

United States Senate
WASHINGTON, DC 20510

July 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 regarding the Department of Health and Human Services' (HHS or the Department) recent announcement that "President Trump has struck an amazing deal" for a large supply of remdesivir, an antiviral drug that has demonstrated effectiveness in reducing recovery time for patients hospitalized with COVID-19, for the American people.¹ Remdesivir has the potential to benefit Americans hospitalized by COVID-19, but it appears that the Department acquired its supply by allowing Gilead Sciences, the drug's manufacturer, to charge American health insurers the highest price in the world²—representing windfall revenues of up to almost half a billion dollars for the company, paid for in whole or in part by increased premiums for American families³—despite having 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

¹ U.S. Department of Health and Human Services, "Trump Administration Secures New Supplies of Remdesivir for the United States," June 29, 2020, press release, <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," June 29, 2020, press release, <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/>.

Outside analysts have concluded that “The deal is amazingly good for Gilead’s executives and shareholders and amazingly bad for everyone else—bad for taxpayers, terrible for public health, and unethical.”⁵ We are therefore requesting information from the Department to help us better understand why President Trump—or whichever Administration officials were responsible—would strike such an expensive deal, and what steps the Administration is taking to ensure sufficient supply of the drug.

On June 29, 2020, the Department announced that “President Trump has struck an amazing deal” through which “HHS has secured more than 500,000 treatment courses of [remdesivir] for American hospitals through September.”⁶ These treatment courses “represent[] 100 percent of Gilead’s projected production for July..., 90 percent of production in August..., and 90 percent of production in September..., in addition to an allocation for clinical trials.”⁷ Remdesivir represents one of the first clinical treatment breakthroughs for COVID-19, and HHS’s efforts to acquire it will likely benefit American patients. In a randomized clinical trial, remdesivir shortened the median recovery time of patients hospitalized with COVID-19 from 15 days to 11 days,⁸ and on May 1, 2020, the Food and Drug Administration granted Gilead an Emergency Use Authorization for the drug.⁹

It appears, however, that the Department acquired its supply of remdesivir at an exorbitant cost. According to the Department’s announcement, “hospitals will receive the product...and will pay no more than Gilead’s Wholesale Acquisition Price (WAC), which amounts to approximately \$3,200 per treatment course.”¹⁰ The same day that HHS made its announcement, Gilead publicized its global pricing system, indicating that governments of other developed countries will be paying \$2,340 for a treatment course.¹¹ In other words, America’s private health insurers—and, ultimately, all families and businesses that pay for these costs via health insurance premiums—will be paying \$860 more than governments in other countries will pay. This

⁵ 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/>.

⁶ U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” June 29, 2020, press release, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

⁷ *Id.*

⁸ New England Journal of Medicine, “Remdesivir for the Treatment of Covid-19 — Preliminary Report,” May 22, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>.

⁹ U.S. Food and Drug Administration, “Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment,” press release, May 1, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>.

¹⁰ U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” June 29, 2020, press release, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

¹¹ 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>.

difference represents a revenue windfall for Gilead of up to approximately \$430 million dollars on many of the “500,000 treatment courses” secured by HHS.¹²

As noted in the press release touting this deal, “for Medicare and most private insurers, the drug’s cost is incorporated into payments made by the insurer, such as Medicare paying for the drug through a diagnostic-related group.”¹³ In other words, the higher prices charged by Gilead will result in higher insurance premiums for individuals and businesses that provide health insurance coverage. Although Medicare and Medicaid beneficiaries may be shielded from these higher costs, the costs of the drug will be borne by taxpayers, who will ultimately foot the bill for reimbursement to hospitals.¹⁴ Similarly, the higher prices for remdesivir will likely result in higher taxpayer costs and higher premiums for individuals who obtain insurance through the *Patient Protection and Affordable Care Act*.¹⁵

This high price is unjustified. There is no reason that Gilead cannot provide the drug to U.S. consumers for the same price that it is providing it to other countries. And even that price may be 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.¹⁶ And it is profoundly unfair to the American taxpayers that furnished over \$70 million in research costs for the drug to now be stuck paying the highest prices in the world.¹⁷

HHS did not have to acquire remdesivir through a deal requiring American taxpayers to pay the highest prices in the world for the drug. Instead, the Administration could have invoked—and could still invoke—a 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

¹² U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” June 29, 2020, press release, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

¹³ U.S. Department of Health and Human Services, “Trump Administration Secures New Supplies of Remdesivir for the United States,” June 29, 2020, press release, <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

¹⁴ Kaiser Family Foundation, “How Could the Price of Remdesivir Impact Medicare Spending for COVID-19 Patients?,” Juliette Cubanski, Karyn Schwartz, and Tricia Neuman, July 14, 2020, <https://www.kff.org/coronavirus-covid-19/issue-brief/how-could-the-price-of-remdesivir-impact-medicare-spending-for-covid-19-patients/>.

¹⁵ Patient Protection and Affordable Care Act, Public Law 111-148.

¹⁶ 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, [http://viruseradication.com/journal-details/Minimum costs to manufacture new treatments for COVID-19/](http://viruseradication.com/journal-details/Minimum%20costs%20to%20manufacture%20new%20treatments%20for%20COVID-19/).

