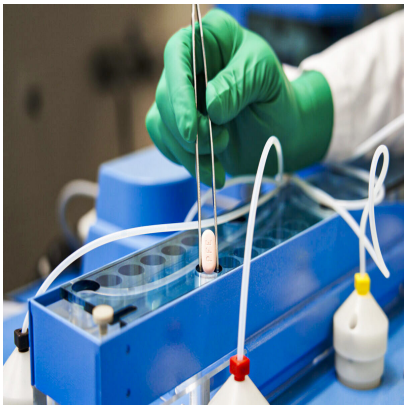

FDA Investigating Reports of COVID Relapses Following Use of Pfizer's Pill

Description

The U.S. Food and Drug Administration (FDA) is investigating reports of relapses among people who took Pfizer's COVID-19 pill.

The FDA "is evaluating the reports of viral load rebound after completing paxlovid treatment and will share recommendations if appropriate," an agency spokesperson told The Epoch Times in an email.

In a recent preprint case report, Veterans Affairs researchers reported that a 71-year-old male who took the pill, also known as nirmatrelvir, experienced a "rapid and progressive reduction" in the viral load of SARS-CoV-2, the virus that causes COVID-19.

But four days after completing the treatment course, there was a "surprising rebound of viral load and symptoms," they reported.

The report "highlights the potential for recurrent, symptomatic SARS-CoV-2 replication after successful early treatment" with the pill, the researchers said.

A number of others have said they saw renewed symptoms after taking paxlovid.

In the FDA's evaluation (pdf) of data on paxlovid, which the agency cleared on an emergency basis in 2021, the agency reported that in an ongoing phase 2/3 trial run by Pfizer, several participants "appeared to have a rebound" in viral load five to nine days after completing their treatment courses.

In light of the new reports, additional analyses of the paxlovid trial data were performed and showed that 1 to 2 percent of the patients had one or more positive COVID-19 tests after testing negative, or an increase in the amount of viral load, after completing the treatment, Dr. John Farley of the FDA said in an interview the agency published on May 4.

“This finding was observed in patients treated with the drug as well as patients who received placebo, so it is unclear at this point that this is related to drug treatment,” he said, adding that, at this time, the reports “do not change the conclusions from the paxlovid clinical trial which demonstrated a marked reduction in hospitalization and death.”

As part of the authorization agreement, the FDA said Pfizer must later submit information regarding “prolonged virologic shedding or rebound in clinical trials.”

Pfizer did not respond to a request for comment.

The company told Bloomberg that the rate of rebound in its trial was not higher among people who took paxlovid than in people who took a placebo.

“This suggests the observed increase in viral load is unlikely to be related to paxlovid,” the company said.

Dr. Clifford Lane, deputy director for clinical research at the National Institute of Allergy and Infectious Diseases, told the outlet that the agency will study the issue, calling it “a priority.”

Lane and the agency did not return queries.

The FDA authorized paxlovid for the treatment of mild to moderate COVID-19 in Americans 12 years or older. To get the pill, a person must test positive for COVID-19 and be deemed at high risk of progressing to severe disease.

By Zachary Stieber

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