May 6, 2020

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

Dear Vice President Pence:

We are writing on behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) to urge the federal government to ensure a fair and equitable distribution of remdesivir now that it has been authorized by the U.S. Food and Drug Administration for emergency use for the treatment of patients hospitalized due to COVID-19.

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.

The U.S. Food and Drug Administration's emergency use authorization of remdesivir on May 1 will expand its use in hospitals across the country.[i] While remdesivir remains an investigational drug, the FDA made this decision based on preliminary clinical trial data suggesting that the benefits or potential benefits of treatment with remdesivir in patients with severe COVID-19 outweigh the risks.

Following the EUA approval, Gilead Sciences announced that they would donate 1.5 million individual doses of remdesivir -- with a 10-day treatment course this will be enough drug to treat 140,000 patients.[ii] This inventory is likely to fall short of demand given that tens of thousands of patients per month are projected to require hospitalization nationwide due to COVID-19 throughout the summer months,[iii] and that the majority of hospitalized patients have acute severe disease and will meet the FDA criteria for treatment.

The plan for distributing remdesivir should be transparent and should be based on state and regional COVID-19 case data and hospitalization rates. Supplies of remdesivir should be distributed on a regional basis with equitable distribution within the region to states and within states to hospitals. This will be imperative to ensure appropriate patient access, reduce the significant health disparities and adverse outcomes already experienced by Black Americans, Latinx communities and other populations, and to prevent a surge in patients at institutions known or thought to have access to the drug or a crush of requests to transfer patients to these hospitals from those who may not have remdesivir access.

Data on the distribution of remdesivir under the EUA should be publicly available. In addition, data from the Adaptive COVID-19 Treatment Trial (ACTT) should be publicly released so that hospitals with a limited supply have the best possible data to inform how to distribute it among patients.

Due to the significant demands that frontline providers face in caring for patients with COVID-19, the **EUA application required for each patient should be significantly streamlined to require only the minimum amount of data and information required to effectively and safely consider the request for emergency use**. This will be essential to facilitate timely access to this medication that has been authorized for emergency use to treat COVID-19 due to the urgency of this ongoing national health crisis, and will ensure that physicians can spend the needed time at the bedside instead of completing paperwork.

If you have questions or require additional information, please do not hesitate to contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at ajezek@idsociety.org, or Andrea Weddle, HIVMA Executive Director at aweddle@hivma.org.

Sincerely,

Thomas M. File, Jr., MD, MSc
Fellow of the IDSA
President, IDSA

Judith Feinberg, MD
Fellow of the IDSA
Chair, HIVMA

CC: Alex Azar, Secretary, U.S. Department of Health and Human Services
Ken Cuccinelli, Acting Deputy Secretary of Homeland Security
Robert Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, HHS
Anthony S. Fauci, MD, Director, NIH National Institute of Allergy and Infectious Diseases
Robert R. Redfield, MD, Director, Centers for Disease Control and Prevention
Stephen N. Hahn, MD, Commissioner of the Food and Drug Administration
Pete T. Gaynor, Administrator, Federal Emergency Management Agency

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[i] U.S. Food and Drug Administration. Approval letter sent to Ashley Rhoades, MBS, RAC, Gilead Sciences. May 1, 2020.

[ii] Gilead Sciences. Press Release: Gilead's Investigational Antiviral Remdesivir Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of COVID-19. May 1, 2020.

[iii] Institute for Health Metrics and Evaluation (IHME). COVID-19 Projections. Accessed May 5, 2020.