February 4, 2022

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Senate Majority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
House Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Senate Minority Leader
United States Senate
Washington, DC 20510

Dear Speaker Pelosi, House Minority Leader McCarthy, Senate Majority Leader Schumer, and Minority Leader McConnell:

As you work with your colleagues on finalizing an omnibus spending bill for FY 2022, the undersigned organizations committed to the health of our nation's mothers, infants, children, and families ask that you include the "Newborn Screening Saves Lives Reauthorization Act of 2021" (H.R. 482), which passed the House with overwhelming bipartisan support last summer.

Each year thousands of babies are born with a genetic, metabolic, hormonal or functional condition that is not otherwise apparent at birth. Fifty years ago, these infants' disorders would have gone undetected until symptoms appeared, leading to possible death or lifelong disability. Today, a simple set of tests performed at birth can detect these life-threatening illnesses before any symptoms begin, allowing crucial time for early treatment to prevent long-term damage.

In 2008, Congress passed the original Newborn Screening Saves Lives Act (P.L. 110-204), which established national screening guidelines for the first time and helped make possible comprehensive newborn screening in every state. The first reauthorization bill was signed into law in 2014. Because of these legislative efforts, today all 50 states and the District of Columbia screen for at least 31 of the 35 currently recommended core conditions. As a result, over 12,000 babies are now identified each year with one of these treatable rare conditions.

Unfortunately, critical gaps and challenges still remain. Discrepancies in the number of tests given from state to state cause children to tragically die or become permanently disabled from otherwise treatable disorders.

Last year, a reauthorization bill to address these issues overwhelmingly passed the House in June but has not been considered in the Senate. Given the very crowded legislative calendar in 2022, we understand it's highly unlikely the Senate companion bill (S. 350) will receive floor time as a standalone measure. Therefore, we ask that H.R. 482 be included as part of the final FY 2022 federal budget package.

H.R. 482 will ensure that infants continue to receive comprehensive and effective screenings by:

- Reauthorizing the Health Resources and Services Administration (HRSA) grants to assist states' efforts to improve their screening programs, educate parents and health care providers, and improve follow-up care for infants with conditions detected through newborn screening;

- Renewing the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, which maintains and updates the Recommended Uniform Screening Panel that states adopt and implement;
- Reauthorizing programs at the Centers for Disease Control and Prevention (CDC) to provide technical assistance to state newborn screening programs to track outcomes of infants identified through newborn screening and the Newborn Screening Quality Assurance Program;
- Reauthorizing the National Institutes of Health (NIH) Hunter Kelly Newborn Screening program, which funds research aimed at identifying new treatments and new screening technologies; and
- Commissioning a National Academy of Medicine (NAM) report to make consensus recommendations to shift to a 21st century newborn screening system.

We greatly appreciate your consideration of our request. This bipartisan bill is a cost-effective strategy that saves lives, prevents disability and improves the quality of life for thousands of infants and families each year. We look forward to working with you to ensure that our nation's critical newborn screening programs are reauthorized without any further delay.

Sincerely,

Non-Profit Advocacy and Association Partners

A Better Balance
ALD Alliance
American Academy of Allergy, Asthma & Immunology
American Academy of Pediatrics
American Association for Clinical Chemistry
American Clinical Laboratory Association
American College of Medical Genetics and Genomics
American College of Obstetricians and Gynecologists
American Society of Hematology
Angelman Syndrome Foundation
Association for Creatine Deficiencies
Association of Maternal & Child Health Programs
Association of Public Health Laboratories
Batten Disease Support and Research Foundation
Big Cities Health Coalition
Black Women's Health Imperative
Boomer Esiason Foundation
Born a Hero Research Foundation
CureDuchenne
Cystic Fibrosis Foundation
Daphne's Lamp
Dreamsickle Kids Foundation, Inc. SCDAA Nevada Chapter
Engage Health, Inc.
EveryLife Foundation for Rare Diseases
Family Voices
Firefly Fund
First Focus Campaign for Children
Galactosemia Foundation
Global Foundation for Peroxisomal Disorders

HCU Network America
Histiocytosis Association
Hunter's Hope Foundation
International Foundation for CDKL5 Research
Jennifer Bush-Lawson Foundation
March for Moms
March of Dimes
Maternal Mental Health Leadership Alliance
Mississippi Metabolics Foundation
MomsRising
MTS Sickle Cell Foundation, Inc.
Muscular Dystrophy Association
National Ataxia Foundation
National Institute for Children's Health Quality
National Organization for Rare Disorders
National Partnership for Women & Families
National PKU Alliance
National WIC Association
National Women's Law Center
Network of Tyrosinemia Advocates
Newborn Screening Translational Research Network
NTM Info & Research
Prader-Willi Syndrome Association USA
Project Alive
Project GUARDIAN
Rare and Undiagnosed Network
Rare Disease Diversity Coalition
Rare Disease Innovations Institute, Inc.
Rare New England
SADS Foundation
Save Babies Through Screening Foundation
Society for Maternal-Fetal Medicine
SYNGAP1 Foundation
Texas Rare Alliance

Newborn Screening Industry Partners

Aeglea BioTherapeutics
Alexion Pharmaceuticals, Inc.
Ambit
Amicus Therapeutics
bluebird bio
Chiesi Global Rare Diseases
Homology Medicines, Inc.
Invitae Corporation
Johnson Group Consulting, Inc.
Rare Access Action Project
Rare Disease Company Coalition
REGENXBIO Inc.

Sanofi
Sarepta Therapeutics, Inc.
Solid Biosciences Inc.
Stoke Therapeutics
StrideBio
Travere Therapeutics

Cc: The Honorable Rosa DeLauro, Chair, House Appropriations Committee
The Honorable Kay Granger, Ranking Member, House Appropriations Committee
The Honorable Patrick Leahy, Chair, Senate Appropriations Committee
The Honorable Richard Shelby, Ranking Member, Senate Appropriations Committee