

Congress of the United States
Washington, DC 20515

May 8, 2020

The Honorable Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Assistant Secretary Kadlec:

We are writing to request additional information about the process and criteria used to distribute the federal government's limited supply of the investigational new drug remdesivir, which the U.S. Food and Drug Administration has indicated may benefit certain people in the hospital with COVID-19.

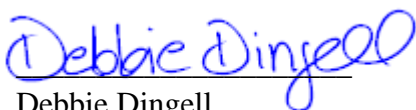
Following preliminary clinical trial data from the National Institutes of Health indicating that remdesivir carries some clinical benefit to patients hospitalized due to COVID-19, the FDA authorized the use of remdesivir under an Emergency Use Authorization (EUA) on May 1. After this EUA issuance, Gilead Sciences, the manufacturer of remdesivir, announced that the company would donate 1.5 million doses of the drug to the federal government. According to media reports, since this time, the your office has coordinated distribution of the federal supply of remdesivir across the United States.

We are seeking information on how the drug is being allocated. Currently, hospitals and providers, including those in the State of Michigan, have been denied access to the drug without explanation. Clarity on the criteria used for distribution will allow providers to more effectively manage treatment of COVID-19 patients in the coming days and weeks.

Transparency in the federal government's role in allocation of remdesivir, and guidance on how remdesivir should be allocated, will provide certainty to providers and facilitate a stronger and more cohesive response to the COVID-19 pandemic. With this in mind, we are requesting additional information on the criteria used to decide where the 1.5 million doses of remdesivir are being distributed, as well as comprehensive data on which providers are receiving the drug and the amounts that they are receiving.

Thank you for your consideration of this request.

Sincerely,



Debbie Dingell
Member of Congress



Fred Upton
Member of Congress