

United States Senate

March 13, 2020

Commissioner Stephen Hahn, M.D.
Food and Drug Administration
United States Department of Health and Human Services
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Hahn:

Last year, I wrote to you concerning the Food and Drug Administration's (FDA) opportunity to better prioritize bringing life-saving drugs to patients faster by expanding FDA's Parallel Track for drug approval to other critical diseases.

Since that time, the need to bring such drugs to patients has only increased with the emergence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and deaths from Coronavirus Disease 2019 (COVID-19) (collectively hereinafter "coronavirus"). Coronavirus is at pandemic levels. Currently, there is neither a vaccine nor antiviral drugs for coronavirus. Many Americans have become infected with coronavirus and many have died. Americans need life-saving treatments as soon as possible.

Sadly, such a situation is not new to the FDA. The FDA faced a similar situation with the HIV/AIDS epidemic. There were no antiviral drugs or vaccines available, and a growing number of Americans were infected and dying. To help confront this epidemic, FDA took the heroic step of creating the Parallel Track to speed access to drugs that were in the FDA approval process. The FDA's actions enabled patients to access a breakthrough drug to treat HIV/AIDS years ahead of the drug's final FDA approval. Simply, the Parallel Track saved lives.

Now, Americans—especially senior citizens and those with medical conditions—face a similar problem. They need access to new drugs to treat coronavirus as soon as possible and cannot wait for access. Waiting for many can mean death.

FDA has the authority to expand Parallel Track to meet this need. All that is needed is for you to act.

Therefore, I urge you in the strongest possible terms to expand Parallel Track—a proven solution—to provide Americans access to drugs and other therapeutics to combat the coronavirus.

Sincerely,

7-18

Ted Cruz
United States Senator