live the remainder of their lives in sanctuary, even if for a short period. The Committee directs the NIH to resume transport of government-owned and supported chimpanzees beginning with chimpanzees at APF. Movement of chimpanzees from Southwest National Primate Research Center (SNPRC) and Keeling Center for Comparative Medicine and Research (KCCMR) should follow transport of the APF chimpanzees to Chimp Haven. The Committee also directs the NIH to provide a written report to the Committee every 180 days, beginning no later than December 31, 2021, that shall include: (1) the number of chimpanzees transported to the national sanctuary over the last quarter; (2) a census of all government-owned and supported chimpanzees remaining, if any, at APF, SNPRC or KCCMR; (3) a list of any chimpanzee deaths that have occurred at any time after January 1, 2020, at either APF, SNPRC, KCCMR, or the national sanctuary system, and (4) the plan, including the timeline, for transferring the chimpanzees from APF, SNPRC, and KCCMR to Chimp Haven.

Maternal Infections.—The Committee requests an update on research to better understand and prevent congenital cytomegalovirus in the fiscal year 2023 Congressional Budget Justification.

Modeling and Simulation Technology Deployment.—The Committee encourages NIAID, NIBIB, and other NIH Institutes and

Centers as appropriate, to support the development and study of in silico approaches to accelerate vaccines for emerging infectious diseases including, but not limited to, computational simulation, data analytics, and the digital patient model, with the objective of reducing the time to market for virus vaccines.

National Laboratories.—NIH funding supports investments which are collaborative with the ongoing work of the Department of Energy. The Committee directs NIH to provide an update in the fiscal year 2023 Congressional Budget Justification on the work to coordinate its efforts with DOE and the National Laboratories, and in more strategic ways to leverage NIH's research needs in the next generation of cancer research, brain mapping, drug development or other emerging ideas in biomedical research that would benefit from DOE's instrumentation, materials, modeling simulation, and data science. In 2015, the Secretary of Energy established the Energy Advisory Board (SEAB) to evaluate the prospects for increased collaboration between DOE researchers and biomedical scientists supported by other agencies, especially NIH. Increased and more effective coordination could be instrumental to assist in the development of the Nation's health, security, novel biomedical technologies, and in the development of more strategic enabling technologies. The Committee supports NIH's collaboration with DOE and the National Laboratories in an effort to maximize utilization of DOE's capabilities, particularly for NIH's rapidly growing data and computational challenges, and encourages NCI to build off the success of previous initiatives and consider additional pilots to address key computation and imaging bottlenecks in cancer research.

National Primate Research Centers.—The Committee does not include funding directed towards expanding non-human primate resource infrastructure. The budget request included \$50,000,000 for this activity.

National SARS-CoV-2 Genomic Surveillance Program.—New SARS-CoV-2 variants continue to emerge across the globe, including variants that may have increased transmissibility and potential to evade vaccines. This dire situation demonstrates the need for a comprehensive genomic sequencing and surveillance program to discover and track the spread of these variants and devise appropriate public health countermeasures. The Committee directs NIH and CDC, in coordination with other HHS agencies as appropriate, to continue to expand national genomic surveillance to rapidly scale up sequencing of viral samples and dissemination of SARS-CoV-2 genomic data.

Native Hawaiian/Pacific Islander Health Research.—The Committee encourages NIH to place high priority on addressing the research needs of Native Hawaiian and Pacific Islander Health Research. The OD, in coordination with NIMHD and other Institutes and Centers, should work closely with NHPI communities and NHPI-serving organizations, which are located in States with significant NHPI populations to allow for the development of future researchers and scientists from these same communities.

Natural History Museums as Critical Contributors to Virus Research.—The Committee notes that the nation's natural history museums provide an unparalleled resource for studying zoonotic diseases such as COVID-19. These museums hold millions of animal samples collected over decades from across the globe, offer

deep and broad scientific expertise, and are uniquely positioned to assist in preparing for and predicting the next pandemic-causing viruses. The Committee encourages increased utilization and support of this largely untapped resource.

