

United States Senate

WASHINGTON, DC 20510

November 16, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Secretary Azar:

We write to follow up on our July 16, 2020 letter to the Department of Health and Human Services (HHS) regarding the Department's pricing negotiations with Gilead Sciences for a large supply of remdesivir.¹ This arrangement allowed Gilead to charge American health insurers the highest price in the world for remdesivir²—representing windfall revenues of up to almost half a billion dollars for the company, paid for in whole or in part by increased insurance premiums for American families³—despite having several other options available to expand remdesivir access in the U.S, and despite the fact that American taxpayers spent over \$70 million to help develop and test the drug.⁴ Last month, the U.S. Food and Drug Administration (FDA) announced full approval of remdesivir,⁵ making the antiviral the first approved COVID-19 treatment in the United States and making questions about remdesivir's pricing and accessibility even more important.

At the time of HHS's initial agreement with Gilead, outside analysts concluded that the deal was “amazingly good for Gilead's executives and shareholders and amazingly bad for everyone else—bad for taxpayers, terrible for public health, and unethical.”⁶ Since then,

¹ Letter from Senator Warren et. al. to HHS Secretary Alex Azar, July 16, 2020, <https://www.warren.senate.gov/imo/media/doc/2020.07.16%20Letter%20to%20HHS%20re%20remdesivir%20pricing.pdf>; U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” press release, June 29, 2020, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

² Reuters, “Gilead's remdesivir could see \$7 billion in annual sales on stockpiling boost: analyst,” Saumya Joseph, June 3, 2020, <https://www.reuters.com/article/us-health-coronavirus-remdesivir/gileads-remdesivir-could-see-7-billion-in-annual-sales-on-stockpiling-boost-analyst-idUSKBN23A2MN>.

³ This price represents the additional revenue generated from selling “more than 500,000 treatment courses” at “approximately \$3,200 per treatment course,” which is \$860 above the “\$2,340 per patient” price for patients in the rest of the world. U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” press release, June 29, 2020, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>; Gilead Sciences, Inc., “An Open Letter from Daniel O’Day, Chairman & CEO, Gilead Sciences,” Daniel O’Day, June 29, 2020, <https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29>.

⁴ Public Citizen, “The Real Story of Remdesivir,” May 7, 2020, <https://www.citizen.org/article/the-real-story-of-remdesivir/>.

⁵ Politico, “FDA approves remdesivir as first coronavirus drug,” Zachary Brennan, October 22, 2020, <https://www.politico.com/news/2020/10/22/fda-approves-remdesivir-coronavirus-431336>.

⁶ STAT, “A powerful law gives HHS the right to take control of remdesivir manufacturing and distribution,” Christopher Morten, Christian Urrutia, and James Krellenstein, July 2, 2020,

randomized control experiments have shown that remdesivir had demonstrated modest effectiveness in reducing recovery time for patients hospitalized with COVID-19, including one that showed the treatment shortened recovery time for hospitalized patients from 15 days to 11 days.⁷ But no rigorous studies have found a survival benefit to the drug,⁸ and last week, researchers at the World Health Organization (WHO) studying remdesivir’s effects in nearly 3,000 patients worldwide found that the treatment had little or no effect in reducing deaths from COVID-19 among hospitalized patients or reducing hospital stays.⁹

Uncertainty around whether the drug provides even modest benefits raise questions about Gilead’s justification for remdesivir’s exorbitant price tag at \$3,200 per treatment course, which is \$860 more than purchasers in other countries pay.¹⁰ In our July 16 letter to you, we wrote that the sky-high high prices charged by Gilead are unjustified and profoundly unfair to American taxpayers who furnished over \$70 million in research costs for the drug.¹¹ We cannot see any reason that Gilead should be charging U.S. consumers the highest price in the world, and even the lower price Gilead charges in other countries is likely too high. According to one study, a full course of remdesivir treatment can be manufactured and sold with a 10% profit margin for about \$9—meaning that the price set by Gilead for health insurers is more than 350 times greater than the price necessary to produce and profit from the drug.¹²

Now that remdesivir is an FDA-approved COVID-19 therapeutic, this Administration can and should invoke any number of legal provisions that allow it to assert control over the production and distribution of remdesivir. One provision, 28 USC § 1498, provides the federal government with compulsory licensing authority. Under this authority, the federal government can “use or acquire patented inventions” in exchange for providing “reasonable and entire compensation” to the patent holder.¹³ The U.S. government frequently used this authority in the 1960s to acquire lower-cost versions of on-patent drugs, and has used it to acquire patented military equipment.¹⁴ Some advocates have argued that using this authority could “provide

<https://www.statnews.com/2020/07/02/powerful-law-gives-hhs-right-to-control-remdesivir-manufacturing-distribution/>.

