



**American Society of Hematology
Statement to the Senate Appropriations
Subcommittee on Labor, HHS, Education, and Related Agencies
FY 2021 Funding for NIH, CDC, and HRSA
May 22, 2020**

The American Society of Hematology (ASH) represents more than 18,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant disorders such as leukemia, lymphoma, and myeloma; life-threatening conditions, including thrombosis and bleeding disorders; and congenital diseases such as sickle cell disease, thalassemia, and hemophilia. Hematologists have been pioneers in the fields of bone marrow transplantation, stem cell biology and regenerative medicine, and gene and immunotherapy.

FY 2021 Request: National Institutes of Health (NIH)

American biomedical research has led to new medical treatments, saved innumerable lives, reduced human suffering, and spawned entire new industries, none of which would have been possible without support from the National Institutes of Health (NIH). Hematology research, funded by many institutes at the NIH, including the National Heart, Lung and Blood Institute (NHLBI), the National Cancer Institute (NCI), the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), the National Institute on Aging (NIA), and the National Institute of Allergy and Infectious Diseases (NIAID), has been an important component of this investment in the nation's health.

With the advances gained through an increasingly sophisticated understanding of how the blood system functions, hematologists have changed the face of medicine through their dedication to improving the lives of patients. NIH-funded research has led to tremendous advances in treatments for children and adults with blood cancers and other hematologic diseases and disorders. Hematology advances also help patients with other types of cancers, heart disease, and stroke. Basic research on blood has aided physicians who treat patients with heart disease, strokes, end-stage renal disease, cancer, and AIDS. Additional federal investment in research will form the basis for continued scientific progress in hematology and other fields of medicine for years to come.

ASH thanks Congress for the robust bipartisan support that has resulted in several consecutive years of welcome and much needed funding increases for NIH, including the more than \$2 billion increase that Congress provided in fiscal year (FY) 2020. For FY 2021, ASH strongly supports the Ad Hoc Group for Medical Research [recommendation](#) that NIH receive \$44.7 billion. This funding level, supported by more than 330 other stakeholder organizations, would allow for meaningful growth above inflation in the base budget that would expand NIH's capacity to support promising science in all disciplines. It also would ensure that funding from the Innovation Account established in the 21st Century Cures Act would supplement the agency's base budget, as intended, through dedicated funding for specific programs.

While we are grateful for Congress's ongoing commitment to NIH as a top national priority through the regular appropriations process, we also urge the inclusion of additional emergency supplemental investments in the NIH as Congress considers future legislation to promote the nation's physical, health, and economic resilience to the current COVID-19 pandemic and future pandemics. The extraordinary research currently underway to identify and develop potential COVID-19 vaccines, antivirals, and other medical countermeasures is all built on the scientific foundation enabled by the federal investment in NIH. Additionally, the emergency supplemental resources provided to NIH in the recently enacted COVID-19 packages are playing an important role in identifying therapies and vaccines, as well as improving testing and diagnostic methods.

Further supplementary funding to NIH will be necessary to help preserve the momentum of the nation's investment in biomedical research and aid in ramping up labs to their prior research capacities. Researchers in every state suspended many laboratory activities for their own personal safety and to comply with physical distancing guidelines as a result of the COVID-19 pandemic. The closure of many research facilities is impacting trainees, technicians, early-stage investigators, and established investigators alike, preventing the research workforce from maintaining momentum toward better prevention, treatments, diagnostics, and cures for diseases such as blood cancers, sickle cell disease, and other hematologic diseases and conditions.

Substantial costs have been incurred for the shut-down and there will be significant additional costs for the eventual ramp-up of research activities. For example, labs will need to replace personal protective equipment that they have donated to support the critical work of first responders and health care providers and will also need to reestablish experimental models. This includes the need to rebuild animal colonies, breed mice and other animal models, and reestablish cell lines used for experiments that were destroyed during the preparation to close labs. This is both costly and time consuming as labs will need to replenish these colonies and retest to ensure reproducibility of previous research findings prior to proceeding with any new experimental work. Additionally, core facilities, such as those that provide DNA sequencing and flow cytometry services, support cross-disciplinary research efforts across federally funded research labs. These facilities are also closed or functioning below capacity to ensure readiness for any ongoing COVID-19 research efforts, and they also need support.

Many new clinical questions are emerging daily from this COVID-19 pandemic. Indeed, as the infections continue, new disease manifestations are developing including severe hematopoietic conditions that have turned COVID-19 into not only a pulmonary disease, but a blood disease as well. Recent emerging outcomes include coagulation and severe inflammation, or the cytokine storm, that is seen in adults and children alike and results in severe complications and even death in some affected. In response to these health issues, the Society has developed a "COVID-19 Research Agenda in Hematology." This document explores the key underlying research questions that, to date, lack scientific evidence to inform clinical practice and treatment efforts. The Society has deemed these questions to be of utmost importance to address in order to best guide physicians on the front lines when treating critically ill patients and attempting to save lives. It is imperative that answers to these questions are provided soon to help successfully defeat this virus and save as many lives as possible.

