

March 18 , 2021

President Joseph Biden
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden,

The sickle cell community would like to extend our congratulations on your election as the 46th President of the United States of America. We acknowledge that the first months of your presidency, and likely beyond, will be focused on providing aid to the American people during the COVID-19 public health emergency. On behalf of the sickle cell disease community and the roughly 100,000 individuals living with sickle cell in the United States, we are grateful to be able to provide policy recommendations for consideration in the roll-out of COVID-19 and other public health support immediately, and throughout your administration.

Sickle cell disease (SCD) is an inherited blood disorder that disproportionately affects Black and Brown populations in the United States, including roughly 1 in 365 Black and African Americans, and 1 in 14,000 Hispanic Americans. Due to racism and patterns of health inequities in the United States, the SCD population has been marginalized in the realms of research, data collection, education, and access to quality care across the healthcare continuum. Without robust funding for research and treatment, the lives of those living with SCD are approximately 40 years shorter than the average U.S. adult lifespan. Furthermore, the lack of coordination and proper preventative care provided by the medical system results in roughly [\\$2.98 billion](#) in annual healthcare costs. The COVID-19 health crisis has only exacerbated the disparities and inequities found in the SCD community.

The undersigned organizations ask you to prioritize the outlined policy initiatives in order to improve the lives of those living with SCD in the United States:

1. Address disparities in the SCD community highlighted by the COVID-19 health crisis by including SCD in the Center for Disease Control and Prevention's future funding relief packages and efforts
2. Request full funding for the Center for Disease Control and Prevention's SCD Data Collection Program, and increasing funding for Health Resources and Services Administration SCD Treatment Demonstration Program and SCD Newborn Screening Follow-Up Program in your Administration's budget request
3. Mandate the inclusion of quality parameters for SCD within CMS state Medicaid guidance, and disallow step therapy and prior authorization for new SCD treatments – similar to what has been done for HIV/AIDS
4. Implement strategies outlined in the 2020 National Academies of Sciences, Engineering, and Medicine report, "Addressing Sickle Cell Disease" and support annual Congressional hearings on the report under the Committee on Energy and Commerce

(1) Address disparities and vaccine hesitancy in the sickle cell community highlighted by the COVID-19 health crisis by including SCD in the CDC’s future funding relief packages

As the data becomes available one year after the onset of the pandemic, it is evident that the SCD community is suffering at an increased rate compared to the wider Black and Brown community and the general population. Additionally, inconsistent telehealth capabilities left many SCD patients with fewer resources to access care. The CDC listed SCD as a priority for Phase 1c, yet many patients remain without access to a vaccine as states and counties opt out of these priorities. Furthermore:

- Researchers reported that [46.1% of children](#) with SCD and [66.8% of adults](#) with SCD required hospitalization.
- Individuals with SCD face [6.2 times the risk](#) of COVID-19 related mortality compared with the broader Black population, which is already being impacted more than the general population. Additionally, [10.6% of individuals](#) with SCD in a recent study died from COVID-19, including one pediatric patient.
- Those with sickle cell trait, roughly 3 million people in the U.S., are at higher risk of hospitalization and complications from COVID-19 than the broader Black and Brown community.

The undersigned organizations request increased funding for COVID-19 education and prioritized access to vaccines for all SCD patients and caregivers. We thank you for the work you have already done to prioritize underserved communities as part of your administration’s COVID-19 equity task force led by Dr. Marcel Nunez-Smith. Still, more funding is needed to enable the SCD community-based organizations and their community health workers to provide education and resources to the SCD population in order to address vaccine hesitancy based on centuries of abuse by the medical system. Furthermore, the CDC’s recommendations for prioritizing SCD has not mandated their inclusion, meaning many are left without access

(2) Promote robust support at the federal level by fully funding the Center for Disease Control and Prevention’s (CDC) SCD Data Collection Program and increasing funding for the Health Resources and Services Administration (HRSA) SCD Treatment Demonstration Program and SCD Newborn Screening Follow-Up Program in your Administration’s budget request

The sickle cell community continues to seek funding for S.2465 (Public Law No. 115-327), the Sickle Cell Disease and Other Inheritable Blood Disorders Research, Surveillance, Prevention, Treatment Act of 2018, sponsored by Senators Tim Scott and Cory Booker. After it was authorized in 2018, this bill was not appropriated until FY2021. As before, there continues to be bipartisan support for sickle cell disease (SCD) funding at the federal level.

In their FY2021 Congressional Justification, the CDC estimates that an annual investment of \$25 million is needed to implement the SCD surveillance provision of the 2018 SCD law. At the end of 2020, appropriations for FY2021 Division H were published, announcing \$2M for the CDC Data Program and \$5M for the Sickle Cell Demonstration Program. The sickle cell community celebrated the first-time

federal support of the CDC Data Program and continues to advocate for robust funding for this program at the federal level.

The undersigned organizations request you include \$25M in funding for the CDC Data Program and \$150M over three years in funding for the HRSA SCD Treatment Demonstration Program and SCD Newborn Screening Follow-Up Program in your FY2022 budget request. Committing to researching and funding this disease on a national scale will help ensure that a lack of data on this population does not continue to prevent their access to the everyday care they need, or to care during a national health crisis like the COVID-19 pandemic.

