Congress of the United States
Washington, DC 20515

May 8, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
1600 Pennsylvania Ave., N.W.
Washington DC 25000

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Vice President Pence and Secretary Azar,

We are unsettled by recent reports that the distribution process for the drug remdesivir — which the Food and Drug Administration (FDA) gave emergency use authorization (EUA) to treat COVID-19 — is opaque, lacking clear guidelines, and without focus on the communities that the disease has most impacted. We call on the federal government to immediately explain how it is distributing remdesivir, including publishing its distribution methodology. The federal government must ensure that the distribution of COVID-19 therapies such as remdesivir, or future vaccines, is transparent and orderly, and that these treatments reach highly impacted areas that are in need of these critical resources the most.

Hospitals across the nation are reporting uneven distribution of remdesivir, with the drug going to hospitals with fewer COVID-19 patients than others. In Massachusetts, four medical centers were notified they would receive an allotment of remdesivir, with many of them surprised by the decision.[1] Two of the Massachusetts medical centers slated to receive the drug have fewer than 100 COVID-19 cases, while two others, each with more than 230 cases, will not be getting it.[2] It is unclear why hospitals with the highest number of COVID-19 patients are not receiving the drug. Now, hospitals and the state are trying to coordinate distribution to areas of greatest need — and fill the void in leadership left by the federal government — but are reluctant to do so for

[1] Eric Boodman and Casey Ross, *Doctors lambaste federal process for distributing Covid-19 drug remdesivir*, STAT News (May 6, 2020), https://www.statnews.com/2020/05/06/doctors-lambaste-federal-process-for-distributing-covid-19-drug-remdesivir/.
[2] *Id.*

fear it will cause the Commonwealth to receive fewer doses.[3] Although the remdesivir EUA provides that the U.S. government will control the drug's distribution, there are as yet no other publicly available guidelines.[4] Additionally, the National Institutes of Health (NIH) has not yet released the full study results that justified the remdesivir EUA, limiting physicians' ability to target the drug toward the patients who are likely to benefit most.[5] In the absence of this information, hospitals are unable to prioritize distribution of the drug, which could lead to rationing decisions that may treat people with disabilities or underlying health conditions inequitably.[6]

HHS's failure to publicly articulate a clear distribution process for this treatment diverges from past federal government practice. During the H1N1 flu outbreak in 2009, the Centers for Disease Control and Prevention (CDC) quickly and clearly communicated with hospitals about new therapies, including creating a website for hospitals to apply for access to a new drug that the FDA had approved.[7] By contrast today, hospitals are in the dark about the distribution of remdesivir, leaving them scrambling to understand whether and when they will receive it, and, if so, how much.[8] This state of affairs also raises serious concerns about the efficiency, transparency, and equity of the distribution of future therapies and vaccines.

Congress and the public need to know whether HHS is making its distribution decisions in backroom deals or is relying on data and evidence to ensure that potentially life-saving drugs reach the patients who need them. A transparent and data-driven process is especially important to eliminate bias and avoid furthering health disparities. Infectious disease doctors from across the nation expect, and have called for, a transparent distribution of remdesivir based on state and regional COVID-19 case data and hospitalization rates.[9] Remdesivir is the first approved treatment for COVID-19, but this process is likely to repeat as future treatments and vaccines

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[3] Rebecca Ostriker, *Who's getting federal distributions of coronavirus drug remdesivir? After much confusion, Massachusetts government, hospitals team up to share*, Boston Globe (May 7, 2020), https://www.bostonglobe.com/2020/05/07/nation/whos-getting-federal-distributions-coronavirus-drug-remdesivir-after-much-confusion-massachusetts-government-hospitals-team-up-share/.

[4] Letter from the Food and Drug Admin to Gilead Sciences, Inc. (May 1, 2020), https://www.fda.gov/media/137564/download.

[5] Christopher Rowland and Laurie McGinley, *Trump administration pushed use of remdesivir, but unequal rollout angers doctors*, Wash. Post (May 7, 2020), https://www.washingtonpost.com/business/2020/05/07/remdesivir-hospitals-doctors/.

[6] Eric Boodman and Casey Ross, *Doctors lambaste federal process for distributing Covid-19 drug remdesivir*, STAT News (May 6, 2020), https://www.statnews.com/2020/05/06/doctors-lambaste-federal-process-for-distributing-covid-19-drug-remdesivir/.

[7] Debra Birnkrant and Edward Cox, *The Emergency Use Authorization of Peramivir for Treatment of 2009 H1N1 Influenza*, New England Journal of Medicine (Dec. 3, 2009), https://www.nejm.org/doi/full/10.1056/NEJMp0910479.

[8] Jaimy Lee, *Infectious disease doctors ask government to explain how it decides who gets Gilead's remdesivir*, MarketWatch (May 7, 2020), https://www.marketwatch.com/story/infectious-disease-doctors-ask-government-to-explain-how-it-decides-who-gets-gileads-remdesivir-2020-05-07?mod=retail.

[9] Letter from the Infectious Diseases Society of America and the HIV Medicine Association to Vice President Pence (May 6, 2020), https://www.hivma.org/globalassets/remdesivir-eua-letter-final.pdf.

become available. The federal government must recognize the gravity of the situation and establish a thoughtful, deliberate, and transparent process for distributing COVID-19 therapeutics and vaccines.

For these reasons, we ask for your responses to the questions below by May 13, 2020:

1. Which federal government entity is responsible for distribution of remdesivir and who is in charge of the effort?
2. What is the distribution methodology for remdesivir? Which health care facilities will receive remdesivir, why, when, and in what quantities?
3. Which health care facilities have already received distributions of remdesivir, when, and in what quantities? How and why were those health care facilities selected?
4. Does the distribution methodology for remdesivir take into account state and regional COVID-19 case data and hospitalization rates? If so, how? If not, why not?
5. Does the Administration intend to modify the existing remdesivir distribution methodology as production of the drug scales up?

Thank you in advance for your attention to these requests. If you have any questions, please contact Adam Axler at adam_axler@markey.senate.gov, Susannah Savage at susannah_savage@warren.senate.gov, or Lynese Wallace at lynese.wallace@mail.house.gov.

Sincerely,

Edward J. Markey
United States Senator

Elizabeth Warren
United States Senator

Ayanna Pressley
Member of Congress