Neurofibromatosis (NF).—The Committee supports efforts to increase funding and resources for NF research and treatment at multiple Institutes, including NCI, NINDS, NIDCD, NHLBI, NICHD, NIMH, NCATS, and NEI. Children and adults with NF are at elevated risk for the development of many forms of cancer, as well as deafness, blindness, developmental delays, and autism. The Committee encourages NCI to continue to support a robust NF research portfolio in fundamental laboratory science, patient-directed research, and clinical trials focused on NF-associated benign and malignant cancers. The Committee also encourages NCI to continue to support preclinical research and clinical trials. Because NF can cause blindness, pain, and hearing loss, the Committee encourages NEI, NINDS, and NIDCD to continue to aggressively fund fundamental basic science research on NF relevant to restoring normal nerve function. 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 support laboratory-based and patient-directed research investigations in these areas. Since NF2 accounts for some genetic forms of deafness, the Committee encourages NIDCD to continue its investment NF2-related research. NF1 can cause vision loss due to optic gliomas. The Committee encourages NEI to support NF1-focused research on optic gliomas and vision restoration.

NIH Division of Police.—The Committee supports vigorous action to improve training for all Federal, State, and local law enforcement officers on racial profiling, implicit bias, procedural justice, the use of force, and the duty for officers to intervene when witnessing the use of excessive force against civilians. The Committee therefore directs the Director to work with the Attorney General and the Federal Law Enforcement Training Centers to implement improved, mandatory training on these topics for all Federal law enforcement officers, along with the development of related standards that can be applied in hiring and performance assessments. These training requirements and standards should be based on the related provisions in H.R. 1280, as passed by the House of Representatives in March 2021.

The Committee further directs the NIH Division of Police, to the extent it has not already done so, to submit its use of force data to the Federal Bureau of Investigation's National Use of Force Data Collection database. The Committee requests a briefing within 90 days of enactment of this Act on current efforts to tabulate and submit use of force data to the FBI.

Office of AIDS Research.—The Committee includes no less than \$3,290,000,000 for HIV/AIDS research, an increase of \$200,000,000 above the estimated fiscal year 2021 level.

Office of Behavioral and Social Sciences Research (OBSSR).—The Committee includes \$49,827,000 for OBSSR, an increase of \$20,000,000 above the fiscal year 2021 enacted level and \$19,523,000 above the fiscal year 2022 budget request. The Committee notes that OBSSR has the mission to enhance NIH's behav-

ioral science research enterprise across all Institutes and Centers. As multiple Surgeons General and NASEM have declared that most health problems facing the nation have significant behavioral components, the Committee strongly supports the continued strengthening of the behavioral science enterprise at NIH and urges OBSSR funding be increased to accomplish this mission. In this regard, the Committee is pleased that an NIH working group has been established to review how better to integrate and realize the benefits of overall health from behavioral research at NIH, and directs that appropriate OBSSR funding levels, authority, and organizational structure be included in this review.

Office of Nutrition Research.—The Committee is encouraged by recent efforts to prioritize nutrition research across Institutes and Centers, including the release of first NIH-wide strategic plan for nutrition research. As such, the Committee supports the transfer of the Office of Nutrition Research to OD and encourages the Director to allocate sufficient resources to this office to ensure it can operate effectively as a trans-NIH entity.

Office of Research on Women's Health.—The Committee includes \$61,480,000 for the Office of Research on Women's Health, an increase of \$17,555,000 above the fiscal year 2021 enacted level and \$9,177,000 above the fiscal year 2022 budget request. This office ensures women's health research and research on the biological and sociocultural influence of sex and gender are included within the larger NIH scientific framework. Congress recognizes that ORWH is the first public health service office to officially promote women's health research within and beyond the NIH scientific community. ORWH provides critical leadership to develop research programs like the Specialized Centers of Research Excellence (SCORE), a program designed to expedite the development and application of new knowledge to human diseases that affect women, to learn more about the etiology of these diseases, and to foster improved approaches to treatment and/or prevention. The Committee applauds ORWH's effort to encourage research across many scientific disciplines to examine how sex and gender factors influence health and contribute to various diseases. Within the total, the Committee includes an additional \$2,000,000 expand the number of sites in the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program, an initiative that aims to increase the number and skills of investigators who conduct research on sex and gender influences on health and disease. ORWH is encouraged to expand the program to less-resourced institutions, such as HBCUs, tribal colleges and Institutions of Emerging Excellence.

Office of the Chief Officer for Scientific Workforce Diversity.—The Committee includes \$22,000,000 for the Office of the Chief Officer for Scientific Workforce Diversity, \$16,000,000 above the fiscal year 2021 enacted level and the same as the fiscal year 2022 budget request.

OIG Transfer.—The Committee includes \$5,000,000, the same as the fiscal year 2021 enacted level and the fiscal year 2022 budget request, for transfer to the HHS OIG to support oversight of NIH activities.

