OPINION | COMMENTARY

Why Is the FDA Attacking a Safe, Effective Drug?

Ivermectin is a promising Covid treatment and prophylaxis, but the agency is denigrating it.

By David R. Henderson and Charles L. Hooper
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Ivermectin in Buenos Aires, Jan. 26.
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The Food and Drug Administration claims to follow the science. So why is it attacking ivermectin, a medication it certified in 1996?

Earlier this year the agency put out a special warning that "you should not use ivermectin to treat or prevent COVID-19." The FDA's statement included words and phrases such as "serious harm," "hospitalized," "dangerous," "very dangerous," "seizures," "coma and even death" and "highly toxic." Any reader would think the FDA was warning against poison pills. In fact, the drug is FDA-approved as a safe and effective antiparasitic.

Ivermectin was developed and marketed by Merck & Co. while one of us (Mr. Hooper) worked there years ago. William C. Campbell and Satoshi Omura won the 2015 Nobel Prize for Physiology or Medicine for discovering and developing avermectin, which Mr. Campbell and associates modified to create ivermectin.

Ivermectin is on the World Health Organization's List of Essential Medicines. Merck has donated four billion doses to prevent river blindness and other diseases in Africa and other places where parasites are common. A group of 10 doctors who call themselves the Front Line Covid-19 Critical Care Alliance have said ivermectin is "one of the safest, low-cost, and widely available drugs in the history of medicine."

Ivermectin fights 21 viruses, including SARS-CoV-2, the cause of Covid-19. A single dose

reduced the viral load of SARS-CoV-2 in cells by 99.8% in 24 hours and 99.98% in 48 hours, according to a June 2020 study published in the journal Antiviral Research.

Some 70 clinical trials are evaluating the use of ivermectin for treating Covid-19. The statistically significant evidence suggests that it is safe and works for both treating and preventing the disease.

In 115 patients with Covid-19 who received a single dose of ivermectin, none developed pneumonia or cardiovascular complications, while 11.4% of those in the control group did. Fewer ivermectin patients developed respiratory distress (2.6% vs. 15.8%); fewer required oxygen (9.6% vs. 45.9%); fewer required antibiotics (15.7% vs. 60.2%); and fewer entered intensive care (0.1% vs. 8.3%). Ivermectin-treated patients tested negative faster, in four days instead of 15, and stayed in the hospital nine days on average instead of 15. Ivermectin patients experienced 13.3% mortality compared with 24.5% in the control group.

Moreover, the drug can help prevent Covid-19. One 2020 article in Biochemical and Biophysical Research Communications looked at what happened after the drug was given to family members of confirmed Covid-19 patients. Less than 8% became infected, versus 58.4% of those untreated. Among 200 healthcare workers and others at high risk of exposure, only 2% of those given ivermectin developed Covid-19. But 10% of the control group did.

Despite the FDA's claims, ivermectin is safe at approved doses. Out of four billion doses administered since 1998, there have been only 28 cases of serious neurological adverse events, according to an article published this year in the American Journal of Therapeutics. The same study found that ivermectin has been used safely in pregnant women, children and infants.

If the FDA were driven by science and evidence, it would give an emergency-use authorization for ivermectin for Covid-19. Instead, the FDA asserts without evidence that ivermectin is dangerous.

At the bottom of the FDA's warning against ivermectin is this statement: "Meanwhile, effective ways to limit the spread of COVID-19 continue to be to wear your mask, stay at least 6 feet from others who don't live with you, wash hands frequently, and avoid crowds." Is this based on the kinds of double-blind studies that the FDA requires for drug approvals? No.

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