



The Honorable Cathy McMorris Rodgers, Ranking Member  
Subcommittee on Consumer Protection & Commerce  
House Committee on Energy and Commerce  
Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Ranking Member McMorris Rodgers,

On behalf of the undersigned organizations, we write to thank you for your long-standing support of the Food and Drug Administration's (FDA) innovation programs, particularly those aimed to facilitate access to emerging technologies for babies, children and families. As novel digital health technologies and wearable consumer wellness devices come to market, some have proven to be life changing for parents and babies. One example is a recent request of FDA to Utah-based Owlet to stop marketing its sock-based, wearable monitoring device for new parents to use in the home. Smart Sock technology has years of use, millions of users, and a robust dataset from which to make decisions.

We understand the importance of regulatory bodies in ensuring only safe, effective, reliable medical and health devices and digital health technologies are available to the public and support that aim. Many other wearable consumer wellness products do not have the ability to quickly get to market as there is not a clear path to approval for technologies that provides the wearer with important notifications.

For many parents, the data available on such devices has helped parents know if babies were sleeping well, and safely - only alerting if something was outside of normal limits. What new parent would not want to know if their baby were having issues during sleep or rest? For some families, such technologies came too late. Babies were lost to SIDS, SUIDS, RSV, pneumonia, or to other asymptomatic or undiagnosed conditions that could potentially have been flagged by the same simple technologies that adults are able to use at home with a simple purchase at the drug store.

No child should suffer potentially preventable injury or death if there are consumer devices available to avoid such horrific consequences. We respectfully ask that you encourage FDA and the appropriate divisions and committees to swiftly provide clarity on the review process for health technologies that exist within the consumer wellness domain. If there is anything we can do to further advise or support your efforts to review existing or emerging technologies that can support and arm parents with tools to ensure the health and safety of their young children - please know we are here to do that. We thank you for your consideration and look forward to working with you. If you have questions or would like to discuss in more depth, please feel free to contact the Newborn Foundation Policy & Technical Committee at [info@newbornfoundation.org](mailto:info@newbornfoundation.org).

Sincerely,

Aspyn Arrows  
Butterflies & Birdies Foundation  
Just In Case Foundation  
Knox Blocks Foundation  
Newborn Foundation  
Silvie Bells  
The Briggs & Barrett Project  
The EAC Foundation (Ellis Ann Foundation) The Grey Effect Foundation  
The Little Fox - Toby's Foundation  
Zoey Renee Project