

United States Senate

WASHINGTON, DC 20510

May 13, 2020

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write to seek transparency and information regarding the distribution process for the coronavirus (COVID-19) therapeutic remdesivir, especially given the likely federal role in distributing other future COVID-19 drugs and vaccines.

On May 1, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for remdesivir for the treatment of hospitalized COVID-19 patients. The EUA stipulates that the “distribution of the authorized remdesivir will be controlled by the United States Government ... in collaboration with state and local government authorities, as needed.” The manufacturer of remdesivir, Gilead, has confirmed, through public statements, that “the U.S. government will coordinate the distribution of remdesivir to hospitals in regions most heavily impacted by COVID-19. Gilead and AmerisourceBergen are not deciding which hospitals will receive remdesivir.”

In the days following this EUA, significant concerns have been raised by hospitals, health providers, patients, and medical societies regarding the opaque process under which the federal government is determining distribution of remdesivir, as well as the future supply to meet patient needs. Organizations including the Infectious Diseases Society of America, the HIV Medicine Association, and the American Society of Health-System Pharmacists have written to urge transparency and orderly allocation of this therapeutic. Unfortunately, reports from our hospitals painted a picture of disarray, confusion, and inequity during the first week of remdesivir distribution. Originally, approximately 25 hospitals appeared to have received direct access to remdesivir, with a seemingly arbitrary process as many academic medical centers treating the highest volumes of COVID-19 patients in their states were been unable to obtain remdesivir.

On May 9, HHS announced that it would be turning the distribution process over to the states, with health departments receiving shipments of remdesivir and allocating them within their states to appropriate hospitals. While states and local health officials have the insights to make decisions about needs across their communities, this announcement leaves many questions unanswered about when states will receive shipments, how the amounts of shipments to each state were/will be determined, and what the federal role may be following such shipments. We are also concerned that the shipments will not adequately address patient needs.

We acknowledge that the limited current supply and substantial demand for remdesivir results in necessary choices about distribution. However, in the midst of this pandemic, it is

unacceptable for our health care system and patients to be left in the dark about if, how, and when, supply of this therapeutic may arrive. And this appears to follow a similar pattern of the supply chain for medical supplies being shrouded in secrecy and poorly coordinated federal intervention, as we have seen with personal protective equipment and testing kit supplies. Given the likelihood of future therapeutics and vaccines being approved or authorized for use in the U.S., it is essential that the Administration assuage concerns about this initial test run of such federal distribution and any potentially unfair system for distributing essential medical supplies.

To ensure equitable distribution of this treatment for COVID-19 patients, we request a briefing by May 19 from the Administration officials in charge of this allocation process. Further, we urge your agencies to establish a public-facing portal to outline the methodology being used to allocate this therapeutic, as well as a process for hospitals to request access to remdesivir. Thank you for your attention to this urgent and important public health matter.

Sincerely,



Richard J. Durbin
United States Senator



Tammy Baldwin
United States Senator

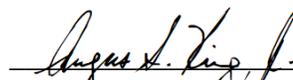


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