



FY2020 House Labor, Health and Human Services Appropriations Bill
Summary of Health and Bioscience Issues
May 12, 2019

Overview

G2G has attended hearings and tracked testimony and markup of the FY2020 LHHS appropriations bill over the past few months. The House Appropriations Committee passed the LHHS bill that totals \$189.9 billion on May 8, which contrasts the 12% cut proposed in President Trump's FY2020 budget. The bill provides \$99 billion for the Department of Health and Human Services (HHS) and includes significant funding increases since FY2019, i.e. NCI's funding is increased from \$5.7 billion to \$6.2 billion and NCATS' funding is increased from \$806 million to \$845 million. It also launches a new multi-year public health surveillance initiative and funds cybersecurity efforts. However, it cuts CMS by \$3 billion from \$276 billion to \$273 billion in FY2020. The bill passed the committee along party lines so we expect many changes when the Senate introduces its companion bill in June. Then both chambers will bring their bills to the floor for passage in July so conference negotiations can occur in August-September. Finally, the House and Senate still need to agree to new budget caps in order to avoid sequestration.

NIH

The bill includes \$41.084 billion for the National Institutes of Health, an increase of \$2 billion over FY2019 despite the loss of \$219 million due to reductions in funding through the 21st Century Cures Act. It provides a 5% increase for all institutes and centers and continues to fund many ongoing NIH initiatives. Some highlights include:

- National Cancer Institute (NCI) – \$6.2 billion
- Cancer Moonshot – \$195 million
- National Center for Advancing Translational Science (NCATS) – \$845 million
- Alzheimer's – \$2.4 billion
- BRAIN Initiative – \$411 million
- All of Us Precision Medicine Initiative – \$500 million
- HIV/AIDS – \$3.2 billion
- Regenerative Medicine – \$8 million
- Traumatic Brain Injury care within CMS - \$12.321 billion
- Substance Abuse and Mental Health Services Administration (SAMHSA) and opioids – \$3.8 billion for treatment and \$212 million for prevention
- Common Fund – \$617.761 million that includes Gabriella Miller Kids First Research Act for the Pediatric Research Initiative
- Centers for Disease Control and Prevention (CDC) – \$921 million
- Data surveillance and analytics at CDC, state and local health departments and the National Center for Health Statistics – \$100 million for the first year of a multi-year effort
- Health Resources Services Administration (HRSA) – \$7.6 billion
- Research Centers in Minority Institutions – \$75 million
- CMS – \$4 billion
- BARDA – \$567 million

NCI

Specified funding and/or special recognition is provided to the following cancers: ovarian, prostate, lung, pancreatic, kidney, liver, metastatic, mesothelioma, melanoma, rare and recalcitrant cancers, plus the five main types of gynecological cancer as well as lymphedema, which is the most common side effect of many cancer treatments. The Report accompanying the LHHS bill addresses several areas of focus for NIH that are listed below in summary form.

Brain Cancer in Children — The Committee recognizes that brain cancer remains the most fatal of all pediatric cancers. Despite progress in other diseases, pediatric brain cancer survival rates have not improved for decades and have lagged behind the strides made in other cancers. The majority of children who survive may experience lifelong impairments and disabilities that result from high levels of toxicity associated with treatment. The Committee strongly encourages NIH to support additional research on pediatric brain cancer, including but not limited to drug delivery methods and new therapies with reduced levels of toxicity and long-term complications.