¹⁷ Public Citizen, “The Real Story of Remdesivir,” May 7, 2020, <https://www.citizen.org/article/the-real-story-of-remdesivir/>.

compensation” to the patent holder.¹⁸ The U.S. government frequently used this authority in the 1960s to acquire lower-cost versions of on-patent drugs, and has used the authority to acquire patented military equipment.¹⁹ Some advocates have argued that using this authority could “provide adequate supply [of remdesivir] while pushing prices down.”²⁰ March-in rights under the *Bayh-Dole Act* also provide the federal government “with the ability to ‘march in’ and grant licenses for patents that result from publicly-funded R&D,”²¹ allowing it to license the drug to a generic manufacturer for production at a lower cost, “if necessary to alleviate health or safety needs.”²² March-in rights may apply to remdesivir. A recent report even indicates that the U.S. Government “appears likely to be the legal co-owner of the key patents on remdesivir itself,” further diminishing Gilead’s rights to be the exclusive manufacturer and distributor of remdesivir in the U.S.²³ 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.

To help us better understand why the Trump Administration agreed to pay exorbitantly high prices to Gilead for remdesivir, rather than utilizing its multiple other options to acquire the drug, please respond to the following questions by July 30, 2020.

1. Under what authority did HHS and other Administration officials engage in price negotiations with Gilead for remdesivir?
2. HHS’s press release indicated that “President Trump has secured an amazing deal” for remdesivir.
 - a. Was this statement accurate? Did President Trump negotiate—or was he involved in negotiation of—the remdesivir price?
 - b. Which other Administration officials from HHS, the White House, or other federal agencies were involved in these negotiations?
 - c. Which representatives of Gilead were involved in the price negotiations?

¹⁸ Yale Journal of Law and Technology, “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health,” Hannah Brennan, Amy Kapczynski, Christine H. Monahan, and Zain Rizvi, 2017, <https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1124&context=yjolt>.

¹⁹ *Id.*

²⁰ 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/>.

²¹ Congressional Research Service, “March-In Rights Under the Bayh-Dole Act,” John R. Thomas, August 22, 2016, <https://crsreports.congress.gov/product/pdf/R/R44597>.

²² *Id.*

²³ “The U.S. Government’s Apparent Co-Ownership of Patents Protecting Remdesivir,” James Krellenstein and Christopher J. Morten, May 20, 2020, <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/5ecd886c5699191ae9bad9ea/1590528109403/The+U.S.+Government%27s+Apparent+Co-Ownership+of+Patents+Protecting+Remdesivir+-+P4A+%26+NYU.pdf>.

3. How did the Administration officials and Gilead come to an agreement under which U.S. private insurers will pay the highest prices in the world for remdesivir? What are the specific terms and conditions of this agreement? Please provide copies of all email, call records, and other communications between Administration officials and Gilead regarding pricing and distribution of remdesivir.
4. Did the Administration consider securing orders of remdesivir under the *Defense Production Act*?²⁴ If so, why did it ultimately decide not to invoke the *Defense Production Act*? If not, why not?
5. Has the Administration conducted an assessment to determine whether march-in rights under the *Bayh-Dole Act* apply to remdesivir? Did it consider whether any of the four conditions under which march-in rights may be invoked were satisfied? If so, why did it ultimately decide not to invoke march-in rights? If not, why not?
6. Does the Administration agree that the U.S. Government “appears likely to be the legal co-owner of the key patents on remdesivir itself?”²⁵ If not, why not?
7. Did the Administration consider invoking its compulsory licensing authority under 28 U.S.C. § 1498?²⁶ If so, why did it ultimately decide not to invoke this authority? If not, why not?
8. The prices paid by Medicaid and Medicare are typically set as a percentage of the prices paid by private sector insurers or other private-sector purchasers and included in bundled payments for the costs of care. In the case of remdesivir, private sector U.S. insurers will pay \$520 per vial. Foreign purchasers will pay \$390 per vial.²⁷ If private-sector U.S. insurers paid this same \$390, what would the savings be for:
 - a. Private-sector U.S. insurers.
 - b. The Medicare program.
 - c. The Medicaid program.

²⁴ Congressional Research Service, “The Defense Production Act of 1950: History, Authorities, and Considerations for Congress,” Michael H. Cecire and Heidi M. Peters, March 2, 2020, <https://crsreports.congress.gov/product/pdf/R/R43767>.

²⁵ “The U.S. Government’s Apparent Co-Ownership of Patents Protecting Remdesivir,” James Krellenstein and Christopher J. Morten, May 20, 2020, <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/5ecd886c5699191ae9bad9ea/1590528109403/The+U.S.+Government%27s+Apparent+Co-Ownership+of+Patents+Protecting+Remdesivir++P4A+%26+NYU.pdf>.

²⁶ 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/>.

²⁷ 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>.

- d. Other government entities, such as the Department of Veterans Affairs, or purchasers eligible for the Health Resources & Services Administration’s 340B Drug Pricing Program.²⁸
9. When the United States uses up the “more than 500,000 treatment courses” secured “through September,”²⁹ 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? What formulation will you use to set the price of the drug under federal programs like Medicare?

Sincerely,



Elizabeth Warren
United States Senator



Tina Smith
United States Senator



Tammy Baldwin
United States Senator



Bernard Sanders
United States Senator

/s/

Chris Van Hollen
United States Senator



Sherrod Brown
United States Senator

²⁸ U.S. Health Resources & Services Administration, “340B Drug Pricing Program,” accessed July 6, 2020, <https://www.hrsa.gov/opa/index.html>.

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