



Thomas A. Schatz, *President*
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August 7, 2020

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

The Honorable Francis S. Collins, Ph.D., M.D.
Director
National Institutes of Health
One Center Drive
Bethesda, Maryland 20892

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

Dear Secretary Azar, Dr. Collins, and Dr. Hahn:

On August 4, 2020, a bipartisan group of state attorney generals sent a letter to you requesting that the government exercise provisions under the Bayh-Dole Act to utilize “march-in” rights for Gilead’s patent for remdesivir, a therapy for COVID-19. According to an August 5, 2020 Fox Business report, a Department of Health and Human Services (HHS) spokesperson pushed back, stating that march-in rights only apply to products with intellectual property that were funded by the government. On behalf of Citizens Against Government Waste’s (CAGW) one million members and supporters, I ask that you strongly and publicly reject this outrageous request from the attorney generals to steal Gilead’s intellectual property.

Intellectual property is the only property protected in the Constitution in Article 1, Section 8, which states: “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” This farsighted provision has allowed the United States to become the global leader in innovation, research, and development in dozens of industries, including biopharmaceuticals. If the state AG’s ploy to use compulsory licensing or allow the government to steal a biopharmaceutical manufacturer’s drug patent and then license other companies to manufacture the drug was permitted, it would discourage other biopharmaceutical companies from stepping forward and risk billions of dollars to discover a vaccine or therapy during the COVID-19 pandemic, tackle a future medical crisis, or develop a drug to address a complex disease such as Alzheimer’s.

The Patent and Trademark Law Amendments of 1980, or the Bayh-Dole Act, was designed to encourage commercialization of universities' and nonprofit entities' discoveries that were funded by the federal government, which at that time were fewer than 5 percent. The Act allowed the patents to be owned by the research entities and transferred to the private sector, which would take the risk and expense to commercialize them. March-in rights could only be used if the invention was not commercialized. According to the National Institute of Standards and Technology, Bayh-Dole was "landmark legislation for U.S. innovation" and march-in rights have never been exercised.

The AG's actions are like proposals being pushed by several senators in a letter to HHS, including Sens. Elizabeth Warren (D- Mass.) and Bernie Sanders (I-Vt.), in which they are unhappy with the \$3,250 cost of a course of remdesivir treatment. They demand that the government should "assert control over the production and distribution of remdesivir" and believe the price is "exorbitant" and "unjustified." They ask that the administration invoke a number of legal provisions to take over the production and distribution of remdesivir using compulsory licensing authority and pay a "reasonable and entire compensation," whatever that means.

A July 21, 2020 *Wall Street Journal* (WSJ) editorial pointed out that much of the information in the senators' letter is incorrect. The Trump administration struck a deal with Gilead that gives the U.S. 100 percent of its production in July and 90 percent in August and September at a price of \$2,340 per course, the same price as in other countries. The editorial noted, the "Institute for Clinical and Economic Review (ICER), a nonprofit often cited by liberals who say drug prices are too high, praised Gilead's 'responsible pricing decision.' ICER's June review suggested that the drug's clinical benefits would merit a price of between \$4,580 and \$5,080 per treatment course." At \$2,340, the cost of remdesivir, which reduces hospital stays and helps patients recover faster, is \$160 less than the \$2,500 average daily per patient stay in a hospital

The AGs and senators claim march-in rights are appropriate because Gilead has benefitted from public funding. But as the WSJ pointed out, "Gilead discovered and developed remdesivir more than a decade ago while exploring potential treatment for Hepatitis C and respiratory syncytial virus. While the drug didn't work against these viruses, the National Institutes of Health has since helped fund in vitro and mouse studies of remdesivir's efficacy against emerging viruses including Ebola, MERS, SARS and now Covid-19."

The AGs claim Gilead's remdesivir's production is too low, the price is too high, and march-in rights would allow the drug to be licensed to multiple third parties to boost production. The WSJ noted that Gilead has already licensed the drug to five generic manufacturers at no cost to sell it in 127 developing countries, something they did not have to do.

These unreasonable and ill-advised demands must stop. The march-in rights proposal and others like the administration's extremely damaging most-favored-nation price controls will hurt medical innovation and dissuade biopharmaceutical companies from spending their valuable research dollars on future cures. That will hurt patients, slow economic growth, and destroy our nation's extraordinary lead in biopharmaceutical research and development.

Sincerely,

Handwritten signature of Thomas Schatz in black ink.