Childhood Cancer Data Initiative — The Committee includes \$50,000,000 for the first year of the Childhood Cancer Data Initiative, as proposed in the fiscal year 2020 budget request. Also, the Committee strongly encourages NIH to support additional research on pediatric brain cancer, including but not limited to drug delivery methods and new therapies with reduced levels of toxicity and long-term complications. *(This aligns with President Trump's budget that proposed \$50 million per year over the next 10 years for pediatric cancer research.)*

Collaboration Between Agencies Regarding Pediatric Investigation of Appropriate New Drugs — The Committee recognizes that Title V of FDA Reauthorization Act (FDARA) amended the Pediatric Research Equity Act (PREA) to support the early evaluation of potentially effective drugs by requiring evaluation of new molecularly targeted drugs and biologics intended for adults with cancer if the drug is directed at a molecular target substantially relevant to the growth or progress of a pediatric cancer. The law directs the FDA, in collaboration with the NCI, to establish, publish, and regularly update a list of molecular targets considered based on data the agency determines to be adequate, to be substantially relevant to the growth or progression of pediatric cancers, and that may trigger the requirement for pediatric investigations.

Colorectal Cancer — The Committee provides an increase of \$2,000,000 for colorectal cancer. The Committee is concerned with the increasing rate of colorectal cancer among younger adults. The Committee urges CDC to identify risk factors that may be associated with this increase among younger adults and further identify trends of increase by race and socioeconomic status.

Cancer Immunotherapy — The Committee finds breakthroughs in cancer immunotherapy are revolutionizing treatments for a growing number of cancers and urges NCI to prioritize research and trials for innovative immunotherapeutic approaches. In some cases, however, the side effects of such treatments are far different than those associated with chemotherapy. Early recognition and management of cancer immunotherapy-related side effects can result in resolution of these side effects before permanent damage is done and allows for continued cancer treatment. The Committee urges NCI to prioritize research and education on the underlying mechanisms of cancer immunotherapy.

Melanoma — Discovery of biomarkers of response and resistance is critical at this point in melanoma research. The Committee urges NCI to support mechanistic research into response and resistance to therapy, and to develop a strategic plan across the public and private sector to systematically focus on biomarker research with the most advanced technologies (genetic, gene expression, or protein-based), so that physicians have the diagnostic tools to deliver personalized medicine to each patient. The Committee also urges NCI to continue the advances in adjuvant therapy by extending research to earlier stage disease and testing shorter, less toxic and more economical regimens. The Committee further encourages research to understand mechanisms that underlie clinical dormancy to provide an effective means of preventing tumor recurrence and improving quality of life and longevity of survivors. Melanoma is a heterogeneous cancer and includes rare subtypes such as uveal melanoma, the most common cancer of the eye, as well as mucosal and pediatric melanoma. States have difficulty capturing and defining cases due to the complex nature of arriving at the true diagnosis. The Committee encourages NCI to support research through national registries to better understand natural history, epidemiology, as well as patient reported and clinical outcomes in these rare melanoma subtypes.

Mesothelioma Registry — The Committee recognizes that CDC undertook a feasibility study for a mesothelioma patient registry in fiscal year 2019 to evaluate case finding methodologies to determine incidence and prevalence, demographics and risk factors. The Committee includes an increase of \$400,000 to take the next step toward establishment of a national mesothelioma patient registry through collecting data on individuals suffering from the disease and identify gaps in treatment in order for researchers to develop new treatments and a cure for this disease, which is among the deadliest and most painful cancers. The Committee encourages CDC to establish priorities for successful outcomes; develop and revise standards of care and treatment best practices; share evidence-based information between physicians across the country; and implement benchmarks to improve care for mesothelioma patients.

Rare Cancer Therapeutic Research and Development Program — For the first time, the Committee includes a section with a rare cancer directive for NCI and NCATS. It states that more than 500,000 Americans are diagnosed with a rare form of cancer every year. Rare cancers account for 374 of 396 distinct forms of cancer, and include all pediatric cancers. Each of these forms of cancer would benefit from targeted therapies that frequently work more effectively and with fewer side effects than traditional chemotherapy and radiation. The NCATS novel scientific model has proven successful in addressing other rare diseases and would benefit rare cancer therapeutic development. Therefore, the Committee urges NCI to collaborate with NCATS as appropriate on a rare cancer translational medicine initiative to accelerate the study of commonalities across rare cancers and the development of platform treatments for rare cancers to help patients who often have no other options.

