Congress of the United States Washington, DC 20515

May 13, 2020

Alex Azar Secretary Department of Health and Human Services 200 Independence Ave. SW Washington, DC 20201

Dear Secretary Azar,

While renewing our request for a response to our April 30 letter regarding taxpayer investments in remdesivir, we write again concerning the clinical trial data and allocation for remdesivir. Even though it is neither a cure nor capable of significantly reducing the death rate, remdesivir appears to assist in reducing the recovery period for some who are hospitalized. Delays in preparation for this pandemic and apparent mishandling of the first distribution of remdesivir have raised concerns about the appropriate allocation of the few available doses.

Though the National Institute of Allergy and Infectious Diseases (NIAID) has apparently promised a preliminary report of the initial clinical trial results in a few weeks, this is a lifetime for many health care professionals and their patients. For state health leaders and hospital medical boards waiting for this information, a few weeks could mean many lives lost or worsened illness. Those few states, which already received some doses, with no guidance nor clinical trial data, face difficult decisions about which patients get the medication. To achieve a semblance of fairness, some hospitals have decided to forego prescribing the treatment until such guidance is released. Though incomplete, the NIAID's clinical trial data is important to make these strategic decisions.

While the Food and Drug Administration's emergency authorization provided for U.S. government allocation, HHS distribution of remdesivir seems akin to winning the lottery—a random stroke of luck rather than a medically-informed decision. Even Dr. Deborah Birx, in a May 7 email, called for an internal assessment of a process "that resulted in the misalignment of the therapeutic and on-the-ground current need in the first shipment so we can be assured this doesn't occur in the future."

We seek a transparent process for distributing available supplies of remdesivir. The need is great in this critical moment and the supply is apparently very limited. According to the May 9 HHS statement, from a total current supply of 1.5 million vials of remdesivir, the U.S. will receive only 607,000 vials, enough to treat approximately 78,000 patients. To assure supplies of remdesivir reach patients with the greatest need, please provide the following information, some of which we previously requested from you:

- 1. The formula HHS used to determine which states would receive how many doses of remdesivir and the delivery schedule for these doses.
- 2. How many doses of remdesivir allocated for the U.S. have not been committed and the formula HHS will use to determine which states will receive them.

- 3. Any guidance provided to states to determine allocation of available doses to their hospitals.
- 4. The formula used to determine how the U.S. was allocated approximately 40% of the available supply and which other countries received how many doses.
- 5. Any agreements the U.S. has already entered into with Gilead for future doses of remdesivir and the terms of those agreements, including amount, price, and timeline.
- 6. Any agreements the U.S. has entered into regarding the construction or retrofitting of manufacturing facilities to produce more doses of remdesivir, and the terms of those agreements, including amount of federal funding and expenditure breakdown, associated purchase and pricing agreements, and timeline.

We appreciate your immediate attention to these important questions and look forward to your separate and complete responses to both of our letters.

Sincerely,

Llovd Doggett

Rosa DeLauro