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August 4, 2020

Alex M. Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dr. Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Stephen Hahn
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Ave., N.W.
Silver Spring, MD 20993

Dear Secretary Azar, Dr. Collins and Commissioner Hahn:

During this unprecedented crisis, we must use every possible resource and tool to save the lives of Americans who are falling ill from COVID-19. Remdesivir, manufactured by Gilead Sciences, Inc. ("Gilead"), has received substantial federal funding,[1] has been fast-tracked by the U.S. Food and Drug Administration (FDA), and has shown promising results in reducing the risk of death and length of hospitalization for those suffering from COVID-19.[2]

[1] Damian Garde and Rebecca Robbins, *Listen: Remdesivir's Controversial Cost, Early Vaccine Promise, and AI at the End of Life*, Stat (Jul. 2, 2020), https://www.statnews.com/2020/07/02/remdesivir-cost-covid19-vaccine-data/.
[2] FDA News Release, *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, FDA (May 1, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment; *see also* Will Feuer, *Gilead Says Remdesivir Coronavirus Treatment Reduces Risk of Death in Severely Sick Patients*, CNBC (Jul. 10, 2020), https://www.cnbc.com/2020/07/10/gilead-says-remdesivir-coronavirus-treatment-reduces-risk-of-death.html; Karen Weintraub, *Remdesivir and COVID-19: New Data Suggests the Experimental Drug can Shorten How Long People are Sick*, USA Today (Jul. 10, 2020), https://www.usatoday.com/story/news/2020/07/10/remdesivir-and-coronavirus-more-good-news-antiviral-covid-drug/5414326002/.

Yet, Gilead is unable to assure a supply of remdesivir sufficient to alleviate the health and safety needs of the country amid this pandemic. Its supply is dangerously limited and its recent announcement of high prices for all patients, governments, and insurers will impede access to treatment in the U.S. and further strain state budgets.[3] Therefore, we respectfully urge the federal government to exercise its rights under the Bayh-Dole Act, which will allow the National Institutes of Health (NIH) and the FDA to ensure that Americans can afford and access a sufficient supply of remdesivir during this pandemic. Alternatively, at a minimum, we ask that you support states by assigning to states the ability to use the march-in rights under this law to achieve the same purposes.

Congress established march-in rights (35 U.S.C. §§ 200 to 212) for agencies to retain patent rights or inventions developed from federal funds.[4] Under this law, federal agencies may use their march-in rights to require the patent holder receiving the federal funds to license the patent or invention to a third party if the patent holder fails to achieve a reasonable price or fails to reasonably "alleviate health or safety needs" of consumers.[5] Here, we think it is clear that Gilead has not established a reasonable price, nor has it met the health and safety needs of the public given the COVID-19 pandemic. We urge the federal government to use its march-in rights to help increase the supply of this drug and lower the price so it is accessible to our state residents.

Americans are struggling to access and afford a treatment course of remdesivir. As the only drug cleared to treat COVID-19, remdesivir has the potential to help avert our nation's health crisis, which has already resulted in more than 4.64 million cases and 154,000 deaths as of August 3, 2020.[6] The U.S. is dealing with Great Depression-like unemployment, a rate as high

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[3] HHS News Release, *Trump Administration Secures New Supplies of Remdesivir for the United States*, HHS (Jun. 29, 2020), https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html.

[4] 35 U.S.C. § 203; *see also March-In Rights Developments: NIH's Recent Rejection to Exercise for Certain Drug Patents*, Practical Law Article (2016).

[5] 35 U.S.C. §§ 201 (f), 203(a)(1) (noting that the term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms); for further evidence, *see also* Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631, 647 (2001), cptech.org/ip/health/bd/arnodavis012001.pdf.; 35 U.S.C. §§ 203(a)(2).