Finally, the Society is concerned about possible new policies that would place the intellectual property of peer reviewed scientific and medical research articles, published in professional journals, in jeopardy. Of particular concern is a potential proposal by the Administration to eliminate the current 12-month embargo to make federally funded scientific research published in journals freely available worldwide. If enacted, such a proposal could significantly threaten scientific rigor, discovery, and innovation. The Society urges the Subcommittee to re-affirm its support for the 2013 *Holdren Memo*, which ensures public access to peer-reviewed articles no later than 12 months after the official date of publication. The current 12-month embargo period allows for robust peer review and curation systems, and copyright and intellectual property protection of American science.

FY 2021 Request: Centers for Disease Control and Prevention (CDC)

The Society also recognizes the important role of the Centers for Disease Control and Prevention (CDC) in preventing and controlling clotting, bleeding, and other hematologic disorders. This is especially important for improving the care and treatment of individuals with sickle cell disease (SCD).

Sickle cell disease is an inherited, lifelong disorder affecting approximately 100,000 Americans. Individuals with the disease produce abnormal hemoglobin which results in their red blood cells becoming rigid and sickle-shaped, causing them to get stuck in blood vessels and block blood and oxygen flow to the body, which can cause severe pain, stroke, organ damage, and in some cases premature death. Though new approaches to managing SCD have led to improvements in diagnosis and supportive care, many people living with the disease are unable to access quality care and are limited by a lack of effective treatment options.

Dedicated federal funding is needed for CDC's SCD Data Collection Program to allow the program to be expanded to include additional states with the goal of covering the majority of the U.S. SCD population over the next 5 years. The *Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018* (P.L. 115—327) authorizes CDC to award SCD data collection grants to states, academic institutions, and non-profit organizations to gather information on the prevalence of SCD and health outcomes, complications, and treatment that people with SCD experience. For FY 2021, the Society urges the Subcommittee to provide at least \$5 million for SCD data collection within the CDC's National Center for Birth Defects and Developmental Disabilities, Division of Blood Disorders (NCBDDD).

The current program was established with funding from the CDC Foundation. It is a population-based surveillance system, which collects and analyzes longitudinal data about people living in the U.S. with SCD. Due to limited funding, implementation of the program has occurred only in two states over the past few years— California and Georgia (approximately 10% of the U.S. SCD population). Data is being collected from multiple sources (newborn screening programs, Medicaid, hospital discharge data, emergency department data, vital records, and clinical data) in order to create individual healthcare utilization profiles, which is unique because it captures all individuals with SCD regardless of insurance status. The program is also valuable because it can follow individuals over time across healthcare systems and create individual profiles of how they accessed healthcare and their outcomes.

In September 2019, CDC announced the transfer of nearly \$1.2 million in FY 2019 funding to help seven additional states (Alabama, Indiana, Michigan, Minnesota, North Carolina, Tennessee, and Virginia) develop systems to collect data on the issues faced by people living with sickle cell disease. This bridge funding is an important step toward improving and expanding the CDC's SCD data collection efforts; however, it is only limited to one year. These states have already made significant progress in building the infrastructure needed to implement the program and it is important to continue to build on this investment. Dedicated funding at \$5 million for NCBDDD to carry out the SCD Data Collection Program in FY 2021 will assure this.

Additionally, ASH supports the public health community's request for at least \$8.3 billion in funding for the CDC in FY 2021. ASH also urges continued support of the Public Health and Prevention Fund which has supported many critical projects at CDC, including investments in health care-associated infections. Currently the fund comprises more than 11 percent of CDC's budget. ASH is concerned about the repeated efforts to eliminate this fund because of the budgetary pressure this would place on other programs within the Subcommittee's jurisdiction.

FY 2021 Request: Health Resources and Services Administration (HRSA)

Finally, ASH seeks continued funding of the SCD Demonstration Program within the Health Resources and Services Administration (HRSA) and FY 2021 level of \$5.2 million. This program supports five regional grantees, whose efforts focus on enhancing access to comprehensive, state of the art SCD care for patients living with the disease by providing educational programs and technical assistance on advances in SCD treatments to a broad array of providers and assuring coordination of care with hematologists, who specialize in the disease.

Thank you again for the opportunity to submit testimony. Please contact ASH Senior Manager, Legislative Advocacy, Tracy Roades at 202-292-0256 or troades@hematology.org, if you have any questions or need further information concerning hematology research or ASH's FY 2021 requests.