



July 14, 2020

The Honorable Mike Pence
The White House
Office of the Vice President
1600 Pennsylvania Avenue, NW
Washington, DC 20500

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Vice President Pence and Secretary Azar:

We are writing on behalf of the Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA) to urge the administration to use every authority it has, and to do whatever is necessary, to ensure an adequate supply of remdesivir for the United States and worldwide and ensure that supply is distributed equitably. IDSA and HIVMA represent over 12,000 infectious diseases and HIV physicians, scientists, and other healthcare and public health professionals on the frontlines of the COVID-19 response.

As cases of COVID-19 climb above 3.2 million in the U.S. and more than 135,000 people have lost their lives to COVID-19 in our country, available treatment options remain limited, and we do not have an effective vaccine. Remdesivir is the primary COVID-19 treatment available outside of a clinical trial. Remdesivir is available through an emergency use authorization (EUA) granted by the FDA following clinical trial data demonstrating that it shortened hospital stays for patients critically ill with COVID-19. Since the availability of remdesivir under the EUA, the drug has been a critical tool helping to shorten the recovery time for hospitalized patients, reducing strains on hospital systems and frontline healthcare workers. While dexamethasone also is being used to treat patients with severe disease, this is based on preliminary study data.

We are concerned that the current supply of remdesivir is insufficient, particularly given dramatically escalating caseloads in many states and the likelihood of a continuing surge into the fall and winter. Added to this concern is the fact that production is limited due to the drug's complex manufacturing requirements and the reliance on a single manufacturer to produce it for developed countries. We appreciate the efforts that have been taken by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) to distribute remdesivir equitably to states and the transparency that has been provided with regards to that distribution. Now that remdesivir is available commercially, the principles of equitable access and transparency remain paramount as hospitals experience treatment shortages and must make difficult decisions regarding how to triage the limited supply available. **As hospitals face potential shortages of remdesivir, we would appreciate the opportunity to meet with you to discuss the following issues and options for improving access to remdesivir.**

Increased Patient Demand: As a growing number of hospitals and intensive care units around the country reach or exceed their capacity, we are concerned that if the administration does not take action to increase production of remdesivir that we will not have a sufficient inventory to treat patients seriously ill with COVID-19 and that hospitals will face even greater strains in caring for patients. Just in the last seven days, there have been more than 394,000 new cases of confirmed COVID-19 cases, and, as a portion of these cases will progress to serious illness over the next few weeks, we expect hospitalizations to rise dramatically. Over the last week, we have already heard reports from infectious diseases physicians in several hard-hit southern and western states that their hospitals had run out of remdesivir. In response, we appreciated the action taken by HHS to ship emergency supplies on June 10 to Florida, Texas, Arizona and California but are concerned that meeting future urgent needs will not be possible if a larger global supply is not available. We also anticipate demand will grow when hospitals are likely to be even further stressed in the fall and winter when there is likely to be an influx of both seasonal influenza and COVID-19 cases.

Global Supply: Remdesivir supply limitations led to the U.S. purchasing around 93% of the 500,000 treatment courses available through September to the exclusion of other developed countries, including countries that participated in the Adaptive COVID-19 Treatment Trial (ACTT) that led to the EUA. While the U.S. accounts for a quarter of cases and nearly a quarter of COVID-19 related deaths, we are concerned by the potential impact of this action. It is imperative to ensure that as treatments and vaccines are developed that they are equitably distributed both within and outside the U.S. We will not achieve control of the COVID-19 pandemic in the U.S. without strong coordination and collaboration with the global community: Microbes like viruses and bacteria get on planes, trains and boats, so if there is uncontrolled infection anywhere, the entire world remains at risk.

National Monitoring and Tracking: Under the EUA, ASPR will continue to oversee the allocation of remdesivir through at least September, with states determining how the drug is distributed to hospitals. To improve this process, we strongly recommend implementing a national mechanism for tracking drug inventories within states and at the hospital level to ensure the drug is reaching populations in greatest need and to assist with national monitoring and planning for future allocations based on real-time data.

As we continue to face challenges in controlling COVID-19, we urge the administration to fully leverage all authorities including the Defense Production Act and other tools to ensure adequate supplies of remdesivir and the other resources essential to controlling the virus. Thank you for considering our recommendations and perspective. Please contact Amanda Jezek, IDSA Senior Vice President of Public Policy & Government Relations at ajezek@idsociety.org or Andrea Weddle, HIVMA Executive Director at aweddle@hivma.org to schedule a meeting.

Sincerely,



Thomas M. File, Jr., M.D., MSc, FIDSA
President, IDSA



Judith Feinberg, M.D., FIDSA
Chair, HIVMA