[6] CDC COVID Data Tracker, *United States COVID-19 Cases and Deaths by State*, www.cdc.com, https://www.cdc.gov/covid-data-tracker/#cases (last visited Aug. 3, 2020).

as 16 percent in May.[7] The resurgence of COVID-19 in 38 states,[8] with the biggest spikes in many Sun Belt states, has led nine states to shutter once again: Arizona, California, Texas, Florida, Nevada, Colorado, New Mexico, Louisiana, and Michigan.[9] The resurgence of confirmed coronavirus cases threatens a rapid economic rebound and instead deepens the economic crisis.[10]

Remdesivir has benefited from millions of dollars of public funding, including a $30-million NIH-funded clinical trial estimated for this fiscal year alone.[11] But despite the large infusion of taxpayer monies, Gilead is unable to guarantee a supply of remdesivir sufficient to alleviate the health and safety needs of the country amid the pandemic. According to Gilead's press release, the company plans to make two million treatment courses by the end of this year.[12] Since a full treatment requires anywhere from six and ten vials, Gilead is projected to produce

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[7] Lucia Mutikani, *Coronavirus Deals U.S. Economy Great Depression-Like Job Losses, High Unemployment*, Reuters (May 8, 2020), https://www.reuters.com/article/us-usa-economy/coronavirus-deals-u-s-economy-great-depression-like-job-losses-high-unemployment-idUSKBN22K1NS; *see also* Rakesh Kochhar, *Unemployment Rose Higher in Three Months Of COVID-19 Than it Did in Two Years of the Great Recession*, PEW (Jun. 11, 2020), https://www.pewresearch.org/fact-tank/2020/06/11/unemployment-rose-higher-in-three-months-of-covid-19-than-it-did-in-two-years-of-the-great-recession/.

[8] NYT, *Coronavirus in the U.S.: Latest Map and Case Count*, www.nytime.com, https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?action=click&pgtype=Article&state=default&module=styln-coronavirus&region=TOP_BANNER&context=storylines_menu (last visited Jul. 16, 2020) (showing ten states where new cases are mostly the same, two states where new cases are decreasing, and the remaining states where new cases are increasing).

[9] Andy Olin, *COVID-19 Hot Spots Emerge Across the Sun Belt as States Expand Reopenings*, Rice University (Jun. 22, 2020) (citing that "13 of the 15 large metros seeing COVID-19 cases double the fastest are in the Sun Belt region. In 11 Sun Belt states, the average of the weekly percent positive is above WHO's positivity rate threshold of lower than 5%: Alabama (9.3%), Arizona (20.4%), Arkansas (5.8%), Florida (11.4%), Georgia (8.3%), Nevada (6.5%), North Carolina (7.3%), Oklahoma (7.2%), South Carolina (10.9%), Tennessee (6.6%), and Texas (10.3%)"), https://kinder.rice.edu/urbanedge/2020/06/23/coronavirus-hot-spots-emerge-across-sun-belt-states-expand-reopenings; *see also* NYT, *See How All 50 States Are Reopening (and Closing Again)*, www.nytimes.com, https://www.nytimes.com/interactive/2020/us/states-reopen-map-coronavirus.html (last visited Jul. 14, 2020).

[10] Jim Tankersley and Ben Casselman, *A Resurgence of the Virus, and Lockdowns, Threatens Economic Recovery*, NYT (Jul. 15, 2020), https://www.nytimes.com/2020/07/15/business/economy/economic-recovery-coronavirus-resurgence.html.

[11] Christopher Rowland, *Taxpayers Paid to Develop Remdesivir But Will Have no Say When Gilead Sets the Price*, WSJ (Mar. 26, 2020), https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/; *see also* Savannah Koplon, *Investigational compound remdesivir, developed by UAB and NIH researchers, being used for treatment of novel coronavirus*, UAB (Feb. 07, 2020) (receiving $37.5 million from NIH Centers of Excellence for Translational Research for a multi-institutional collaboration between Gilead and UAB along with Southern Research, Vanderbilt University, and the University of North Carolina, to accelerate the development of remdesivir to treat 2019-nCoV), https://www.uab.edu/news/health/item/11082-investigational-compound-remdesivir-developed-by-uab-and-nih-researchers-being-used-for-treatment-of-novel-coronavirus; Twitter, *NIH email correspondence with Wall Street Journal reporter Joseph Walker*, www.twitter.com, https://twitter.com/joewalkerWSJ/status/1233493135570980869.

[12] Gilead Press Release, *Working to Supply Remdesivir for COVID-19*, www.gilead.com (Jun. 24, 2020), https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19.

between 12 million to 20 million vials. Despite the company's efforts to scale up its production capacity, Gilead's production projection remains dangerously low and insufficient to handle the current domestic demands, let alone future demands for the antiviral drug.

These supply chain problems are exacerbated by Gilead's use of AmerisourceBergen as the sole distributor of remdesivir, further contributing to supply and cost issues.[13] As a result of the distribution by AmerisourceBergen, the drug was not made available to some hospitals with substantial COVID-19 populations, while others with limited need received the drug.[14] Accordingly, we must consider having a robust backup plan, with multiple distributors and suppliers in place, to prepare for any disruption AmerisourceBergen and Gilead may experience.

