

White House to direct supply of COVID drug amid access fears

May 9 2020, by Ricardo Alonso-Zaldivar



White House coronavirus response coordinator Dr. Deborah Birx listens as President Donald Trump holds a meeting about the coronavirus response with Gov. Greg Abbott, R-Texas, in the Oval Office of the White House, Thursday, May 7, 2020, in Washington. (AP Photo/Evan Vucci)

Trying to head off another chaotic scramble for scarce supplies, the

White House said Friday it will step in to help coordinate distribution of the first drug that appears to help some COVID-19 patients recover faster.

Press Secretary Kayleigh McEnany told reporters that Dr. Deborah Birx, a member of White House Coronavirus Task Force, will become one of the chief consultants on where the intravenous medication [remdesivir](#) will be distributed.

Alarm is growing in the medical community about access to the drug, which was cleared for emergency use last week by the Food and Drug Administration.

Birx is "the person who's constantly reviewing the numbers, constantly reviewing the data," McEnany said. "And she really has the best grasp as to how that should be distributed." McEnany provided no additional detail.

As has happened with personal protective gear and coronavirus tests, the availability of remdesivir could become another foreseeable debacle in the nation's response to the coronavirus pandemic.

"Understandably, hospitals with COVID-19 patients are desperate to access the product," the head of a national organization that represents hospitals pharmacists wrote Vice President Mike Pence earlier this week.

"The process for hospitals to access the drug remains unclear," wrote Paul Abramowitz, CEO of the American Society of Health-System Pharmacists.

The company that makes the antiviral drug, California-based Gilead Sciences, has said it is donating its entire current stockpile to help in the

U.S. pandemic response.

But Abramowitz said that initial supply will be "very limited," 1.5 million doses that translate to 5 to 10 days of treatment for 140,000 patients.

"It is clear that the majority of current COVID-19 patients will not receive it," Abramowitz wrote to Pence.

A leading hospital in Michigan was denied doses of remdesivir, Rep. Debbie Dingell, D-Mich., said Friday. Michigan Medicine at the University of Michigan has treated more than 500 COVID-19 patients, including more than 80 currently hospitalized, she said.

"If leading educational hospitals don't have access to doses, it indicates there may be a problem," Dingell said in a statement calling the situation "deeply concerning."

A senior Michigan Republican also has concerns.

"We know remdesivir has shown promising results for those severely infected by COVID-19, but we now we need to know if it is getting into the hands of those who need it most," Rep. Fred Upton said in a statement.



White House press secretary Kayleigh McEnany speaks during a press briefing at the White House, Friday, May 8, 2020, in Washington. (AP Photo/Evan Vucci)

It's unclear how the Trump administration will address the growing concern about access.

"We urge the administration to take immediate action to ensure transparent and orderly allocation of remdesivir to our nation's hospitals," Abramowitz, of the pharmacists' group, wrote Pence.

He raised potentially troublesome scenarios, such as one hospital in a region getting a supply, and then another hospital in the state being overwhelmed by a spike in severe cases.

"Hospitals should have the ability to send remdesivir doses where they are most needed," he wrote.

The pharmacists' group is asking for the allocation process to be made public, with as much information as possible on how remdesivir will be distributed. Gilead is ramping up production.

The eventual price of the drug is also a question mark, since Gilead's promise to donate the medication applies only to its current stockpile. President Donald Trump was hoping to sign major legislation to rein in the price of prescription drugs ahead of the November elections, but that effort was overtaken by the [coronavirus](#) pandemic.

Gilead said Friday it began shipping remdesivir on May 2 to drug wholesaler AmerisourceBergen, which has been designated the sole distributor for the drug.

"Initial supplies were distributed within days to a first set of hospitals identified by the government," Gilead's statement said. "Hospitals with intensive care units and other hospitals that the government deems most in need will receive priority."

AmerisourceBergen said it's distributing remdesivir under the direction of the Federal Emergency Management Agency, which is choosing which facilities get the drug and how much.

Only a week ago, Trump had announced at the White House that remdesivir had received an emergency use authorization from the FDA.

The FDA acted after preliminary results from a government-sponsored study showed that the drug shortened the time to recovery by 31%, or about four days on average, for hospitalized COVID-19 patients.

Those given the drug were able to leave the [hospital](#) in 11 days on average vs. 15 days for the comparison group. The drug may also help avert deaths, but that effect is not yet large enough for scientists to know for sure.

Scientists want to see more studies, but for now remdesivir has provided a glimmer of hope. It works by blocking an enzyme the virus uses to copy its genetic material.

No drugs are currently FDA-approved for treating COVID-19, and remdesivir will still need formal approval. The [drug](#) does have side effects, including potential liver inflammation.

Nonetheless, the National Institutes of Health's Dr. Anthony Fauci has said remdesivir would become a new standard of care for severely ill COVID-19 patients.

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