Deadliest Cancers — The Committee notes that while more effective screening methods and treatments have lowered overall cancer incidence and death rates, several cancer types with particularly low survival rates have limited screening methods, and effective treatments for these cancers are also limited. The Recalcitrant Cancers Research Act of 2012 defined "recalcitrant cancers" as those with a five-year survival rate below 50 percent. These cancers account for nearly half of all cancer deaths in the U.S. and include cancers of the brain, esophagus, liver, lung, ovary, pancreas, and stomach. The Committee notes that in fiscal year 2020, NCI will report on the effectiveness of the scientific framework process NCI undertook to carry out implementation of the Recalcitrant Cancers Research Act.

Metastatic Cancer in the Surveillance, Epidemiology, and End Results Registry — The Committee notes recent discussions about modernizing the Surveillance, Epidemiology, and End Results (SEER) Registry and filling in key data gaps, such as metastatic recurrence. The Committee encourages NCI to advance this effort in a systematic and meaningful way that ultimately improves SEER Registry infrastructure and capabilities.

Gene and Cellular Therapies — The Committee is encouraged by the promise of the new cancer treatment, CAR T-cell therapy that is already producing remarkable results for patients. The Committee urges the Secretary to ensure coordination between NIH, FDA, and CMS to develop policies that support the innovation of new gene and cell therapies and protect patient access by providing equitable reimbursement for these therapies and the associated services needed by patients being treated. The Committee requests an update in the fiscal year 2021 Congressional Budget Justification on activities to ensure appropriate patient access to these treatments.

Regenerative Medicine

Regenerative Medicine — The Committee provides \$8,000,000 for regenerative medicine activities authorized in the 21st Century Cures Act. Regenerative medicine and tissue engineering are emerging disciplines that aim to revolutionize the treatment of disease by providing cures rather than treating symptoms. Approaches include the use of Induced Pluripotent Stem Cell technology, derived from adult skin cells, to provide limitless supplies of cells for transplant therapy and disease modeling as well as bioengineering and tissue engineering to generate replacement tissues and organs. The Committee encourages NIH to support research into the fields of regenerative medicine and tissue engineering.

Regenerative Cell Therapy Pilot Registry — The Committee looks forward to reviewing the state of the science report required by P.L. 114–104 on using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the C.W. Bill Young Cell Transplantation Program.

Traumatic Brain Injury — The Committee understands that re-generative medicine, including the use of adult stem cells and neuroplasticity may play an important role in developing treatment of TBI. The Committee strongly encourages NINDS to work with all relevant parts of NIH, including NIA, to support a robust and coordinated portfolio of TBI research that explores all promising avenues to facilitate functional repair of damaged circuitry in TBI, including research on regenerative medicine and neuroplasticity. The Committee requests an update in the fiscal year 2020 Congressional Justification on efforts in these specific areas of TBI research.

Wound Care Research — In its fiscal year 2019 Congressional Justification, NIGMS estimates the direct cost of chronic wounds to the healthcare system to exceed \$50 billion. Patients with non-healing wounds are likely to be older adults, nonambulatory or paralyzed, unable to provide self-care, and/or suffering from dementia. The Committee urges NIH to explore ways to optimize resources for specific chronic and acute wound care research at multiple Institutes. The research may include understanding the development of chronic wounds, including transition from acute wounds, and on development of treatments that simultaneously reduce pain, promote healing, and prevent infection and on methods to diagnose and monitor chronic wounds. The Committee directs NIH to provide a report to the Committee summarizing NIH's investments in wound care funding over the past five years within 90 days of enactment of this Act.

Influenza

Universal Influenza Vaccine — The Committee directs NIAID to allocate at least \$200,000,000 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.

Influenza Vaccine — The Committee includes an increase of \$10,000,000 to improve the effectiveness of and reduce barriers to seasonal influenza vaccination. Furthermore, the Committee encourages CDC to consider including vaccines produced through recombinant DNA technology in addition to traditionally-produced vaccines in future solicitations to facilitate the competitive process for all vaccine manufacturers.