In an interview with CNBC, Gilead's CEO Daniel O'Day mentioned that a large part of the supply would go to the U.S. without specifying the amount.[15] Hypothetically speaking, if Gilead supplies 85 percent of its remdesivir to the U.S. alone, only 1.7 million of the 4.6 million confirmed COVID-19 patients in the U.S. (as of August 3, 2020) would have access to a full treatment. Even at 90 percent, just 1.8 million patients will receive remdesivir. This dangerously low supply and unmet demand is an example of market failure. As such, we believe march-in rights are a necessary step towards addressing this supply chain problem to adequately fulfill market demand. By exercising these rights and licensing remdesivir to a third party (or multiple third parties), we can and will reach sufficient production rates to mitigate the health and safety concerns.

Aside from production issues, the large infusion of taxpayer dollars into remdesivir has not resulted in the product being made available at a reasonable price. A study from four institutions, including the University of Liverpool and Howard University, found that remdesivir can be manufactured at $0.93 per day or $12.50 per patient.[16] Yet, in June, Gilead announced that the company will charge government programs, including the U.S. government's Indian Health Services and the Department of Veterans Affairs, $2,340 for a six-vial, five-day

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[13] AmerisourceBergen, *Coronavirus (COVID-19) Updates*, (May 10, 2020), https://www.amerisourcebergen.com/coronavirus-covid-19-information/latest-updates; Stephanie Armour and Joseph Walker, *Health-Care Leaders Question How Remdesivir Is Being Distributed*, WSJ (May 8, 2020) https://www.wsj.com/articles/health-care-leaders-question-how-remdesivir-is-being-distributed-11588889219

[14] Gina Kolata, *Remdesivir, the First Coronavirus Drug, Gets a Price Tag*, NYT (June 29, 2020) https://www.nytimes.com/2020/06/29/health/coronavirus-remdesivir-gilead.html; *see also* Armour and Walker, WSJ.

[15] CNBC, *Gilead CEO Daniel O'Day on Remdesivir Pricing and Ensuring Access to Treatment*, www.youtube.com (Jun. 29, 2020), https://www.youtube.com/watch?v=0O9P1E0vq_c.

[16] Andrew Hill et al., *Minimum Costs to Manufacture New Treatments for COVID-19*, Journal of Virus Eradication (Apr. 2020), https://www.nytimes.com/2020/07/15/business/economy/economic-recovery-coronavirus-resurgence.html; for additional estimated cost, *see also* Damian Garde and Ed Silverman, *Less Than a Movie Ticket or 'Impossible to Overpay'? Experts Name Their Price for Remdesivir,* Stats (May 15, 2020), https://www.statnews.com/2020/05/15/gilead-remdesivir-pricing-coronavirus/.

treatment course ($390 per vial).[17] For patients with private insurance, as well as Medicare and Medicaid, Gilead will charge 33% more or $3,120 (the equivalent of $520 per vial) for the exact same treatment.[18] Gilead did not announce the pricing structure for the uninsured.[19]

It is unfortunate that Gilead has chosen to place its profit margins over the interests of Americans suffering in this pandemic. Record unemployment and ongoing financial troubles will prevent many Americans from paying for remdesivir. Even for the insured, Gilead's excessive pricing makes copayments and out-of-pocket expenses cost-prohibitive. Moreover, Gilead's pricing will challenge the growing numbers of Americans that lack health coverage as a result of the pandemic.[20] If Americans who need remdesivir find themselves unable to afford a treatment course, then federal agencies have sufficient reason to require Gilead to "license both the background patents and the patents stemming from the contract work" under the Bayh-Dole Act.[21]

In light of the unprecedented COVID-19 crisis, we request the NIH and FDA exercise their march-in rights under the Bayh-Dole Act. Failing that, we ask that the NIH and FDA assign to the states these rights to ensure that drug manufacturers are licensed to meet the market demand during this health crisis. Alongside either exercise, we urge you to make full and immediate use of your legal authority under the Defense Production Act to put the weight of the federal government behind a rapid scaling up of remdesivir production and distribution. Under the authority already delegated to Secretary Azar of HHS under the Executive Order of March 18th, 2020, the Secretary has the power to invoke the Defense Production Act to identify specific health and medical resources needed to respond to the COVID-19 crisis, and to require performance of contracts or orders to meet the needs of the country over other priorities.[22]

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[17] Gilead Sciences, *An Open Letter from Daniel O'Day, Chairman & CEO*, www.gilead.com (Jun. 29, 2020), https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/an-open-letter-from-daniel-oday-chairman--ceo-gilead-sciences; see also Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (Jun. 29, 2020), https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/.

