

December 7, 2020

Chiquita Brooks-LaSure
Team Lead
The Biden-Harris Agency Review Team
U.S. Department of Health and Human Services

Dear Ms. Brooks-LaSure:

On behalf of the Spina Bifida Association (SBA), I thank the entire Health and Human Services (HHS) Agency Review team for its leadership and commitment to facilitate a smooth transition of the agency for President-Elect Biden and Vice-President-Elect Harris. Your work is essential, and we are impressed by the broad array of experience and the diverse makeup that this team boasts.

In particular, we are pleased to see that Dr. Jose Cordero is a member of such an esteemed group of individuals. As the first Director of the National Center for Birth Defects and Developmental Disabilities (NCBDD) at the Centers for Disease Control and Prevention (CDC), Dr. Cordero was a skilled leader, a very capable manager, and a terrific friend to the Spina Bifida community. SBA had the pleasure of working closely with Dr. Cordero for years on many key initiatives critical to the Spina Bifida community, and we appreciated his steadfast commitment and support. We look forward to working with all of you to ensure that the HHS programs meet the needs of the diverse communities served by the agency.

Further, we commend the incoming Biden-Harris administration for prioritizing a national response to the pandemic, address racial equity, and reduce health disparities. In particular, we appreciate the prioritization of addressing health inequities for traditionally underserved communities, including individuals with disabilities. We stand ready to work with you and your colleagues and welcome an opportunity to be a resource to you in the weeks and months ahead.

Spina Bifida Overview

Since 1973, SBA has been the only national voluntary health agency solely dedicated to enhancing the lives of those impacted by this challenging birth defect through education, advocacy, research, and clinical care. SBA also is the only entity conducting groundbreaking work to improve care for individuals with Spina Bifida through the CDC's National Spina Bifida Program and, more specifically, its key initiatives, the National Spina Bifida Registry and the Spina Bifida Clinical Care Monitoring and Tracking Program.

Spina Bifida is the most common permanently disabling congenital disability compatible with life in the United States and affects approximately 1500 babies

each year. Spina Bifida and related neural tube defects are sometimes preventable through adequate daily folic acid consumption. As such, to help prevent Spina Bifida and other birth defects, the CDC recommends that women of child-bearing age consume 400 mcg of folic acid daily.¹

Still, there are an estimated 166,000 individuals, more than 65% of whom are adults, many in their 50s, 60s, and 70s, living with all forms of this complex birth defect. This disease has witnessed its first generation of adults, an incredible milestone, considering that the original designation of Spina Bifida as a childhood condition meant that the vast majority did not experience life beyond youth.

While considerable strides have been made, there remain a plethora of unmet needs affecting this population. Yet, because living with Spina Bifida can be difficult, individuals with Spina Bifida and their family members often cannot engage in advocacy to press policymakers for needed changes. They rely on SBA and its allies to articulate their challenges and advocate for policies, programs, and funding necessary to support the Spina Bifida community.

A generation of adults is a milestone worth celebrating, yet with adulthood comes additional health challenges, some inherent in aging for all individuals, and some that are particularly difficult for an already medically fragile and compromised group. In recent years, the Spina Bifida community has seen a growing incidence of sudden death in its over 25 population. There is speculation that this sudden loss of life has something to do with the central nervous system, but the cause or causes remain unknown.

There has been much energy and resources devoted to ensuring that people with Spina Bifida can experience middle age and old age. As such, we must explore and understand this sudden death phenomenon to reverse this troubling trend. Moreover, we must support – and expand investment in – research to address other issues related to Spina Bifida and associated secondary and comorbid conditions, such as hydrocephalus, latex allergy, neurogenic bladder, developmental delay, and impaired executive functioning.