Parkinson's disease (PD) and Dementia.—The Committee recognizes that although Parkinson's is often thought of only as a movement disorder, most PD patients also develop dementia; common

symptoms include difficulty with problem solving, speed of thinking, memory and other cognitive skills. Because people with PD usually develop these symptoms several years after their diagnosis of Parkinson's, PD represents an under-explored opportunity to study the onset and progression of dementia. The Committee strongly urges NINDS and NIA to put a higher priority on PD, both before and after onset of dementia, within their overall dementia research portfolios. The Committee requests an update on these activities in the fiscal year 2023 Congressional Budget Justification.

Polycystic Ovary Syndrome (PCOS).—PCOS affects up to 15 percent of women and is a significant risk factor for multiple cardio-metabolic conditions, such as type 2 diabetes, lipid disorders, high blood pressure, obesity, sleep disorders, and others which may significantly increase risk for adverse COVID-19 outcomes. Emerging data also link the risk of severe COVID-19 with certain factors such as low vitamin D levels, hyperandrogenism, inflammation, and ethnicity predisposition, all of which are directly associated with PCOS. The Committee encourages NHLBI, NICHD, ORWH, and NIDDK to support research investigating the risk of severe SARS-CoV-2 infection in the PCOS patient population and the strong overlap of risk factors for both worse PCOS cardio-metabolic manifestations and severe COVID-19. Findings should be disseminated to health care providers, PCOS patients, and the public, as well as highlighted for clinical practice. The Committee also encourages NIH to report on research that has been conducted on PCOS and its impact on cardio-metabolic health to date in the fiscal year 2023 Congressional Budget Justification. Finally, the Committee requests that PCOS be added to the NIH Research, Condition, and Disease Categories reporting.

Post-acute COVID and Chronic Fatigue Syndrome (ME/CFS).—The Committee commends NIH on its ongoing ME/CFS efforts, including the rapid expansion of research regarding post-acute COVID-19 syndrome (PACS) and its potential connections to ME/CFS, its leadership in the Interagency Working Group for ME/CFS, and the recent success of mapMECFS and searchMECFS projects. The Committee recognizes the scientific and clinical opportunities in post-viral research and strongly encourages NIH to continue and expand its efforts to understand the underlying causes and risk factors for individuals with PACS and ME/CFS, with a focus on diagnosis, treatment, and prevention. The Committee encourages NIH to accelerate and expand efforts related to PACS and ME/CFS; such as (1) investing and collaborating to form large data sets through patient registries, biobanks, and interdisciplinary research investment (2) issuing PACS and ME/CFS disease specific funding announcements (3) coordinating an initiative to develop consensus on the diagnosis of PACS and the selection criteria for study participants involved in ME/CFS research, and (4) implementing mechanisms to incentivize new and early career researchers to enter and contribute data to the ME/CFS scientific field.

Primary Mitochondrial Disease Research.—The Committee is aware that NIH has spearheaded a number of initiatives to identify new mitochondrial disorders, discover the linkages between mitochondrial disorders, and translate advances in mitochondrial research to treatments, cures, and other medical interventions for

mitochondrial disorders and their secondary diseases, such as Alzheimer's disease, Parkinson's disease, and cancer. Given the advancements seen through peer-reviewed research into mitochondrial disorders at several academic sites across the nation, the Committee encourages NIH to increase its funding of primary mitochondrial disease research and requests the agency provide an update on these efforts within 180 days of enactment of this Act.

Psychedelic Treatments.—Despite the recent Department of Veterans Affairs' 2020 National Veteran Suicide Prevention Annual Report that showed there were no significant increases in the veteran suicide rate from 2017 and 2018, the Committee is concerned that over 17 veterans on average continue to commit suicide each day, which is a number that has remained persistent over the past decade. There have been many recent studies and clinical trials demonstrating the positive impact of alternative therapies, including psychedelics, for treatment resistant post-traumatic stress disorder (PTSD) and major depressive disorder, particularly for veteran participants. In light of growing interest in this area, the Committee encourages NIH and other relevant Federal agencies to undertake, and where appropriate expand, research to evaluate the effectiveness of psychedelic therapies in treating PTSD, major depressive disorder, and other serious mental health conditions.

Rare Disease Research.—The Committee is aware that nearly one in ten individuals in the U.S. is affected by a rare disease, and that rare diseases frequently are genetic or have a genetic component. The Committee urges NIH to expand research on rare genetic and chromosomal abnormalities, such as 7q11.23 Duplication Syndrome and Hereditary Spastic Paraparesis 49 (TECPR2). The Committee directs NIH to provide an update on these two conditions in the fiscal year 2023 Congressional Budget Justification.

