Dear Chairman Calonge and members of the Advisory Committee for Heritable Disorders in Newborns and Children,

Thank you for the opportunity to offer comments here today on behalf of the national rare disease community. My name is Dylan Simon and I serve as the Director of Policy for the EveryLife Foundation for Rare Diseases. The EveryLife Foundation is a nonprofit, nonpartisan organization dedicated to empowering the rare disease patient community to advocate for impactful, science driven legislation and policy that advances the equitable development of and access to lifesaving diagnoses, treatments, and cures.

Among the areas in which the patient community and the Committee find strong alignment is our commitment to ensuring the timely implementation of conditions that have been nominated for addition to the RUSP. To that end, while we appreciated the Committee's August discussion around 'Strengthening the Newborn Screening System', we fear that the discussion may have conflated the many legislative approaches underway and thus we feel it important to provide clarity as to the approach we have been proud to be leading.

Since 2016, the EveryLife Foundation has been working with the rare disease community and state leaders to pass State RUSP Alignment legislation. Fueled by a desire to ensure that state health departments are resourced, implementation timelines are reduced, and patient advocacy organizations can focus precious resources on community follow up, rather than state implementation efforts across 50 states, we have been leading a community effort to create state implementation pathways for RUSP conditions. Our collaborative and systematic approach has resulted in our community helping to pass legislation in eight states and consulting in two additional states to pass RUSP alignment legislation. Those states include California, Florida, Georgia, Ohio, North Carolina, Arizona, Pennsylvania, Iowa, Mississippi, and Maryland.

We are incredibly proud of our success and of our collaborative approach.

When we begin RUSP alignment efforts in a state, we seek to engage every newborn screening stakeholder, including patient advocates, policymakers, public health labs, and department officials. We work with these stakeholders to craft legislation or regulation that ensures that each particular state can successfully add new RUSP conditions within a predictable timeline. A key part of that process is initiating conversations with the newborn screening programs and their legislative representatives. In every state we work in, we reach out to both the Department and local advocates to aid in the development of legislation that will work best for that state.

We are also aware that we are not the only community members advocating for newborn screening legislation within the states which is why we think it important for the Committee to understand what distinguishes our legislation.

To be considered State RUSP Alignment legislation and/or regulation, it typically includes three key components:

1.The first component is an auto-inclusion or vote-for-inclusion piece, either requiring the state to add a new RUSP condition or requiring the state's Newborn Screening Advisory Council or Department of Health to consider a new RUSP condition for their state's panel. The bills do not name specific

conditions, nor do they allow for conditions that have not met the evidentiary criteria of the federal RUSP to be required to be added by a state.

2. The second component of RUSP alignment is the timeline, which requires a state to add, or consider adding, a new RUSP condition within a stated period of time. Dependent on the state, that period of time is somewhere between two and three years.

3.The third component of RUSP alignment is the allocation of resources. While different in every state, this typically includes the ability for the department or public health lab to raise the fee as they see fit or the creation of a newborn screening line item in the state budget.

In order for a bill to be considered State RUSP Alignment, it must consider all three components. The EveryLife Foundation and our community advocates are committed to ensuring that conditions which have been nominated for inclusion on the RUSP have pathways for timely and resourced implementation in all 50 states.

As an organization, we work with newborn screening stakeholders every day to determine the best ways to enhance policy efforts that improve and strengthen newborn screening. The State RUSP Alignment efforts reflect many organizations that support the legislation, state health departments and representatives who we have worked with to pass the legislation, and most importantly -- the families that the legislation has impacted.

We appreciate the opportunity today to provide additional information about our efforts and know that we all share the same goal of ensuring that newborn screening reaches as many families as possible to ensure that as families across the country can access this life-saving program.

Thank you for the opportunity to speak with the Committee today. We are grateful for your commitment to strengthening the newborn screening system.

Sincerely,

The EveryLife Foundation