Spina Bifida and Health Disparities

Of concern within the Spina Bifida community is the prevalence of health disparities. Hispanic women have the highest rate of having a child affected by Spina Bifida than non-Hispanic white and non-Hispanic black women. CDC used data to estimate the total number of pregnancies affected by

¹ <https://www.cdc.gov/ncbddd/folicacid/features/folic-acid-helps-prevent-some-birth-defects.html>

Spina Bifida compared to the total number of live births (also called the prevalence of Spina Bifida) for each racial/ethnic group:²

- Hispanic: 3.80 per 10,000 live births
- Non-Hispanic black or African-American: 2.73 per 10,000 live births
- Non-Hispanic white: 3.09 per 10,000 live births

The higher prevalence of Spina Bifida among Hispanic women has long been a concern and priority for SBA. We are eager to work with the incoming administration to advance efforts to improve health equity and address health disparities, such as those seen in the Spina Bifida community.

HHS Plays an Essential Role in Preventing Spina Bifida and Improving Outcomes Associated with Spina Bifida

Through its various agencies and programs, HHS plays a critical role in preventing Spina Bifida and advancing efforts that seek to improve outcomes and reduce adverse effects associated with Spina Bifida.

Centers for Disease Control and Prevention (CDC)

The first of its kind, Spina Bifida Patient Registry, created in 2008 by the CDC through the National Spina Bifida Program, established by Congress in 2002, is starting to yield results. The registry provides clinicians, researchers, patients, and families a "window" into what care models are effective and what treatments do not make a measurable difference. This information helps clinicians deliver "best practices" and continue to improve quality-of-life and outcomes for people with this birth defect. However, due to limited resources, the registry collects data from only 21 clinics; additional funding could expand the number of participating clinics and increase the amount of information reported, which in turn, will provide further insights into how to continue to improve care and outcomes for people with Spina Bifida.

While we have a coordinated system of care designed to treat children with Spina Bifida in the United States, there is no equivalent for an adult. Thus the "graduating child" now enters into a very fractured medical system where individuals struggle to find physicians willing to provide treatment. Unfortunately, many of these physicians lack basic knowledge of this complex condition, and hence thousands of young to middle-aged adults are left with few options other than to seek care in the emergency room – or some continue to see their pediatric care team at Spina Bifida Clinics, which are designed for children.

² <https://www.cdc.gov/ncbddd/SpinaBifida/data.html>

People with Spina Bifida deserve no less than the rest of us as we age. We must ensure that adults with Spina Bifida can receive evidence-based medical care tailored for their condition and receive that care in age-appropriate, non-emergency settings. The CDC's Spina Bifida Clinical Care Monitoring and Tracking Program is positioned to best guide the health care community in optimal treatment options for people living with Spina Bifida. Still, it needs additional resources to do so. We are working closely with our colleagues on both sides of the aisle as the FY 2021 spending bills are finalized. We look forward to working with you and the Biden-Harris administration to ensure that the program receives adequate funding in FY 2022.

In addition to the National Spina Bifida Program at CDC, the National Birth Defects Prevention Study, conducted by CDC, is the most extensive population-based U.S. study looking at potential risk factors and causes of birth defects. CDC, understanding the critical role that daily consumption of folic acid by women of reproductive age plays in preventing birth defects,³ is undertaking a number of projects related to folic acid, including:

- Looking at how a woman's intake of micronutrients, including folic acid, may affect the risk for specific birth defects, including Spina Bifida.
- Studying why Hispanics appear to be at higher risk for neural tube defects.
- Learning about women's behaviors related to preventing birth defects, like Spina Bifida, including folic acid use and alcohol use.

Also housed within the CDC, the National Health and Nutrition Examination Survey is a program of studies designed to evaluate adults and children's health and nutritional status in the United States. The survey is unique in that it combines interviews and physical examinations. The CDC uses information from this study to look at the population's folic acid intake and blood levels of folate and other micronutrients. In turn, this information helps inform other efforts to reduce and prevent birth defects, like Spina Bifida.

