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How the FDA Misled Us During the COVID Pandemic

The FDA's incorrect and biased assessment of ivermectin caused thousands of Americans to die of COVID as a result. The FDA failed the public and is likely to do it again.

Charles L. Hooper is president of the health care consultancy Objective Insights and author of Should the FDA Reject Itself? (Chicago Park Press, 2021).

David R. Henderson, a research fellow with Stanford University's Hoover Institution, was the senior economist for health care with President Reagan's Council of Economic Advisers.

COVID-19 is steadily attracting less attention, which is welcome news. Before we put the pandemic behind us, however, we should learn important lessons so we can avoid repeating mistakes. One catastrophic mistake is that the Food and Drug Administration (FDA) perpetrated misinformation that probably killed hundreds of thousands of Americans. Unless steps are taken to rein in the FDA's powers, similar results are likely to happen in the future.

Case study: ivermectin

You may think ivermectin was shown to be useless for treating COVID-19. But that's the FDA talking, not the clinical data. The FDA presented an incorrect and biased assessment of ivermectin, and Americans died as a result. The FDA failed us. If something doesn't change, it will fail us again.

Before the pandemic hit, ivermectin was a "wonder drug" from Merck & Co. that had been dosed over four billion times in areas of the world where parasites are common.[1]

The Nobel Committee for Physiology or Medicine, which hadn't given an award for a treatment for an infectious disease in six decades, recognized the discovery of ivermectin in 2015. Why? For its impressive utility against some of the world's most devastating tropical diseases.

While ivermectin has been used safely by pregnant women, children, and infants, during the pandemic this miracle treatment became a political lightning rod.

In March 2021, in "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," the FDA claimed that "ivermectin is not an anti-viral," even though ivermectin had shown activity in the laboratory against 21 viruses, including SARS-CoV-2, the virus that causes COVID-19.[2,3,4,5,6]

To discourage usage, the FDA used scary words and phrases such as "serious harm," "hospitalized," "dangerous," "very dangerous," "seizures,"

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383101/
[2] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19
[3] https://www.sciencedirect.com/science/article/abs/pii/S0166354219307211
[4] https://www.sciencedirect.com/science/article/pii/S1413867020300817
[5] https://www.sciencedirect.com/science/article/pii/S0166354220302011
[6] https://pubmed.ncbi.nlm.nih.gov/30266338/

"coma and even death" and "highly toxic." And yet the FDA never explained how a drug it had declared safe for antiparasitic use in humans could be so dangerous when used for SARS-CoV-2 infections.

Although the FDA has approved ivermectin for human antiparasitic use, it has never approved ivermectin for antiviral (e.g., SARS-CoV-2) use. So, at issue is the "off-label" prescribing of ivermectin. That occurs when a physician uses a drug for a use, an "indication," not specifically approved by the FDA. Off-label prescribing is widespread, medically accepted, and completely legal. It occurs when doctors discover that a drug approved for one purpose also works for some other purpose. Roughly half of all cancer drugs, for example, are used for off-label purposes.

Evidence that ivermectin works against COVID

In its most recent update on ivermectin, in December 2021, the FDA claimed that "one of the FDA's jobs is to carefully evaluate the scientific data on a drug to be sure that it is both safe and effective for a particular use. Currently available data do not show ivermectin is effective against COVID-19."[7]

We must wonder what, if any, data the FDA has evaluated to reach that conclusion.

Even after we remove questionable studies, we are left with 99 clinical studies involving 1,089 researchers and 137,255 patients.[8] On average, across all studies, ivermectin has reduced mortality by 49%, the need for mechanical ventilation by 29%, ICU admissions by 38%, hospitalizations by 34%, and cases by 81%, and has improved recovery by 43% and viral clearance by 42%.[9] Any drug company—or doctor or patient—would be thrilled with such results.

Ivermectin v. alternatives: efficacy

One might think we don't need ivermectin, given the FDA's approval of Pfizer's Paxlovid (nirmatrelvir and ritonavir), Gilead's Veklury (remdesivir), and Merck & Co.'s Lagevrio (molnupiravir). All received FDA approval, and one, Lagevrio, received a limited Emergency Use Authorization.[10, 11] But none of these drugs can touch ivermectin's safety and efficacy.

The results for reduced mortality, arguably the most important measure, shows Paxlovid at 36%, Veklury at 10%, and Lagevrio at 24%, versus 49% for ivermectin.[12] Results for other health metrics are even more skewed in favor of ivermectin. Paxlovid doesn't appear to help prevent the need for mechanical ventilation, while ivermectin reduced it by 29%. Paxlovid increased viral clearance by 15% compared to ivermectin's 42%.

Ivermectin v. alternatives: safety

The difference in safety between these drugs is stark. Some researchers point to ivermectin's "excellent safety."[13] Others conclude that "the immense number of patients who have been

[7] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19
[8] https://c19ivm.org
[9] https://c19ivm.org
[10] https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19#:~:text=What%20treatments%20are%20available%20for,hospitalized%20and%20non%2Dhospitalized%20settings
[11] https://www.fda.gov/media/155056/download
[12] https://c19early.org
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/

treated with ivermectin shows that it is a safe and a well-tolerated drug."[14] Paxlovid, however, can cause dangerous drug interactions in about 15% of patients. Sixty-six drugs have been identified that can interact with Paxlovid to cause serious adverse events. Dozens of other drugs can also cause problems.[15] Veklury can cause acute kidney failure. Lagevrio treatment can lead to mutagenicity, carcinogenicity, teratogenicity, and embryotoxicity. In plain English, Lagevrio can alter human DNA.

Ivermectin v. alternatives: cost

The economics aren't even close. The list price for a course of therapy of Paxlovid is $1,390 while ivermectin, long since generic, is priced at about $20.[16, 17]

What motivates the FDA? If it seems as if the FDA isn't even trying, it's because it isn't! The FDA isn't in the public health business that you probably think it is or should be. It's here to monitor deep-pocketed drug companies struggling to get their patent-protected drugs through the complex approval process.

To the FDA, drugs such as ivermectin are an annoyance. Pfizer's application for Paxlovid gets to the front of the line at the FDA while ivermectin languishes outside in the cold, with no sugar daddy to escort it inside. Because it's a generic, no drug company has an incentive to push for its use.

The FDA appears to care more about money and process than your health.

If the FDA can't be trusted to make careful and accurate statements about off-patent drugs for emergency uses, it should be prohibited from making any statements. Because ivermectin could have reduced deaths from COVID-19 by half, the FDA's modus operandi killed many of our family, friends, and neighbors. We need to shut down the FDA's deadly misinformation machine before putting this pandemic in the rearview mirror.

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5835698/
[15] https://ascpt.onlinelibrary.wiley.com/doi/pdf/10.1002/cpt.2646
[16] https://www.wsj.com/health/healthcare/pfizer-covid-drug-paxlovid-pricing-80f83785
[17] https://www.medscape.com/viewarticle/966690

Goodman Institute
FOR PUBLIC POLICY RESEARCH

6335 W Northwest Hwy - #2111 • Dallas, TX 75225 • email: info@goodmaninstitute.org • +1 214 302.0406