



FDA Tells Doctors in 8 States to Stop Using COVID-19 Treatment

Description

USA: U.S. drug regulators have directed health care workers in eight states to stop using a COVID-19 treatment because it may not be effective against an Omicron coronavirus subvariant that's rising in prevalence.

The Food and Drug Administration ([FDA](#)) said sotrovimab, a monoclonal antibody used to treat COVID-19, can no longer be used in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

Providers in Puerto Rico and the Virgin Islands also have been told to stop using sotrovimab.

Regulators believe that the treatment, which was given emergency use authorization in May 2021, "is unlikely to be effective against the BA.2 subvariant," the FDA said in a statement.

BA.2 is a subvariant of Omicron, a variant of the [CCP \(Chinese Communist Party\) virus](#), the pathogen that causes COVID-19.

According to genomic surveillance conducted by the Centers for Disease Control and Prevention, BA.2 was responsible for 12.6 percent of COVID-19 cases in the United States in the week ending on March 5. But the agency projected an increase to 35 percent in the week ending on March 19, and the subvariant was pegged as circulating widely in the northeast.

Based on the estimates, BA.2 is responsible for the majority of the cases in the states where the administration of sotrovimab is now limited.

The FDA had [indicated in February](#) that it would limit the treatment.

Several studies have indicated that sotrovimab doesn't perform well against BA.2, including one [published in Nature Medicine](#).

But GlaxoSmithKline and Vir Biotechnology, the makers of the drug, [have said](#) that testing suggested that the treatment retained neutralizing activity against BA.2.

The companies said on March 25 that they were aware of the FDA's move and are preparing to send a data package to the agency and other regulatory authorities that show a higher dose of sotrovimab works against BA.2.

COVID-19 treatments that do appear to be effective against BA.2 include Pfizer's pill, paxlovid; the antiviral from Gilead Sciences known as remdesivir; and the [recently authorized bebtelovimab](#), a monoclonal made by Eli Lilly, according to the FDA.

"We will continue to monitor BA.2 in all U.S. regions and may revise the authorization further to ensure that patients with COVID-19 have effective treatments available. Health care providers should also monitor the frequency of BA.2 in their region as they choose appropriate treatment options for patients," the agency said.

The FDA previously [cut off authorization](#) for REGEN-COV, a monoclonal from Regeneron, and a separate treatment from Eli Lilly because laboratory testing suggested that they didn't hold up well against Omicron.

By Zachary Stieber

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