⁷ New England Journal of Medicine, “Remdesivir for the Treatment of Covid-19 —Final Report,” May 22, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>.

⁸ Politico, “FDA approves remdesivir as first coronavirus drug,” Zachary Brennan, October 22, 2020, <https://www.politico.com/news/2020/10/22/fda-approves-remdesivir-coronavirus-431336>.

⁹ TIME, “What the Conflicting Results on Promising COVID-19 Drug Remdesivir Really Mean,” Alice Park, October 19, 2020, <https://time.com/5901087/remdesivir-conflicting-studies/>.

¹⁰ Letter from Senator Warren et. al. to HHS Secretary Alex Azar, July 16, 2020, <https://www.warren.senate.gov/imo/media/doc/2020.07.16%20Letter%20to%20HHS%20re%20remdesivir%20pricing.pdf>.

¹¹ *Id.*; Public Citizen, “The Real Story of Remdesivir,” May 7, 2020, <https://www.citizen.org/article/the-real-story-of-remdesivir/>.

¹² Journal of Virus Eradication, “Minimum costs to manufacture new treatments for COVID-19,” Andrew Hill, Junzheng Wang, Jacob Levi, Katie Heath, and Joseph Fortunak, April 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7331548/>.

¹³ Yale Journal of Law and Technology, “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health,” Hannah Brennan, Amy Kapeczynski, Christine H. Monahan, and Zain Rizvi, 2017, <https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1124&context=yjolt>.

¹⁴ *Id.*

adequate supply [of remdesivir] while pushing prices down.”¹⁵ Gilead has licensed generic manufacturers to produce the drug for other countries, further driving down the price abroad, and the federal government can—and should—do the same in the United States.

We are still awaiting answers to our questions from July 16 letter regarding HHS’s negotiations with Gilead. In addition to those responses, we are requesting answers to the following questions regarding HHS’s current status of pricing negotiations with the company and whether it has plans to challenge Gilead’s monopoly control to ensure that the drug is accessible. Please respond to the following questions by November 30, 2020:

1. While patients are unlikely to see itemized charges for remdesivir on their hospital bills, Americans are paying for the drug through taxes and premiums. Now that remdesivir is an approved treatment for COVID-19, how will HHS ensure that U.S. taxpayers and health care programs are not price gouged by Gilead for a medicine the U.S. government helped to invent? What formula will be used to determine how providers will be reimbursed for remdesivir under (a) Medicare (b) Medicaid?
2. Will the Administration consider invoking its compulsory licensing authority under 28 U.S.C. § 1498?¹⁶ If not, why not?
3. Now that the original terms of the agreement between HHS and Gilead for 500,000 doses of remdesivir have been fulfilled,¹⁷ what is your plan to secure the domestic supply of remdesivir? Will you use federal procurement and production authorities, including those under the *CARES Act* and the *Defense Production Act*, to ensure there is not a shortage of remdesivir and the materials necessary to administer it?

Sincerely,

/s/
Elizabeth Warren
United States Senator

/s/
Tina Smith
United States Senator

¹⁵ STAT, “A powerful law gives HHS the right to take control of remdesivir manufacturing and distribution,” Christopher Morten, Christian Urrutia, and James Krellenstein, July 2, 2020, <https://www.statnews.com/2020/07/02/powerful-law-gives-hhs-right-to-control-remdesivir-manufacturing-distribution/>.

¹⁶ Kaiser Family Foundation, “What’s the Latest on Medicare Drug Price Negotiations?,” Juliette Cubanski, Tricia Neuman, Sarah True, and Meredith Freed, October 17, 2019, <https://www.kff.org/report-section/whats-the-latest-on-medicare-drug-price-negotiations-appendix/>.

¹⁷ U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” press release, June 29, 2020, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

_____/s/
Tammy Baldwin
United States Senator

_____/s/
Bernard Sanders
United States Senator

_____/s/
Chris Van Hollen
United States Senator

_____/s/
Sherrod Brown
United States Senator