National Institutes of Health (NIH)

- The NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development is funding research to illuminate the causes of Spina Bifida further. The funding will be used to establish an international registry of patients with Spina Bifida and fund new studies investigating how folic acid reduces disease risk. Additionally, the specific efforts of NICHD to understand early human development help identify ways to create foundations for a healthy pregnancy

³ <https://www.cdc.gov/ncbddd/folicacid/features/folic-acid-helps-prevent-some-birth-defects.html>

and lifelong wellness of women and children and promote the gynecological, andrological, and reproductive health for people with Spina Bifida.

- In addition to the NICHD, a broader understanding of the issues related to the treatment and management of Spina Bifida and its related conditions is made possible by other parts of NIH, including the National Institute on Aging (NIA), National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), and National Institute of Neurologic Disorders and Stroke (NINDS). These institutes support the study of the causes and care of the neurogenic bladder and kidney disease; investigation into hydrocephalus and sudden death in the adult Spina Bifida population; and research regarding myriad comorbid conditions associated with both paralysis and developmental delay.

Ongoing NIH funding and these institutes are essential to identifying ways in which Spina Bifida can be prevented, and its myriad complications can be reduced. We know that the incoming Biden-Harris administration supports robust funding for NIH. Thank you in advance for ensuring the FY 2022 budget proposes adequate funding levels for all the institutes that play a critical role in Spina Bifida.

Centers for Medicare and Medicaid Services (CMS)

CMS plays an integral role in the provision of health insurance coverage to individuals with Spina Bifida. For many years, members of the Spina Bifida community were eligible for Medicare only due to their disabilities, not because of their age. Many people with Spina Bifida become dually eligible for Medicaid and Medicare due to their disabilities. Until recently, very few community members became eligible for Medicare due to aging into the program. As noted above, due to improvements in treatment and care, longevity for individuals with Spina Bifida is slowly improving, and many more members of our community are aging into Medicare. As such, the coverage and reimbursement policies of both Medicaid and Medicare have a significant impact on access to care for our community.

We appreciate the incoming administration's interest in – and commitment to – ensuring access to affordable care for all Americans, particularly those most vulnerable. As part of your efforts to strengthen the health care system, we urge you to review Medicare and Medicaid policies concerning access to durable medical equipment (DME) for people with Spina Bifida. While for many, access to affordable prescription drugs is the difference between life and death or high or low quality of life, for our community, health, longevity, and well-being hinge on affordable, unencumbered access to DME, such as catheters, power wheelchairs, braces, and other equipment.

Further, too many from our community – as they age out of pediatric care, and move into the adult care system, lose access to the providers who know how to

treat Spina Bifida. This is because many academic medical institutions will accept Medicaid for under 21 patients with Spina Bifida. Still, once they turn 21, they are considered adults, and their Medicaid coverage is not accepted. We understand and appreciate that much of Medicaid is governed at the state level, but we urge you to review both Medicare and Medicaid policies as they pertain to the Spina Bifida community and we stand ready to work with you to make changes that will improve access to developmentally appropriate primary and specialty care and DME for people with Spina Bifida across their life-span.

Conclusion

SBA believes that people should have access to the best health care supports to live an active and engaged life enabling them to thrive.

SBA looks forward to working with the new administration and both chambers of Congress to continue to make meaningful strides to improve the lives of the approximately 166,000 Americans living with Spina Bifida. We are poised to serve as a resource to your team during this transition period and beyond and are excited about the collaborative opportunities in the near future. We could not agree more with the "Build Back Better" plan to ensure that every American has access to quality, affordable health care by providing a public option and lowering costs for care and prescription drugs. We are excited to see this plan come to fruition.

Please feel free to contact me or either of our Public Policy representatives, Julie Hyams (julie.hyams@faegredrinker.com, 617/759-1628) and Ilisa Halpern Paul (ilisa.paul@faegredrinker.com, 202/288-6210) if we can provide additional information or be of any assistance to you and the incoming administration.

Sincerely,



Sara Struwe
President & CEO