

FDA warns that Ivermectin should not be used to treat COVID-19

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Ivermectin, a medication better known for treating parasite infestations, when it comes to the unfounded treatments for COVID-19, is perhaps the stepchild of the drug Hydroxychloroquine, which had been touted by then-President Donald Trump for its supposed ability to prevent and mitigate COVID-19 disease.

However, unlike the ignominious end to the controversy over Hydroxychloroquine and COVID-19, the still unproven use of Ivermectin has persevered, especially across Latin America, where in the midst of unchecked coronavirus transmission, people desperate for any remedy have flocked to purchase the over-the-counter drug, which has been used for decades to treat farm animals and people infected with parasitic worms.

Over the weekend, the Food and Drug Administration (FDA) warned that Ivermectin was not an anti-viral drug, ahead of its call giving Pfizer's mRNA COVID-19 vaccine full authorization. The drug remains unproven in preventing or reducing the risk of developing severe COVID-19. In an official tweet, the FDA wrote: "You are not a horse. You are not a cow. Seriously, y'all. Stop it."

The FDA's cautioned against Ivermectin use on the heels of a statement released by the Mississippi State Department of Health after reports surfaced that an increasing number of people had turned to use the drug to prevent COVID-19 infection. One man was recently hospitalized in the state for ingesting livestock Ivermectin from a feed store. The state, which has only managed to vaccinate 37 percent of its citizens fully, has recently been battered by a massive wave of infection with the Delta variant.

Ivermectin was discovered in 1975 and came into medical and veterinary use in the 1980s. It is one of the essential medicines on the World Health Organization (WHO) list and has FDA approval as an anti-parasitic agent. Though the drug, prescribed by a physician for appropriate indications, is fairly free of toxicity, it can be neurotoxic in large doses, leading to seizures or suppression in a person's ability to breathe, possible loss of consciousness, coma and even death.

During a press briefing, Dr. Thomas Dobbs, a Mississippi health officer, warned: "There are potential toxicities [with Ivermectin]. So, it's something, you know ... some people are trying to use it as a preventative, which I think is really kind of

crazy. So, please don't do that!" Despite evidence of safe and effective vaccines widely available, it has found appeal among those opposed to the vaccines and public health measures.

The Department of Health issued an alert that they have been receiving reports about rising incidents of Ivermectin poisoning: "The Mississippi Poison Control center has received an increasing number of calls from individuals with potential Ivermectin exposure taken to treat of preventing COVID-19 infection. At least 70 percent of the recent calls have been related to ingestion of livestock or animal formulations of Ivermectin purchased at livestock supply centers. Eighty-five percent of the callers had mild symptoms, but one individual was instructed to seek further evaluation due to the amount of Ivermectin reportedly ingested."

Early in the pandemic, scientists and physicians were repurposing every medicine sitting on the shelves that could potentially stem the severity of COVID-19. Like Hydroxychloroquine, Ivermectin had demonstrated *in vitro* (an experiment conducted in a culture dish outside a living organism) inhibition of the ability for SARS-CoV-2 to replicate.

Australian researchers published their data in the journal *Antiviral Research* in June 2020, demonstrating that a single treatment could affect a 5,000-fold reduction in viral RNA at 48 hours. However, the concentrations required to produce this effect would be impossible to achieve *in vivo* and prove highly toxic to humans. Spurred further by unreliable and later retracted studies compounded by lack of any substantiated benefit from any other pharmaceuticals, in Latin America, as the journal *Nature* noted, "Ivermectin's reputation was already cemented."

Ivermectin is commonly used in South America to treat river blindness, lymphatic filariasis and neglected tropical diseases. Despite the lack of evidence to support its use in a clinical setting, news of its potential benefit spread quickly. In May 2020, northern Bolivia's health care workers passed out more than 350,000 doses to residents. The same month in Peru, 20,000 bottles of livestock grade Ivermectin sold on the black market were confiscated by the police. By July, the University of Peru announced it would increase production to bolster the country's supply.

Quickly and in succession, countries in the region like Peru, Colombia, Bolivia, Venezuela and Brazil, facing massive waves of infections and death, began implementing public health policies for the use of Ivermectin for the treatment of mild-to-moderate COVID-19.