Research on Long COVID.—The Committee commends NIH for undertaking a major initiative to research the causes of, and the best ways to prevent and treat, what is often referred to as Long COVID, which occurs when individuals experience a variety of symptoms long past the time that they have recovered from the initial stages of COVID-19 illness. Symptoms can include fatigue, exercise intolerance, shortness of breath, trouble with memory and concentration, headache, sleep disorders, orthostatic tachycardia, chest, muscle and joint pains, fevers, gastrointestinal symptoms, anxiety, post-traumatic stress disorder, and depression, can last for months or longer, and can range from mild to incapacitating. In addition, it is unclear to what extent COVID-19 and its long-term effects may interact with pre-existing conditions such as vascular and neurodegenerative diseases, potentially changing their course and morbidity. The Committee directs NIH to sustain and strengthen its research into Long COVID. As part of this research, the Committee urges NIH to study Long COVID in children and youth.

Furthermore, the Committee recognizes that the COVID-19 pandemic has exposed an array of related health disparities, including a difference in severity and outcomes between female and male patients due to sex and gender influences. This is also true for individuals who continue to experience COVID-19 symptoms and/or damage to organs to varying degrees months after their initial diagnosis. To better understand how sex differences are implicated in

the severity of the COVID-19 pandemic, the Committee encourages the Institutes and Centers of the NIH in coordination with the NIH Office of the Director and Office of Women's Health Research to support research that studies how sex as a biological variable impacts short and long-term outcomes due to infection with SARS-CoV-2.

SARS-CoV-2 Genomic Sequence Data.—The Committee is concerned by reports that early SARS-CoV-2 genomic sequence data from China, specifically the Wuhan region, were withdrawn from the Sequence Read Archive (SRA) at the National Institutes of Health. The Committee is aware of allegations that the Chinese Communist Party has refused to provide raw data to international scientists and the World Health Organization to impede the investigation into the origins of Covid-19. From the beginning of the pandemic, there have been suggestions that the Chinese Communist Party barred scientists from releasing data and even delayed the release of the genetic map of the virus to the world. The Committee understands that it is difficult to identify, early in pandemics, what data may be most relevant because of the disperse nature of initial reports and the uncertainty surrounding an emerging virus—however, some scientists have cited difficulties in studying the origins of the virus due to a lack of early data from Wuhan. Furthermore, the Committee is aware that there are legitimate reasons to request the withdrawal of genomic sequence data from SRA, including insufficient data quality and incomplete consent procedures, however, the early sequence data at issue here may be key to understanding the origin of SARS-CoV-2. Within 30 days of the enactment of this Act, the Director of the National Institutes of Health shall report to the Committee on the withdrawal of SARS-CoV-2 genomic sequence data from the Sequence Read Archive. The report should include the total number of requests for withdrawals of SARS-CoV-2 data broken down by institution, the number of sequences that were subsequently withdrawn from the SRA, the reasons provided by the institution for the request for withdrawal, any characteristics provided for the sequences and other pertinent information, as well as any pending requests for SARS-CoV-2 genomic sequence withdrawals.

Sickle Cell Disease (SCD).—The Committee commends NIH for its ongoing support of clinical research for SCD, which imposes major morbidity on an estimated 90,000 to 100,000 individuals in the U.S., with three million Americans carrying the sickle cell trait. The Committee encourages NIH to support clinical trials for prenatal and postnatal treatment of SCD, which includes a wealth of promising approaches to eradicate this disease, save lives, and dramatically reduce the substantial health care costs associated with SCD for both children and adults. The NIH is encouraged to consider programs both domestically and globally to evaluate the effectiveness of screening technologies for infants and children with the sickle cell trait and disease and to develop different innovative technologies to cure SCD. The Committee encourages NHLBI and NHGRI to collaborate on research on Sickle Cell Trait. It is critical to better understand the risks for health complications and the potential link to severe illness and risk of death from COVID-19 for the one to three million Americans living with Sickle Cell Trait, the single gene mutation for SCD.

Spina Bifida Research.—The Committee encourages NIA, NIDDK, NICHD, and NINDS to study the causes and care of the neurogenic bladder and kidney disease in order 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 sudden death in the adult Spina Bifida population; 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; and report out by Institute research findings on Spina Bifida and issues related to it. 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, NIH 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 for adults as well as children. Finally, the Committee encourages NIH to support research on the potential causes behind a growing incidence and prevalence of bladder cancer in individuals with Spina Bifida.