(3) Mandate quality standards for CMS and disallow step therapies and prior authorization for sickle cell disease treatments

In 2020, leadership from the American Society of Hematology (ASH) met with ADM Brett P. Giroir, MD, Former HHS Assistant Secretary for Health to discuss the impacts of prior authorization on the access to treatment for those living with sickle cell disease (SCD). Practices such as prior authorization and “fail first” (step therapies) not only increase delays in care but may also further discourage the use of recommended therapy for a population that is already undertreated and underserved.

With roughly [42,000 Medicaid and CHIP beneficiaries](#) living with SCD in the United States, it is crucial that these programs recognize each person’s experience with the disease and allow for individualized treatment without restrictions to care or medication.

The undersigned organizations call for HHS to mandate the inclusion of the following quality parameters by state Medicaid programs:

- Percent of pediatric SCD patients receiving annual Transcranial Doppler Ultrasound (TCD) screenings to measure the risk of stroke
- Percent of pediatric SCD patients receiving pneumococcal and influenza vaccines
- Percent of pediatric SCD patients receiving penicillin prophylaxis
- Percent of SCD patients with an annual health screening
- Percent of SCD patients receiving Hydroxyurea

The undersigned organizations call for HHS to disallow prior authorization for all SCD treatments

- Disallow prior authorization for **Oxbryta**[®] (voxelotor) created by Global Blood Therapeutics, **ADAKVEO**[®] (crizanlizumab-tmca) created by Novartis Oncology, Endari[™] (oral L-Glutamine) created by Emmaus Life Sciences, and future sickle cell disease treatments, unless specific justifications are stipulated in the FDA approval

(4) Implement strategies outlined in the 2020 National Academies of Sciences, Engineering and Medicine (NASEM) report, “Addressing Sickle Cell Disease” and support annual Congressional hearings on the report under the Committee on Energy and Commerce

In 2020, NASEM published a report entitled, “Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Action.” This report includes recommendations for:

- Nationwide data collection
- Building a national registry
- Providing clinical and nonclinical support through existing health programs (SSA, OMH, etc.)
- Managing the quality of sickle cell disease care
- Addressing disparities by reducing barriers to access care and treatment

The undersigned organizations request the implementation of strategies outlined by the NASEM report to address disparities and discrimination in the health care system and make crucial advances in sickle cell disease care and treatment. Additionally, we request that this administration support an annual hearing on the NASEM report within the Committee on Energy and Commerce, calling the following witnesses: Admiral Brett Giroir, former Assistant Secretary for Health; Ashley Valentine, Co-founder and President of Sick Cells; a NASEM staff member; a sickle cell disease patient advocate.

We thank you for including the sickle cell disease community in important advances in public health policy at the federal level. As a community, we are ready to work with this administration to implement historic changes in the care and treatment available to those living with SCD in the United States. We are happy to provide insight into the experience of the patient and caregiver community, which should remain central in the decision-making process. We welcome the opportunity to meet with you to discuss the priorities of the sickle cell community and facilitate engagement with sickle cell disease nonprofits across the country for much-needed change. Please contact Ashley Valentine at avalentine@sickcells.org for inquiries related to the contents of this letter or to schedule a meeting.

We look forward to working with your administration to transform health outcomes for sickle cell disease patients across the country.

Signed in alphabetical order:

Advancing Sickle Cell Advocacy Project, Inc.

Ambassadors of Change Inc.

Axis Advocacy

Bridging the Gap Adult Sickle Cell Disease Foundation of Nevada

Cayenne Wellness Center

Citizens for Quality Sickle Cell Care, Inc.

Dreamsickle Kids Foundation, Inc.

Falling Angels Sickle Cell Foundation

Foundation for Sickle Cell Disease Research

Greater Boston Sickle Cell Disease Association

Kids Conquering Sickle Cell Disease Foundation

Martin Center Sickle Cell Initiative

New York State Sickle Cell Advocacy Network, Inc.

Northeast Louisiana Sickle Cell Anemia Foundation
Ohio Sickle Cell and Health Association
RedMoon Project, Inc.
Sick Cells
Sickle Cell 101
Sickle Cell Anemia Foundation of Oregon, Inc.
Sickle Cell Association
Sickle Cell Association of Kentuckiana
Sickle Cell Association of Texas Marc Thomas Foundation
Sickle Cell Awareness Foundation Corp. Int.
Sickle Cell Community Consortium
Sickle Cell Disease Association of America, Central Alabama Chapter
Sickle Cell Disease Association of America, Inc.
Sickle Cell Disease Association of America, Inc. Northwest Louisiana Chapter
Sickle Cell Disease Association of America, Miami-Dade County Chapter, Inc.
Sickle Cell Disease Association of America, Michigan Chapter
Sickle Cell Disease Association of America, Philadelphia/Delaware Valley Chapter
Sickle Cell Disease Association of America, Southern Connecticut
Sickle Cell Disease Association of America, St. Petersburg Chapter
Sickle Cell Disease Association of America, West Alabama Chapter, Inc.
Sickle Cell Disease Association of Broward County
Sickle Cell Disease Association of Florida, Inc.
Sickle Cell Disease Association of Illinois
Sickle Cell Foundation of Minnesota
Sickle Cell Reproductive Health Education Directive
Sickle Cell Thalassemia Patients Network
Sickle Cell Warriors, Inc.
Supporters of Families with Sickle Cell Disease, Inc.
The Association for the Prevention of Sickle Cell Anemia for Harford & Cecil Counties
The Maryland Sickle Cell Disease Association
The Sickle Cell Association of New Jersey
The Sickle Cell Foundation of Tennessee
Uriel E. Owens Sickle Cell Disease Association of the Midwest
William E. Proudford Sickle Cell Fund Inc.