Proponents argued that its safety profile and several decades of experience with the use of the medicine, in light of the lack of any benefit from other pharmaceuticals, warranted adding it to their guidelines for treating coronavirus infections. Bolivia's health minister, Marcelo Navajas, went as far as acknowledging, during a press conference on May 12, 2020, that the drug "does not have scientific validation."

Dr. Carlos Chaccour, a Venezuelan researcher at the Barcelona Institute of Global Health in Spain, working to eliminate malaria, told *Nature*, "I do not judge a doctor who has a dying patient before him and, desperate, tries anything [to save them]. The problem is when non-evidenced-based public policies are made."

In Brazil, where the death toll is approaching 600,000, fascist President Jair Bolsonaro's Ministry of Health has promoted a cocktail of unproven drugs known as *tratamento precoce* (early treatment) that include Ivermectin, Chloroquine, Azithromycin (an antibiotic), blood thinners, and an assortment of vitamins and zinc. Espousing policies based on utter pseudoscience, the Brazilian government spent millions on social media promoting quack concoctions to absolve themselves all criminal responsibility for the death of its people.

Dr. Jesem Orellana, an epidemiologist at Fiocruz Amazonia based in Manaus, where the Gamma variant first exploded, told NPR, "It's not because they believe it works, but because it is a way for them to escape their responsibility for controlling the pandemic."

In February 2021, the US National Institutes of Health issued a COVID-19 treatment guidelines update, stating, "Despite [the] in vitro activity, no clinical trials have reported a clinical benefit for Ivermectin in patients with these viruses," adding that "there is insufficient evidence for the COVID-19 Treatment Guidelines panel to recommend either for or against the use of Ivermectin for the treatment of COVID-19," citing the urgent need for adequately conducted studies to address the pressing question.

A month later, a randomized controlled trial published in *JAMA* on March 4, 2021, comparing Ivermectin to a placebo, found no benefit in treating mild COVID-19. This was followed by an announcement by the WHO, based on a comprehensive review by a panel of experts, that the evidence on the use of Ivermectin remained inconclusive and that, until more data were available, its use should be limited to clinical trials.

They wrote: "The group reviewed pooled data from 16 randomized controlled trials (total enrolled 2,407), including both inpatients and outpatients with COVID-19. They

determined that the evidence on whether Ivermectin reduces mortality, need for mechanical ventilation, need for hospital admission and time to clinical improvement in COVID-19 patients is of 'very low certainty,' due to the small sizes and methodological limitations of available trial data, including small number of events."

In a blow to promoters of Ivermectin, just last month, a significant study purporting the safety and efficacy of Ivermectin to reduce mortality, which had been placed in a preprint on Research Square in November 2020, was retracted over revelations of plagiarism and widespread flaws in the data. The editors wrote, "... we were presented with evidence of both plagiarism and anomalies in the dataset associated with the study, neither of which could reasonably be addressed by the author issuing a revised version of the paper."

Jack Lawrence, an independent journalist and British medical student with a master's in biomedical sciences, was the individual who had raised these concerns with Research Square. His report detailed the findings of this investigation. Dr. Ahmed Elgazzar from Benha University in Egypt, also the chief editor of the *Benha Medical Journal*, has yet to provide responses to questions posed to him.

According to the *Guardian*, "The study found that patients with COVID-19 treated in hospital who 'received Ivermectin early reported substantial recovery' and that there was 'a substantial improvement and reduction in mortality rate in Ivermectin treated groups' by 90 percent." Nick Brown, a data analyst affiliated with Linnaeus University in Sweden, told the *Guardian*: "The main error is that at least 79 of the patient records are obvious clones of other records. It's certainly the hardest to explain away as innocent error, especially since the clones aren't even pure copies. There are signs that they have tried to change one or two fields to make them look more natural."

The need for a scrupulous and principled approach to the conduct of trials and investigations cannot be understated. In concluding, it is worth noting that last week, Dr. Didier Raoult, the French scientist who had been discredited for his promotion of Hydroxychloroquine treatment of COVID-19, is being forced out of the Marseille-based infectious disease institute that he had founded on concerns over his role in promoting conspiracy theories and the unethical conduct of his studies. However, he is receiving support from Marine Le Pen's former campaign director, Florian Philippot, and a broader constituency of the far-right fascist elements.



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