[18] *Id.*

[19] Sydney Lupkin, *Remdesivir Priced at More Than $3,100 for a Course of Treatment*, NPR (Jun. 29, 2020), https://www.npr.org/sections/health-shots/2020/06/29/884648842/remdesivir-priced-at-more-than-3-100-for-a-course-of-treatment

[20] Sheryl Gay Stolberg, *Millions Have Lost Health Insurance in Pandemic-Driven Recession*, NYT (Jul. 13, 2020), https://www.nytimes.com/2020/07/13/us/politics/coronavirus-health-insurance-trump.html.

[21] Arno and Davis, *supra* note 5 at 664. Evidence in the legislative history of the Bayh-Dole Act suggests that Congress contemplated high prices as an appropriate justification for exercising march-in rights, and that Congress worded the definition of "practical application" to encompass a requirement to offer patented products at a reasonable price. *See, e.g.*, *Government Patent Policy: Hearings before the Subcomm. On Domestic and Int'l Planning and Analysis of the H. Comm. On Sci. and Tech*., 94th Cong. 784-85 (1976) (supplemental materials of William O. Queensberry).

[22] Executive Order 13909. "Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of Covid-19." (Mar. 18, 2020), https://www.federalregister.gov/documents/2020/03/23/2020-06161/prioritizing-and-allocating-health-and-medical-resources-to-respond-to-the-spread-of-covid-19

Critically, this delegation of power to the HHS Secretary already extends to drugs—not just to PPE and ventilators—and can help states.[23]

Now more than ever, the American public needs the support of the federal government in helping them afford COVID-19-related treatment. This is not the time for any company to extract large corporate profits from uninsured and underinsured Americans—nor can we allow the individual market priorities and weaknesses of one company to determine the fates of hundreds of thousands of people. Gilead should not profit from the pandemic and it should be pushed to do more to help more people.

We look forward to a prompt response in bringing relief to millions of COVID-19 patients and working with our federal partners to rapidly scale up remdesivir production and distribution.

Sincerely,



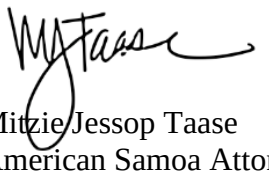
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American Samoa Attorney General

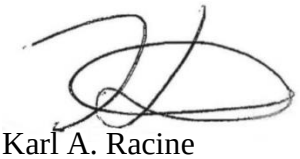


William Tong
Connecticut Attorney General



Kathleen Jennings
Delaware Attorney General

[23] Executive Order 13603. "National Defense Resources Preparedness." (Mar. 16, 2012), https://www.federalregister.gov/documents/2012/03/22/2012-7019/national-defense-resources-preparedness



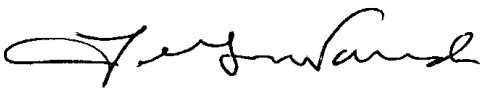
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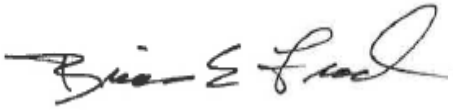
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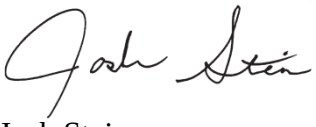
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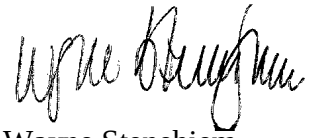
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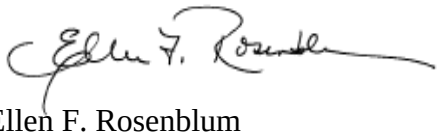
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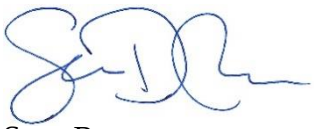
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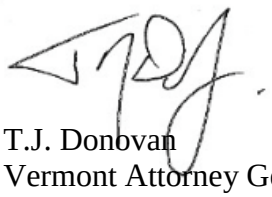
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