

May 13, 2020

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

The Honorable Robert Kadlec
Assistant Secretary for Preparedness and
Response
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Azar and Assistant Secretary Kadlec:

I write today to inquire about the methodologies employed to distribute remdesivir. The U.S. Department of Health and Human Services (HHS) is expected to uphold its duty in protecting the health of all Americans. This includes distribution of remdesivir to all communities, especially those that became COVID-19 hotspots. Now more than ever, it is critical that we support healthcare providers in fighting COVID-19 by providing the appropriate tools and medication to fight this illness.

As you know, on May 1st the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of remdesivir to treat hospitalized COVID-19 patients.¹ This occurred two days after the National Institutes of Health's (NIH) clinical trial showed that patients who received the treatment had a 31% faster recovery time compared with those who received a placebo, a significant step forward in battling COVID-19.² Under the Federal Food, Drug and Cosmetic Act, distribution of any drug receiving an EUA is to be controlled by the United States Government for use.³ It is my understanding that HHS is responsible for consulting with state and local government authorities in this distribution.

¹ U.S. Food and Drug Administration. *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*. 01, May 2020. Accessed on 08, May 2020 Retrieved from: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>

² U.S. National Institute of Health. *NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID-19*. 29, April 2020. Accessed on 11, May 2020. Retrieved from: <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>

³ Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb-3(e)(i))

However, media reports suggest that doctors across the country are announcing they were “denied access” to remdesivir for their patients.⁴ Furthermore, many doctors don’t understand the process for obtaining the drug due to a lack of guidance and transparency from HHS.⁵

On Friday, my office was informed that Wyckoff Heights Medical Center, a hospital in my district that serves a large minority population, was denied access to remdesivir. According to Wyckoff Heights Medical Center Staff, they have experienced over 1,000 COVID-19 positive patients, 226 resulting in deaths. Additionally, reports on the ground suggest that Wyckoff Heights’ experience is prevalent at hospitals across the nation, many that also serve a large population of minority patients.⁶

To better understand HHS’s decision-making process in distributing doses of remdesivir donated to the U.S. federal government by Gilead Sciences, I request answers to the following questions by Friday, May 15, 2020:

1. Of the 1.5 million remdesivir vials donated globally by Gilead Sciences⁷ it is our understanding that Gilead has committed to supplying approximately 607,000 vials of the experimental drug over the next six weeks. On Saturday, HHS announced cases were distributed to 10 states with each case containing 40 vials.⁸ What guidance was given to HHS staff in determining the allocation and prioritization of the donated cases?
2. Considering HHS expects that cases will be delivered to all 50 states and territories, does HHS plan to consult with local governments for future remdesivir distributions?
 - a. Have these methodologies changed since the initial distribution?
 - b. Does HHS plan to consult directly with hospitals and health care providers in future remdesivir distributions?
 - i. Under what circumstances will HHS consult with hospitals and health care providers?
3. Current data suggest a disproportionate burden of illness and death among racial and ethnic minority groups.⁹ Given this information, did your methodology consider or

⁴ Washington Post. *Trump administration pushed use of remdesivir, but unequal rollout angers doctors*. 07, May 2020. Accessed on 09, May 2020. Retrieved from:

<https://www.washingtonpost.com/business/2020/05/07/remdesivir-hospitals-doctors/>

⁵ *Id.*

⁶ New York Times. *Haphazard Rollout of Coronavirus Drug Frustrates Doctors*. 08, May 2020. Accessed on 08, May 2020. Retrieved from: <https://www.nytimes.com/2020/05/08/health/coronavirus-remdesivir-hospitals.html>

⁷ Gilead. *Gilead’s Investigational Antiviral Remdesivir Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of COVID-19*. 01, May 2020. Accessed on 11, May 2020. Retrieved from:

<https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid-19>

⁸ U.S. Department of Health and Human Services. *HHS announces shipments of donated remdesivir for hospitalized patients with COVID-19*. 9, May 2020. Accessed on 11, May 2020. Retrieved from:

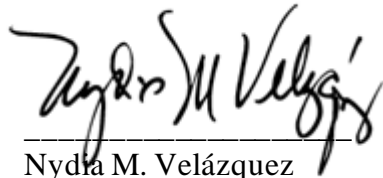
<https://www.hhs.gov/about/news/2020/05/09/hhs-ships-first-doses-of-donated-remdesivir-for-hospitalized-patients-with-covid-19.html>

⁹ Center for Disease Control and Prevention. *COVID-19 in Racial and Ethnic Minority Groups*. 22, April 2020. Accessed on 11, May 2020. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>

prioritize regional locations where hospitals are serving low-income communities or communities of color?

Thank you for your attention to this urgent issue and I look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Nydra M. Velázquez". The signature is fluid and cursive, with the first name "Nydra" being more prominent.

Nydra M. Velázquez
Member of Congress