

United States Senate

November 3, 2021

The Honorable Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

As we continue to battle the COVID-19 pandemic, it is clear there will be a lasting impact on patients around the world. While many individuals who contract COVID-19 are able to recover, there is a growing number who suffer long-term symptoms. In addition to studying these long-hauler patients with continuous symptoms, we must learn more about other potential long-term impacts of COVID-19. Studies have shown coronavirus links to heart disease, lung damage, and diabetes to name a few. The long-term impact for individuals of all ages following COVID-19 is also unknown. We therefore ask that you update Congress on FDA-NIH collaboration to study the impacts of the virus and your agency's participation in the COVID-19 Diagnostics Evidence Accelerator.

Consistent with some of the provisions in the *Ensuring Understanding of COVID-19 to Protect Public Health Act* (S.176), we are encouraged to see the National Institutes of Health utilizing funds to support research focused on the prolonged consequences of COVID-19 and how best to treat them. We also note that Congress provided funding to the Food and Drug Administration (FDA) to evaluate vaccines, therapeutics, and diagnostics to address COVID-19, and that your agency has a key role in the design and implementation of studies to support safe and effective treatments. This is critical not only for acutely ill patients, but also for those suffering from long-haul COVID-19, as well as those with long-term impacts that may have yet to surface. Ensuring that a diverse population is included in these studies is also vital to understanding how this virus and possible treatments impact people in different ways.

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We request that you provide Congress an update on how FDA and NIH are collaborating to ensure adequate data is available for regulatory decision-making purposes, including identification of existing gaps and any future plans to fill in those gaps. We also request an update on the collaboration announced last year regarding FDA's participation in the COVID-19 Diagnostics Evidence Accelerator, organized by the Reagan-Udall Foundation for the FDA and Friends of Cancer Research, including how FDA is utilizing appropriated funds in recent months to support this work. Public-private partnerships have been key to fighting this pandemic and will continue to play a significant role in our recovery.

We appreciate your time and attention, and look forward to receiving your timely response and working with you on this important issue.

Sincerely,



Jacky Rosen
United States Senator



Marco Rubio
United States Senator



Catherine Cortez Masto
United States Senator

s/ Robert P. Casey, Jr.
Robert P. Casey, Jr.
United States Senator

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Dianne Feinstein
United States Senator

A handwritten signature in blue ink, appearing to read "Susan Collins".

Susan Collins
United States Senator

A handwritten signature in blue ink, appearing to read "C. Murphy".

Christopher S. Murphy
United States Senator