

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. SCDA 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  
Traverse 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