

Congress of the United States
Washington, DC 20510

June 5, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

We write to encourage the Food and Drug Administration (FDA) to consider establishing a Center of Excellence for Rare Diseases in an effort to improve treatments and health outcomes for those suffering from these conditions.

In December 2016, Congress authorized the FDA to establish Centers of Excellence to coordinate actions to address major diseases in an effort to improve treatments for patients as part of the 21st Century Cures Act. These Centers of Excellence are intended to combine expertise from a range of areas to leverage the FDA's ability to facilitate the development of life-saving medical therapies.

It is critical that we work to increase the number of safe, effective, and affordable treatments that are available for people with rare diseases—especially in light of the coronavirus (COVID-19) pandemic, which has put many of those with these conditions at greater risk of infection and adverse health outcomes. Developing therapies for small patient populations presents unique challenges, and we believe that a Center of Excellence for Rare Diseases could help to improve treatments for some of the patients who need them most. We also recognize that a Center of Excellence for Rare Diseases has the potential to leverage statistical analysis, systems biology, trials design, toxicology, and other areas of expertise across the FDA.

It is for these reasons that we ask you to consider establishing a Center of Excellence for Rare Diseases. We also respectfully request that you provide us with information concerning the expected cost of and timeline for establishing such a Center of Excellence. In addition, we ask that you provide more information on how a Center of Excellence for Rare Diseases could strengthen the FDA's ability to treat and prevent rare diseases, as well as how the FDA would work with other federal agencies to establish and develop such a Center of Excellence.

Thank you for your consideration of this important matter. We look forward to your response.

Sincerely,

/S/ Amy Klobuchar
Amy Klobuchar
United States Senator

/S/ Roger F. Wicker
Roger F. Wicker
United States Senator

/S/ G. K. Butterfield
G. K. Butterfield
Member of Congress

/S/ Gus M. Bilirakis
Gus M. Bilirakis
Member of Congress

/S/ Darren Soto
Darren Soto
Member of Congress

/S/ Eliot Engel
Eliot Engel
Member of Congress

/S/ Brian Fitzpatrick
Brian Fitzpatrick
Member of Congress

/S/ Tom Malinowski
Tom Malinowski
Member of Congress

/S/ Ted Deutch
Ted Deutch
Member of Congress

/S/ John Garamendi
John Garamendi
Member of Congress

/S/ Juan Vargas
Juan Vargas
Member of Congress

/S/ André Carson
André Carson
Member of Congress

/S/ Zoe Lofgren
Zoe Lofgren
Member of Congress

/S/ Brian Mast
Brian Mast
Member of Congress