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OPINION | COMMENTARY

Is Fluvoxamine the Covid Drug We've Been Waiting For?

A 10-day treatment costs only \$4 and appears to greatly reduce symptoms, hospitalization and death.

By Allysia Finley (Follow)

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The Food and Drug Administration last week authorized two oral antiviral medicines for the early treatment of Covid-19. But don't get too excited. The U.S. will still have a meager treatment arsenal this winter.

The U.S. has been relying on monoclonal-antibody treatments, but most don't hold up against the Omicron variant. One, by <u>GlaxoSmithKline</u> and <u>Vir Biotechnology</u>, does better at neutralizing the variant, but supply is limited. <u>Pfizer</u>'s newly authorized antiviral pack Paxlovid will also have to be rationed. There will be more of Merck and Ridgeback Biotherapeutics' newly authorized antiviral, molnupiravir, but patients may be reluctant to take the drug. Some scientists worry it could cause DNA mutations in people, though the FDA determined that the likelihood of this was low when used on a short-term basis.



President Biden's Omicron Strategy





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Yet a promising alternative isn't getting its due: fluvoxamine, a pill the FDA approved in 1994 to treat obsessive-compulsive disorders. Doctors often prescribe it off-label for anxiety, depression and panic attacks. Studies show that fluvoxamine is highly effective at preventing hospitalization in Covid-infected patients, and it's unlikely to be blunted by Omicron.

Doctors <u>hypothesize</u> that fluvoxamine can trigger a cascade of reactions in cells that modulate inflammation and interfere with virus functions. It could thus prevent an overreactive immune response to pathogens—what's known as a cytokine storm—that can lead to organ failure and death. It also increases nighttime levels of <u>melatonin</u>—the hormone that makes you sleepy—which evidence suggests can also <u>mitigate</u> inflammation.

While experimenting with mice in 2019, researchers at the University of Virginia discovered that fluvoxamine could be an effective treatment for sepsis, or blood-borne infection. A large study in France during the early months of the pandemic found that Covid-19 patients treated with selective serotonin reuptake inhibitors such as fluvoxamine were significantly less likely to be intubated or to die.

A small randomized control trial last year by psychiatrists at the Washington University School of Medicine in St. Louis was a spectacular success: None of the 80 participants who started fluvoxamine within seven days of developing symptoms deteriorated. In the placebo group, six of the 72 patients got worse, and four were hospitalized. The results were <u>published in November 2020</u> in the Journal of the American Medical Association and inspired a real-world experiment.

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Soon after the study was published, there was a Covid <u>outbreak</u> among employees at the Golden Gate Fields horse racing track in Berkeley, Calif. The physician at the track offered fluvoxamine to workers. After 14 days, none of the 65 patients who took it were hospitalized or still had symptoms. Of the 48 who didn't take the drug, six, or 12.5%, were hospitalized and one died. Twenty-nine had lingering symptoms, which might have resulted from inflammatory damage to their organs. Those who took the placebo were more likely to be asymptomatic when they tested positive, so they would have been expected to fare better.

The studies drew the attention of Francis Collins, director of the National Institutes of Health. "A big need right now is for a drug that you could take by mouth, that you could be offered as soon as you had a positive test, and that would reduce the likelihood that the virus is going to make you really sick," he said in an interview with "60 Minutes" in March. "Fluvoxamine could certainly be something you want to put in the tool chest," Dr. Collins added. "It looks as if it has the promise to reduce the likelihood of severe illness."

Researchers at McMaster University in Hamilton, Ontario, last winter launched a large clinical trial in Brazil. The results from their trial, published in the Lancet in October, were stunning: Fluvoxamine reduced the odds of hospitalization or emergency care by 66% and death by 90% among unvaccinated high-risk patients who mostly followed the treatment regimen—comparable to monoclonal antibodies. There was no difference in adverse effects between the fluvoxamine and placebo groups.

The three fluvoxamine trials were conducted while different variants were circulating, so there's no reason to think the drug wouldn't work as well against Omicron. <u>A 10-day course of fluvoxamine</u> costs \$4, compared with the \$2,100 the U.S. government has been paying for monoclonal antibodies, and \$530 to \$700 for a course of the Pfizer and Merck treatments. Multiple drugmakers manufacture fluvoxamine and could ramp up supply without much difficulty were demand to increase.

While the FDA doesn't need to grant fluvoxamine emergency-use authorization for doctors to prescribe it, some may be reluctant to do so unless the NIH recommends it in its Covid-19 treatment guidelines. Physicians have been investigated by state medical boards for prescribing the antiparasite ivermectin off-label for Covid-19.

The NIH states that "there is insufficient evidence . . . to recommend either for or against

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when Dr. Collins made his statement in March. If the NIH doesn't budge, states could enact laws that protect doctors who prescribe fluvoxamine, They could also order doses to administer to patients, which would cost little but could save many lives.

Ms. Finley is a member of the Journal's editorial board.

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