Trump administration pushed use of remdesivir, but unequal rollout angers doctors

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Demand for remdesivir exploded after the Food and Drug Administration, citing the results, made an emergency use authorization for the experimental drug. The Trump administration has maintained control of distribution of the drug, which is in limited supply.

Doctors in several hospitals, including some that have seen surges in people with covid-19, the disease caused by the novel coronavirus, say they cannot get access to remdesivir for their patients — and that they don't understand the process for obtaining the drug. In Boston, Massachusetts General Hospital said it is in line to receive the drug, but two other large teaching hospitals have been denied supplies without explanation, doctors said.

"The thing that is upsetting is the process at the federal level. There's no transparency. We don't know who made the decision, or how it has been done. The process is just a staggering injustice," Benjamin P. Linas, an infectious-disease doctor at Boston Medical Center, which treats large numbers of African American and Hispanic patients on Medicaid, said in an interview.

Linas noted in a tweet this week that the hospital has the second highest coronavirus case count in Boston: "Today, the family of a dying patient asked me why we do not have [remdesivir]. What am I supposed to say?"

The White House, the president's coronavirus task force, the Office of the Assistant Secretary for Preparedness and Response (ASPR) — which is coordinating distribution of the drug — and the Department of Health and Human Services, ASPR's parent agency, did not respond to questions about the physicians' complaints Thursday.

ASPR has retained the large drug distribution company AmerisourceBergen to deliver the drug around the country. The company said it is taking direction from the government about where to distribute remdesivir, and in what quantities.

Doctors also complain that they have yet to see the full results of the National Institutes of Health clinical trial that cleared the way for the FDA's emergency authorization of remdesivir — which means they still don't know which patients stand to benefit the most from the drug.

Without all the results, doctors say they have no information about how the drug affects patients in different age or racial groups, those with underlying conditions such as heart disease or diabetes, or those who may require oxygen, or the use of ventilators.

There are some indications that remdesivir helps people treated earlier in the progression of the disease, but doctors were hoping to see confirmation in the NIH study. So far they continue to operate without strong evidence.

The FDA in its emergency authorization offered little guidance on which patients to prioritize for scarce supplies of remdesivir, beyond specifying it should be used "in adults and children hospitalized with severe disease."

"What the situation requires us to do is make decisions without the information we need, so we are flying blind," said Mark J. Siedner, an infectious-disease doctor at Massachusetts General.

Yet as the limited supplies of the drug arrive in hospitals, doctors will have to make decisions on whom to treat — and explain those decisions to patients and families who are denied access.

Siedner said Mass General is expecting to receive doses of the drug but not enough to treat everyone who is hospitalized with the coronavirus.

"What we are asking is that the owners of this data make it publicly available so that we know exactly why the FDA made this decision and we can decide ethically and transparently who gets this medicine and who doesn't."

Remdesivir has been the subject of stock market speculation and multiple clinical trials as scientists and doctors around the world hunt for a treatment to slow the devastating impact of the coronavirus on some patients. The drug is not officially approved by the FDA, but the emergency authorization allows it to be used immediately based on early evidence that it carries some benefit.

The rush to get it to patients has outpaced supply. Gilead has said it has enough of the drug to treat up to 140,000 patients, which it has said it is donating for emergency distribution by ASPR and AmerisourceBergen, but that supply is expected to be used up quickly.

Anthony S. Fauci, the director of the NIH branch that ran the government's remdesivir trial, the National Institute of Allergy and Infectious Diseases, announced the drug's success in shortening the recovery time for some patients late last month. The unusual announcement was made at the White House and included only two points of trial data, which critics said were insufficient to gain a full understanding of the drug's effectiveness and safety.

With Trump looking on in the Oval Office, Fauci said the trial showed the drug reduced "time to recovery" by four days, from 15 to 11.