Antibiotic Resistance — The Committee includes an increase of \$5,000,000 and recognizes the importance of addressing the problem of antibiotic-resistant bacteria through a “One Health” approach, and by tracking resistance through local, regional, national, and global surveillance. The Committee encourages CDC to competitively award research activities that address aspects of antibiotic resistance related to “One Health,” including global surveillance, and research and development for new tools to counter antibiotic resistance among entities, including public academic medical centers, veterinary schools with agriculture extension services, and public health departments whose proposals are in line with CDC’s strategy for addressing antibiotic resistant bacteria. Furthermore, the Committee is pleased with CDC’s Antimicrobial Resistance (AMR) Challenge and its implementation of a “One Health” approach to encourage governments, private industries, and non-governmental organizations across the world to combat AMR.

Threat of Emerging Infectious Diseases — The usage of machine learning, data-driven dynamical modeling, and other big data techniques, to identify early warning signals for outbreaks of rare diseases, is an integral part of scientific research on the ecology and evolution of infectious diseases. The Committee recognizes the threat of Emerging Infectious Diseases (EID) from animals and urges NIH to support further research in disease mapping and forecasting in order to identify early warning signals for outbreaks of emerging diseases. The Committee directs NIH to include a progress report on the use of machine learning and validated mechanistic models to advance critical biomedical research, improve decision support for epidemiological interventions, and enhance human health in the fiscal year 2021 Congressional Justification.

Psoriatic Disease — The Committee recognizes the growing body of evidence linking psoriatic disease, which impacts more than eight million Americans, to other comorbidities such as cardiovascular disease, mental health and substance abuse challenges, kidney disease, and other conditions. The Committee commends CDC for identifying opportunities for expanded research on psoriatic disease in its Public Health Agenda for Psoriasis and Psoriatic Arthritis.

Harmful Algal Blooms — The Committee includes \$1,000,000 to support the work that CDC is doing to conduct surveillance for and report health concerns related to harmful algal blooms and urges CDC to continue this work with a focus on fresh water and other affected waters: (1) to provide more outreach to numerous State and local public health officials to use these surveillance and re-ported systems; (2) to work with other agencies, in addition to the U.S.

Army Corp of Engineers, including the Environmental Protection Agency, National Institute of Environmental Health Sciences, National Oceanic and Atmospheric Administration, and United States Geological Survey, to integrate disparate sets of data to allow for a broader understanding of the spatial and temporal dynamics of the environmental and health impacts of harmful algal blooms (HABs); and (3) to continue to work together on efforts that support HAB surveillance, emergency response, and mitigation of public health impacts.

Heart Disease and Stroke — The Committee includes an increase of \$20,000,000 to support, strengthen, and expand evidence-based initiatives, given that almost half of the U.S. population has some form of cardiovascular disease.

High Obesity Rate Counties — The Committee continues to include \$15,000,000 to support the rural extension and outreach services grants for rural counties with an obesity prevalence of over 40 percent. CDC is encouraged to give preference to projects in States where at least 10 percent of counties meet the requirements of the program.

Telementoring Training Center — The Committee includes \$3,000,000 within the total for Rural Health Outreach Programs to support a telementoring training center to train academic medical centers and other centers of excellence in the creation of technology-enabled telementoring learning programs that facilitate the dissemination of best practice specialty care to primary care providers and care teams across the country. Also, the Committee includes \$28,500,000 for Telehealth, an increase of \$4,000,000 above the fiscal year 2019 enacted level and \$18,500,000 above the fiscal year 2020 budget request, which includes Telehealth Centers for Excellence.

