September 9, 2020

The Honorable Richard Shelby
Chairman
Senate Committee on Appropriations
S-128, The Capitol
Washington, DC 20510

The Honorable Patrick Leahy
Vice Chair
Senate Committee on Appropriations
S-128, The Capitol
Washington, DC 20510

The Honorable Roy Blunt
Chairman
Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee
S-128, The Capitol
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee
S-128, The Capitol
Washington, DC 20510

RE: Support for Appropriations for Newborn Screening Programs

Dear Senators Shelby, Leahy, Blunt, and Murray:

Thank you for your leadership on the Fiscal Year (FY) 2021 Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations. The undersigned organizations, committed to the health of our nation's mothers, infants, children, and families, want to sincerely express our gratitude for the FY 2020 appropriations that have provided critical support to state newborn screening (NBS) programs. As negotiations on appropriations continue, we urge that $19 million be appropriated to the Centers for Disease Control and Prevention's (CDC) Environmental Health Laboratory to support its newborn screening activities, approximately $22 million be appropriated to the Health Resources and Services Administration's (HRSA) Heritable Disorders program, and adequate funding is provided for the National Institutes of Health (NIH) Child Health and Human Development program in the final FY 2021 LHHS appropriations bill that is negotiated by the House of Representatives and Senate.

For almost 60 years, newborn screening has been saving and improving the lives of children across the United States through early identification of diseases, which, if not identified and treated early, can cause permanent disability or death. It is unquestionably one of the most successful public health programs of our time, positively impacting millions of children and their families, and the researchers who use those blood spots in order to further understand and refine the tests for those diseases. For example, the CDC has demonstrated the impact of newborn screening for critical congenital heart disease (CCHD), finding that infant deaths from CCHD decreased more than 33% in states with mandatory screening compared to states with no mandatory screening policies. Additionally, deaths from other or unspecified cardiac causes decreased by 21% due to the NBS program.[1]

[1] Rahi, A., Grosse, SD, Ailes, EC, Oster, ME. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart Disease With Early Infant Cardiac Deaths. JAMA. 2017;318(21):1-8.

The CDC, HRSA, and NIH play a crucial role in supporting state newborn screening programs. The CDC's Environmental Health Laboratory performs quality testing for more than 500 laboratories to ensure the accuracy of newborn screening tests in the United States and around the world. Further, the CDC helps states implement new screening tests and works with partners to develop new screening tests for specific disorders.

HRSA's Heritable Disorders Program provides assistance to states to improve and expand their newborn screening programs and to promote parent and provider education. HRSA also supports the work of the Advisory Committee on Heritable Disorders in Newborns and Children, which provides states with a Recommended Uniform Screening Panel (RUSP) to help ensure every infant is screened for 35 conditions that have a recognized treatment. We hope that if funding is appropriated at our requested levels in FY 2021, this will allow for continued research and development on the RUSP, which has not added any new conditions since 2018.[2]

The NIH's National Institute of Child Health and Human Development (NICHD) conducts research to improve technical aspects of newborn screening tests in order to advance their sophistication and utility. The NICHD research aims to identify, develop, and test the most promising newborn screening technologies, increase the specificity of newborn screening, expand the number of conditions for which screening tests are available, and improve and evaluate treatments and disease management strategies for detectable conditions that can currently be treated and for other genetic metabolic, hormonal, and/or functional conditions that can be detected through newborn screening for which treatment is not yet available.[3]

In 2007, prior to the passage of the Newborn Screening Saves Lives Act, only 10 states and the District of Columbia required infants to be screened for all 29 disorders that were recommended at that time. Today, all 50 states, the District of Columbia, and Puerto Rico require screening for at least 30 of the 35 core conditions on the RUSP.[4]

We understand the difficulties presented by the constrained budget environment, particularly as the country is grappling with the COVID-19 pandemic. We deeply appreciate your historical support for these vital public health programs. The modest federal investment in state newborn screening programs yields outstanding dividends in health outcomes and infants' and families' quality of life. We thank you for your attention to our request and look forward to working with you to ensure that the United States identifies and treats each of the 1 in 300 infants who has a condition that can be detected through newborn screening. If you have questions, please do not hesitate to reach out to Richard White, rwhite@rarediseases.org, at NORD with any questions.

Sincerely,

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[2] Health Resources & Services Administration, Recommended Newborn Screening Panel, https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html

[3] National Institutes of Health, National Institute of Child Health and Human Development, https://www.nichd.nih.gov/health/topics/newborn/researchinfo/goals

[4] National Organization for Rare Disorders, State of the State Report 5th Edition https://1m3a2dwbacf3a4s843x6zi3m-wpengine.netdna-ssl.com/wp-content/uploads/2020/01/NRD-2021-StateOfTheStatesReport_5thEd_FNL.pdf

American Academy of Pediatrics

American Association for Clinical Chemistry

American College of Medical Genetics and Genomics

American College of Obstetricians and Gynecologists

Association of Maternal & Child Health Programs

Association of Public Health Laboratories

Cure Duchenne

Cure SMA

EveryLife Foundation for Rare Diseases

Firefly Fund

HCU Network America

Immune Deficiency Foundation

March of Dimes

Muscular Dystrophy Association

National Organization for Rare Disorders

Newborn Foundation

Rare Disease Innovations Institute

Save Babies Through Screening Foundation