It did not have a statistically significant impact on death rates, which dropped from 11 percent in patients given a placebo to 8 percent in patients treated with the drug, Fauci said. He also called remdesivir the new standard of care, given the absence of any other treatment. The FDA issued its emergency authorization two days later without providing additional data.

NIAID said Thursday that it planned to publish a preliminary report of the initial results "in the next few weeks."

Conan MacDougall, an infectious-disease clinical pharmacist at the University of

California at San Francisco, has been trying to track the distribution of remdesivir by conducting informal surveys with hospitals.

“Right now, it’s not clear what criteria are being used to decide allocation — there seems to be more allocation in some areas with a high density of cases (New York, Massachusetts) although there’s also a center in Tennessee on the list,” he said in an email exchange.

“Obviously there’s limited supply and that not all centers will be able to receive supply,” he said. “In the absence of transparent rules or clear patterns, people are going to be suspicious as to what is guiding selection of the hospitals.”

Katherine Yang, also an infectious-disease clinical pharmacist at the University of California at San Francisco, said hospitals still don’t know when they will be able to get remdesivir for their patients or how the drug allocation decisions are being made.

“It’s incredibly frustrating,” she said in an interview Wednesday. “It’s difficult to plan. Everyone is holding their breath to see when we will get the drug.”

The Infectious Diseases Society of America, which represents physicians treating coronavirus patients, on Wednesday wrote Vice President Pence — who leads Trump’s coronavirus task force — calling for a transparent and rational process to distribute the drug. It said that decisions should be made based on regional case data and hospitalization rates and that they should ensure fair access for black and Hispanic communities, which have been experiencing higher death rates due to the coronavirus.

It also needs to prevent “a surge in patients at institutions known or thought to have access to the drug,” the society said.

At another Boston hospital that did not receive any of the drug, Tufts Medical Center, Helen Boucher, chief of the division of geographic medicine and infectious diseases, said 76 out of a total of 280 patients are being treated for covid-19.

“It’s really hard to explain why we didn’t get any and somebody else did,” she said. “Many patients will go somewhere that has the drug. This is the only drug we have, and even if it’s not a home run, it’s the only tool in the toolbox.”

With the limited number of doses from Gilead, shortages were inevitable as soon as the Trump administration acted last week to make the drug available.

“Decisions on which hospitals and the quantity of the product they will receive are being made by the government with AmerisourceBergen using our infrastructure and expertise to efficiently move any product we receive from Gilead in keeping with the government’s directives,” AmerisourceBergen spokeswoman Lauren Esposito said in a statement Thursday. The company declined a request for an interview about how allocations are being made.

On its website, the company said that “hospitals with intensive care units and other hospitals that the U.S. government deems most in need” would be prioritized, and that neither Gilead nor AmerisourceBergen are making the decisions.

Gilead said in a news release on Tuesday that it was seeking commercial partners around the world to help manufacture the drug on an accelerated timetable. The

company did not respond to requests for comment Thursday.

Remdesivir is a liquid that must be administered intravenously, and the company has said it requires a more complex manufacturing process than a simple pill. The drug is given over 10 days in the hospital, but Gilead said its own clinical studies have shown that the course of treatment can be shortened to five days, which could allow more patients to receive the drug during May.

Gilead discovered the drug about a decade ago, but much of the lab work and tests in animals have been performed by government-funded labs.

The company has not announced a price for remdesivir, but public debates about pricing have already begun. Public Citizen, among other groups, has said it should be provided to patients at a cost of $1 a day, which is what one academic team estimated it costs to make.

But an independent nonprofit that analyzes the value of pharmaceuticals, the Institute for Clinical and Economic Review, said Gilead would be justified charging up to $4,500 for a 10-day course of treatment, based on the savings to health systems and other factors.

Fauci made his announcement on the same day the medical journal the Lancet published full results from a randomized clinical trial in China that showed no benefit of the drug. But that study was stopped early because it failed to recruit enough patients.

Some experts in clinical trials raised questions about the NIH trial because NIAID changed the primary outcome measure two weeks before Fauci's announcement.