SAMHSA & NIDA

Opioids — The Committee continues to support the HEAL (Helping to End Addiction Long-Term) Initiative, a trans-NIH effort to speed scientific solutions to stem the national opioid public health crisis. This initiative builds on extensive, well-established NIH research, including basic science of the complex neurological pathways involved in pain and addiction, implement science to develop and test treatment models, and research to integrate behavioral interventions with medication-assisted treatment for opioid use disorder. The Committee includes no less than the fiscal year 2019 enacted level of \$250,000,000 within NINDS for this research. Also, the Committee requests in the FY2021 Congressional Justification an update on the progress of the development and advancement of non-opioid chronic pain therapies. Finally, the Committee encourages NIDA to continue its partnership with the CDC, SAMHSA, and the Appalachian Regional Commission in support of research to help communities develop comprehensive approaches.

The HEALTHy Brain and Child Development Study — The Committee recognizes and supports the NIH HEALTHy Brain and Child Development (HEALTHy BCD) Study, which will establish a large cohort of pregnant women, including those affected by the opioid crisis, and follow them and their children for at least 10 years. This knowledge will be critical to help predict and prevent some of the known impacts of pre- and post-natal exposure to drugs or adverse environments, including risk for future substance use, mental disorders, and other behavioral and developmental problems. The Committee recognizes that the HEALTHy BCD Study is supported in part by the HEAL Initiative, and encourages other NIH Institutes, such as NICHD, NIMH, NHLBI, NCI, NIAAA, NIMH, NINR, as well as the Office of the Director, to support this important study.

Infectious Disease

Threat of Emerging Infectious Diseases — The Committee Report states the usage of machine learning, data-driven dynamical modeling, and other big data techniques, to identify early warning signals for outbreaks of rare diseases, is an integral part of scientific research on the ecology and evolution of infectious diseases. The committee recognizes the threat of Emerging Infectious Diseases (EID) from animals and urges NIH to support further research in disease mapping and forecasting in order to identify early warning signals for outbreaks of emerging diseases.

CDC

The Committee provides a large increase for the CDC: \$8,258,363,000, an increase of \$920,622,000 over FY2019. The bill begins a multi-year initiative to modernize public health capacity at CDC and its public health partners with \$100,000,000 to modernize the public health system away from antiquated data reporting to a common data platform that will enable using real-time data to predict and prevent public health threats in the future.

Infectious Diseases and the Opioid Epidemic — The Committee includes an increase of \$15,000,000 to strengthen efforts to conduct surveillance to improve knowledge of the full scope of the burden of infectious diseases (including viral, bacterial and fungal pathogens) associated with substance use disorders, and in collaboration with state and local health departments, health care facilities, and providers, deploy existing authorities to prevent and detect infectious diseases associated with substance use disorder and strengthen linkages to addiction, mental health and infectious diseases treatment.

Chronic Disease Education and Awareness — The Committee recognizes CDC's work with stakeholders to expand public health education and awareness activities that help to improve surveillance, diagnosis, and proper treatment for chronic diseases. The committee includes \$3,000,000 for a new effort to award grants to address chronic diseases and their risk factors that do not already have a specified amount under CDC in this report.

Maternal Health

Safe Motherhood and Infant Health — The Committee recognizes CDC's ongoing efforts to address the pressing public health issue of rising maternal mortality rate in the U.S. Each year, almost 700 women die during or within a year of the end of their pregnancy in the U.S. as a result of pregnancy or delivery complications. These statistics are all the more concerning given that accurate and complete data regarding the cause of pregnancy-related deaths is lacking. The Committee includes \$12,000,000 in the Safe Motherhood and Infant Health Program for CDC to continue its technical assistance to existing State Maternal Mortality Review Committees (MMRCs) to build stronger data systems, improve data collection at the State level and create consistency in data collection across State MMRCs. The Committee believes this investment will lead to better information necessary to provide accurate national statistics for U.S. maternal mortality rates and will inform data-driven actions for preventing these deaths. Furthermore, the Committee commends CDC for funding State-based Perinatal Quality Collaboratives (PQCs) that focus on improving maternal and neo-natal outcomes using known prevention strategies such as reducing early elective deliveries. CDC is encouraged to continue support for PQCs particularly due to the rise in maternal mortality rates and neonatal abstinence syndrome (NAS) as a result of the opioid crisis. PQCs are working to address a number of important health threats to women and infants, including the impacts of opioid use disorder and NAS. This platform can also be integrated into existing State-based bio-surveillance efforts to pilot the integration of a maternal health component,

ensuring any additional efforts work within the PQC infrastructure and strengthen those existing efforts to improve the data available and its ability to impact and improve clinical care and community linkages.

