Congress of the United States
Washington, DC 20515

May 17, 2019

Acting Commissioner Norman E. "Ned" Sharpless, 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 Acting Commissioner Sharpless,

With the change in leadership at the Food and Drug Administration (FDA), there is a unique opportunity for the FDA to better prioritize bringing life-saving drugs to patients faster and at a lower cost by expanding the FDA's Parallel Track for drug approval to other critical diseases.

In recent years the FDA has sought to streamline its drug approval process, and such efforts should be commended. However, significant barriers to ready access remain. Despite FDA's efforts, it still takes on average 10 to 12 years and as much as $2.9 billion to bring a new treatment from lab to patients. Many patients with critical illnesses cannot wait that long.

One unused solution that the FDA already has at its disposal is to expand the existing Parallel Track to other diseases.

Created in 1992, the Parallel Track allowed individuals to access a breakthrough drug to treat HIV/AIDS years ahead of the drug's final FDA approval, while the drug was still in Phase II and III clinical trials. Thousands of sufferers had their lives saved because of quicker access to this drug.

Today, millions of Americans are similarly afflicted by or dying from debilitating diseases such as Alzheimer's disease, cancer, and amyotrophic lateral sclerosis (ALS). Similar to the HIV/AIDS crisis, potentially life-saving drugs for these diseases are mired in Phases II and III of the drug-approval process. Although demonstrating amazing results for the few Americans allowed to participate in clinical trials, these much-needed drugs and therapies remain years and billions of dollars of investment away from FDA approval and full access by patients.

In order to bring these drugs and therapies more quickly and at a lower cost to Americans, we strongly urge the FDA to expand the Parallel Track to target these devastating diseases. Under an expanded Parallel Track, the sponsors of any drug or therapy that has successfully passed safety criteria would have the option to allow patients with critical illnesses—not already enrolled in controlled clinical trials—to access these drugs and therapies after consulting with their doctor.

As we examine the budget of the FDA and its potential new leadership, we are looking for evidence that the agency seeks to act as a bridge—not a barrier—to innovation.

It is time for the FDA to create and encourage an environment that promotes patient choice, patient access, and patient affordability. Expansion of the Parallel Track is a proven solution to do just that, and we strongly encourage the FDA to act immediately on this issue.

Sincerely,

Rand Paul

Mike Braun