Thalassemia.—Nutrition can be an important tool in the management of rare diseases. Currently, there is no guidance on nutrition approaches for the management of thalassemia, which occurs most often in African Americans and in people of Mediterranean and Southeast Asian descent. In addition to the possibility that thalassemia itself creates nutritional deficits, there is concern that necessary iron chelation therapy may create *additional* deficits. Research is needed to provide practitioners with evidence-based advice for patients, both on diets that would help improve and manage their condition, and those that may be harmful. The Committee encourages the Office of Nutrition Research to coordinate across NIH on the impact of nutrition on thalassemia management and current gaps in clinical understanding in this area.

Trans-NIH Pediatric Research Consortium.—The Committee is aware of the Trans-NIH Pediatric Research Consortium (N-PeRC) that was established in 2018 to better coordinate and support pediatric research activities across multiple Institutes and Centers. The Committee supports the goals and objectives of N-PeRC and requests that NIH update the Committee as to multi-Institute or Center pediatric research projects implemented as a result of N-PeRC and projects in the planning stage. Additionally, the Committee requests a report in the fiscal year 2023 Congressional Budget Justification on how N-PeRC plans to support studies of the physical, mental and behavioral health impacts of COVID-19 on children, including multisystem inflammatory syndrome in children (MIS-C), as well as plans for N-PeRC's focus over the coming three years.

Undiagnosed Diseases.—The Committee recognizes the important role the NIH-funded Undiagnosed Diseases Network (UDN) has played to improve diagnosis of rare diseases and other undiagnosed conditions and encourages NIH to continue supporting this work, including by developing a plan to sustain the work of the UDN.

BUILDINGS AND FACILITIES

Appropriation, fiscal year 2021	\$200,000,000
Budget request, fiscal year 2022	250,000,000
Committee Recommendation	250,000,000
Change from enacted level	+50,000,000
Change from budget request	---

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

NIH INNOVATION ACCOUNT

This account supports NIH programs authorized in the 21st Century Cures Act (P.L. 114–255).

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

Appropriation, fiscal year 2021	\$0
Budget request, fiscal year 2022	6,500,000,000
Committee Recommendation	3,000,000,000
Change from enacted level	+3,000,000,000
Change from budget request	–3,500,000,000

The Committee includes \$3,000,000,000 to establish the Advanced Research Projects Agency for Health (ARPA–H), \$3,000,000,000 above the fiscal year 2021 enacted level and \$3,500,000,000 below the fiscal year 2022 budget request.

The Committee strongly supports the goals and vision behind the proposal for ARPA–H and believes that once established, ARPA–H will be able to make pivotal investments in breakthrough technologies and broadly applicable platforms that have the potential to transform medicine, research, and health. The Committee looks forward to working with the Administration to establish ARPA–H and expects to expand its capacity to support innovative projects in future fiscal years.

The Committee agrees that ARPA–H projects focused on developing treatments and cures for cancer, Alzheimer’s disease, and diabetes would be a worthy investment, given the prevalence and immense burden of these diseases on society, as well as the potential for such an investment to achieve progress. The Committee strongly encourages NIH to pursue ARPA–H projects related to finding treatments and a cure for ALS, given its devastating impact on those who suffer from ALS and their families. The Committee expects to be kept apprised of NIH’s proposed criteria for selecting and prioritizing projects for ARPA–H funding.

For ARPA–H to be successful, the Committee believes ARPA–H must be a distinct Institute within NIH, with a unique culture and organization that should focus on time-limited projects with goals, benchmarks, and accountability. The Committee strongly encourages NIH to recruit an ARPA–H Director with extraordinary technical and leadership skills, who has a proven track-record in innovation and partnership-building. As the success of this endeavor will be largely dependent upon the recruitment and empowerment

of a diverse cohort of program managers, the Committee urges NIH to consider recruiting from a wide range of industry, academia, and other sectors. The Committee encourages NIH to collaborate with DARPA to develop the foundational policies, procedures, and staff training for ARPA-H employees.

The Committee is aware that there may be ongoing activities within NIH's current Institutes and Centers that may be better aligned with ARPA-H's mission. The Committee encourages NIH to closely examine whether there is duplication or misalignment of programs once ARPA-H is stood up and to notify the Committee of any proposed reorganization.