Women's and Maternal Health — The Committee maintains \$50,000,000 for an initiative to reduce maternal mortality rates from FY2019 and adds \$5,000,000 through the Maternal and Child Health Bureau; provides an increase of \$2,500,000 to educate midwives to address the national shortage of maternity care providers; and increases funding through the Office on Women's Health. It expands the WISEWOMAN program that helps uninsured and under-insured low-income women ages 40 to 64 understand and reduce their risk for heart disease and stroke to 50 states and D.C. with an increase of \$25,650,000.

Maternal Mortality — The Committee remains concerned about the maternal mortality rate in the U.S., which doubled in the last two decades. In light of studies exploring the effect of Cesarean sections on maternal mortality, the Committee urges CDC to provide technical assistance for State databases and data collection of pregnancy-associated and pregnancy-related deaths, to include data on whether a delivery was vaginal, via Cesarean section, or otherwise. Furthermore, the Committee is concerned that implicit bias may be a factor in the disproportionately high mortality rate of black mothers compared to their white counterparts. Accordingly, the Committee encourages the CDC to provide technical assistance to State Maternal Mortality Review Committees that includes evidence-informed interventions to address implicit bias in health care providers and to States establishing Maternal Mortality Review Committees.

Public Health Data Surveillance/IT Systems Modernization — The Committee acknowledges that CDC has taken important steps to modernize its surveillance infrastructure through the implementation of its Surveillance Strategy, but recognizes that more needs to be done to ensure that CDC can develop and deploy world-class data and analytics that scale rapidly in emergencies, provide predictive capacity to identify emerging threats, reduce burden on public health partners who are reporting data and ensure bidirectional information flows. The nation's public health data systems are antiquated, rely on obsolete surveillance methods, and are in dire need of security upgrades. Lack of interoperability, reporting consistency, and data standards leads to errors in quality, timeliness, and communication. In addition, CDC must take steps to ensure that the public health workforce possesses and maintains state of the art data science skills needed to put the data to use through public health action. The Committee includes \$100,000,000 for the first year of a multi-year initiative for CDC to lead the effort to improve public health data by providing support to Federal data modernization efforts including the National Center for Health Statistics, State, local, tribal and territorial partners, and to work with academic and private sector partners to innovate new tools and approaches for maximizing the public health impact of the data that keeps our communities safe and healthy. Within 120 days of enactment of this Act, the Committee requests a multi-year plan for this initiative, including at least five years of budget projections, as well as the innovation strategy for surveys conducted by the National Center for Health Statistics.

Childhood Lead Poisoning — The Committee includes an increase of \$5,000,000 to strengthen blood lead surveillance by supporting additional State and local programs to improve blood lead screening test rates, identify high-risk populations, and ensure effective follow-up for children with elevated blood lead levels

CMS

The funding for the Centers for Medicare and Medicaid (CMS) decreased by \$3 billion, from \$276 billion in FY2019 to \$273 billion in this FY2020 bill. Some language changes in the Report accompanying the bill are listed below, demonstrating interest in key areas.

Biosimilars — The Committee is concerned about the underutilization of lower cost biosimilars, particularly those in Medicare Part B, and encourages the Administration to support development and implementation of new policies such as reducing patient co-pays or creating shared cost savings programs with healthcare providers that would help to increase the uptake of biosimilars in the United States. The committee encourages CMS to identify the uptake rate for biosimilars in the Medicare and Medicaid populations.

