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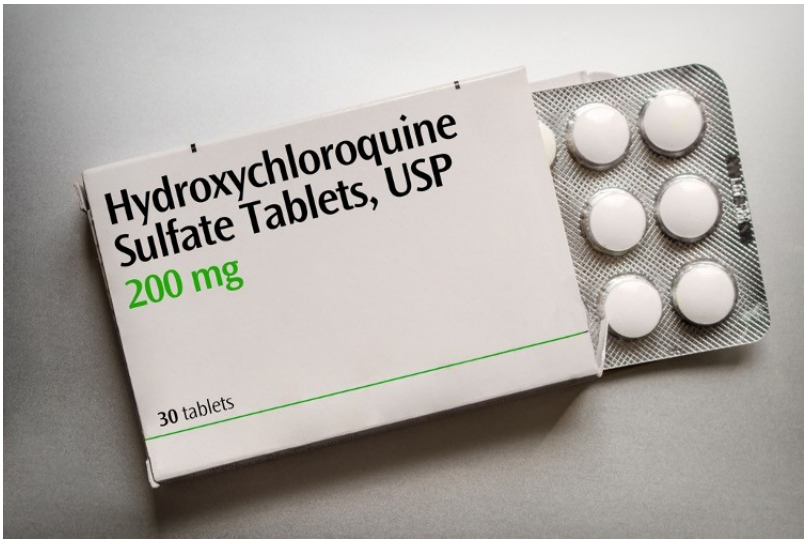
Written by **Rebecca Terrell** on January 19, 2022

FDA Denies Effective Remedies as New COVID Treatments Flop



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Competition is heating up for Pfizer's new but scarce antiviral medicine, Paxlovid. Following in the footsteps of a U.S. Emergency Use Authorization (EUA) granted last month, Mexico has given a thumbs up to the pharmaceutical giant's oral treatment against COVID-19, Reuters reports. Bloomberg notes that the Africa Centers for Disease Control and Prevention has joined the race to secure supplies of the medication, which are already falling grossly short of demand.

"The first 10 million doses of the new Pfizer medication, Paxlovid, ordered by the federal government will not be available until June," states a press release issued Monday by the Association of American Physicians and Surgeons (AAPS), an organization with a near 80-year history of representing physicians nationwide. "Only 250,000 courses of treatment will be accessible by the end of January, which is too little, too late."

Pfizer announced last week that it has bilateral agreements for the drug with roughly 100 countries worldwide. The pills can take up to eight months to manufacture, according to the San Diego NBC News affiliate, and government rationing limits treatment to only those at high risk. New York's health commissioner, Dr. Mary Bassett, complained that the amount allocated to her state will treat around 20,000 people. "We need more of these drugs in order to make them alter the course of the pandemic and reduce hospitalization," she told NBC.

"With the Omicron variant surging, the availability of and accessibility to treatment options is of utmost importance, as millions of people are being diagnosed with COVID-19 each and every day," Pfizer chairman and CEO Albert Bourla acknowledged. He made the comment in response to the U.S. government's doubling earlier this month of its original order — from 10 million to 20 million treatment courses.

Stockpiling and Rationing

Meanwhile, federal bureaucrats continue to sit on massive stockpiles of a proven remedy: hydroxychloroquine (HCQ). Early in the pandemic, pharmaceutical companies donated 60 million doses to help stem the COVID tide. "Why has the government been touting a medication that is mostly unavailable, while withholding from the public a medication that was donated for use against Covid?"

asks AAPS executive director Jane Orient, M.D. "No one is helped by promoting an expensive new treatment that patients cannot obtain."

Her organization's June 2020 lawsuit attempted to gain release of the donated HCQ from the U.S. Food & Drug Administration's (FDA) Strategic National Stockpile. It noted the medicine's 65-year track record of safety with FDA, as well as research confirming that HCQ reduced mortality by 50 percent in U.S. COVID-19 patients. Other countries witnessed greater returns. "The mortality rate from COVID-19 in countries that allow access to HCQ is only one-tenth the mortality rate in countries where there is interference with this medication, such as the United States," explained AAPS General Counsel Andrew Schlafly. "This irrational hoarding by government is an abuse of power."

As the AAPS lawsuit lingers in appeal and suffering patients await the manufacture of Paxlovid, the U.S. Department of Health and Human Services (HHS) continues its rationing of monoclonal antibody therapy for COVID-19 on the pretext of addressing a surge in demand for the treatment. The FDA approved these drugs for COVID infections in November 2020 because they help trigger a healthy immune response. Fed up with federal rationing policies, some states have successfully bypassed HHS to secure plentiful amounts directly from suppliers. Hospitals in other areas that still labor under HHS rations report treating fewer patients with antibodies now than they did at the height of the pandemic, according to AAPS.

Dangerous "Solution"

The untreated will apparently have to wait for Paxlovid, or they can try another experimental anti-viral pill with recent FDA emergency authorization, molnupiravir. The drawback with this option is its attendant risks. In a recent two-part *Forbes* article (here and here), former Harvard Medical School Professor William A. Haseltine described the drug's ability to cause cancer and birth defects, as well as its potential to "supercharge SARS-CoV-2 mutations." Haseltine even recommended that FDA issue a black-box warning, the strongest measure short of pulling a medication from the market. "This drug could harm the very people it's meant to help, those receiving the drug and all of us around them, should new more powerful variants be unleashed," concluded Hazeltine.

Nevertheless, 10 countries have authorized molnupiravir, including the United States, Japan, and the United Kingdom. This week, manufacturers Merck and Ridgeback Biotherapeutics announced a long-term supply agreement with the United Nations Children's Fund (UNICEF), according to *Contract Pharma* magazine. "Under the agreement, Merck will allocate up to 3 million courses of molnupiravir to UNICEF throughout the first half of 2022 for distribution in more than 100 low- and middle-income countries," reads the report.

"Why is the government recommending a new medication that that may be unsafe for many?" Dr. Orient asks. "Hydroxychloroquine, in contrast, was FDA approved for safety in 1955 and has been safely used by hundreds of millions of people."