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## FLCCC Alliance Statement on Misleading FDA Guidance on Ivermectin

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WASHINGTON, D.C. — The Front Line COVID-19 Critical Care Alliance (FLCCC), a group of highly published, world-renowned critical care physicians and scholars, is troubled by the recently updated consumer guidance on Ivermectin from the FDA. The guidance from the FDA is misleading and has the potential to raise unwarranted concern over an important drug in the prevention and treatment of COVID-19.

We support the FDA’s direction that humans should never take medication formulations meant for animals. We also agree that self-dosing of medications without the guidance of a physician is potentially dangerous and could cause serious harm.

However, the FLCCC feels that other statements recently made by the FDA are misleading and serve to alarm the public about using Ivermectin as a treatment prescribed by a physician.

The FDA consumer guidance statement admits that they have not reviewed data on the use of Ivermectin to treat or to prevent COVID-19. However, the agency felt compelled to use language to discourage any discourse and interest in using Ivermectin as a front-line treatment of COVID-19. To do this is to ignore the growing body of scientific evidence from peer-reviewed research, over 40 medical trials, and results from Ivermectin’s use in medical settings worldwide, showing the safe and effective use of the drug in fighting COVID-19. [Source available [↗ here](#)]<sup>1</sup>

According to the American Medical Association Journal of Ethics, 10–20% of all prescriptions in the U.S. are prescribed ‘off-label.’ [Source available [↗ here](#)]<sup>2</sup> Ivermectin is often one of many drugs prescribed by a physician for a number of conditions it is known to be effective for, but might not have gone through FDA approval. It is therefore misleading to suggest that because a drug has not received FDA approval for COVID-19 it should not be used. FDA approval would only come many months to years from now after a very large Phase III trial is done and our patients cannot wait for that.

“Due to its extensive record of safe use, medical professionals can feel confident about prescribing Ivermectin,” said Dr. Pierre Kory, president and chief medical officer of the FLCCC. “In the 40 years since it was first approved for use, more than 3.8 billion people have been treated

with an average of only 160 adverse events reported per year. [Source available [↗ here](#)]<sup>3</sup> This is a better safety record than several vitamins.”

During this time of a pandemic, the FDA should be working as fast as it can to approve the use of Ivermectin in the prevention and treatment of COVID-19 instead of issuing misleading guidance that could prevent people from taking a life-saving drug. In the meantime, the public deserves to have clear and science-based information on safe and effective treatments for COVID-19.

### The Front Line COVID-19 Critical Care Alliance

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### Sources

- <sup>1</sup> FLCCC Alliance. 2020. *One Page Summary of the Clinical Trials Evidence for Ivermectin in COVID-19*. <https://flccc.net/one-page-summary-of-the-clinical-trials-evidence-for-ivermectin-in-covid-19/>
- <sup>2</sup> Katrina Furey & Kirsten Wilkins. 2016. Prescribing “Off-Label”: What Should a Physician Disclose? *AMA Journal of Ethics* 18(6). 587–593. <https://journalofethics.ama-assn.org/article/prescribing-label-what-should-physician-disclose/2016-06>
- <sup>3</sup> VigiAccess™ is a web application that will allow anyone to access information and encourage the reporting of adverse effects from medicinal products. <http://www.vigiaccess.org/>

Media: For more information, or to arrange for an interview, please contact [press@flccc.net](mailto:press@flccc.net).

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*The FLCCC Alliance was organized in March, 2020 by a group of highly published, world renowned Critical Care physician/scholars – with the academic support of allied physicians from around the world – to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. Their **MATH+ Hospital Treatment Protocol** – introduced in March, 2020, has saved tens of thousands of patients who were critically ill with COVID-19. Now, the FLCCC’s new **I-Mask+ Prophylaxis and Early At-Home Outpatient Treatment Protocol** with Ivermectin has been released – and is a potential solution to the global pandemic.*

*For more information: [www.FLCCC.net](http://www.FLCCC.net)*

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