Drug Pricing Report — The Committee directs the Secretary of Health and Human Services to submit a report to the Committees on Appropriations not later than 120 days after the date of enactment of this Act regarding price changes of prescription drugs since 2008. The report should include comparative prescription drug prices (net of rebates) paid by the following programs for the 10 most frequently prescribed drugs and the 10 highest-cost drugs for each of the following:

- (1) The Medicare program under part B of title XVIII of the Social Security Act;
- (2) The Medicare prescription drug program under part D of title XVIII of the Social Security Act;
- (3) The Medicaid program under title XIX of the Social Security Act; and
- (4) The Department of Veterans Affairs.

The report should also provide a breakdown of the comparative prices (net of rebates) for each of the 10 most frequently prescribed drugs and the 10 highest-cost drugs between ambulatory settings and retail settings. In addition, the report should include total annual costs due to prescription drugs to the Medicare program under part B of title XVIII of the Social Security Act, the Medicare prescription drug program under part D of title XVIII of such Act, and the Medicaid program under title XIX of such Act. Finally, the report should list the drugs that have been registered for sale by the Food and Drug Administration (FDA) in the past five years that have benefited significantly from government grants or research subsidies in either the pre-clinical or clinical stages of development, as well as the price (net of rebates) and total spending in Medicare and Medicaid for each of those drugs.

Orphan Drugs — The Committee understands that 1 in 10 Americans is impacted by a rare disease and that the Orphan Drug Act incentivizes the discovery of diagnostics and treatments that confirm prognosis, prolong life, and realize health system savings. Despite progress, however, treatments exist for only 5% of rare diseases. Scientific advancement is discovering the next generation of biologic and gene therapy medicines that have the potential to both modify disease progression and revolutionize the treatment of fatal and debilitating rare diseases. To realize these potentials, the committee urges CMS to support access to biologic and gene therapies, including potential testing of health insurance benefit designs that eliminate specialty tiers.

There are additional sections of the LHHS bill and Report that may be of interest listed below.

Sepsis — The Committee is concerned that sepsis and antibiotic resistant bacteria continue to be leading public health threats that are responsible for a significant number of deaths, as well as rising costs within the healthcare system. According to the most recent data, the national average compliance rate for CMS's sepsis treatment measure, known as SEP-1, is only 49

percent. The Committee urges CMS to issue a Request for Information to gather views on proposals to modernize and optimize CMS's current SEP- 1 measure. The Committee requests an update on these activities in the fiscal year 2021 Congressional Budget Justification.

HIV Initiative — The Committee supports the Administration's HIV Initiative to decrease new HIV diagnosis by 75 percent by 2025 and 90 percent by 2030. The initiative builds on existing HIV programs and new innovations to ramp up HIV testing, care and treatment, and prevention services, including Pre-Exposure Pro-phylaxis. The Committee includes the full amount of funding requested for the HIV Initiative under HRSA, CDC, and NIH. Moreover, the Committee provides additional increases—beyond the fiscal year 2020 budget request—of \$46,376,000 for the Ryan White HIV/AIDS program; \$5,000,000 for the Minority AIDS program in SAMHSA; and \$6,100,000 for Minority HIV/AIDS prevention and treatment activities under the Office of the Secretary. The Committee directs the Secretary to submit to the Committees on Appropriations a comprehensive multi-year plan outlining the HIV Initiative, including metrics the Department will use to measure progress on reducing HIV transmission, as well as cost estimates for the initiative for fiscal years 2021 through 2025. The Secretary shall submit an initial plan within 90 days of enactment of this Act and then annually thereafter.

BARDA (Biomedical Advanced Research and Development Authority)

The Committee includes \$566,700,000, an increase of \$5,000,000, for the Biomedical Advanced Research and Development Authority (BARDA). BARDA supports the advanced development of vaccines, drugs, and therapeutics for potential serious public health threats, including chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging and re-emerging infectious diseases.

Cybersecurity

Office of the Assistant Secretary for Administration—Cybersecurity

The Committee provides \$58,860,000 for information technology cybersecurity in the Office of the Assistant Secretary for Administration. These funds provide for continuous monitoring and security incident response coordination for the Department's computer systems and networks.