An Open Letter to the FDA on Ivermectin and COVID-19 Treatments

Below is an open letter to the U.S. Food and Drug Administration (FDA) in response to a letter sent by the agency to the Federation of State Medical Boards and the National Association of Boards of Pharmacy discouraging the use of ivermectin for treating and preventing COVID.

Shannon Glueck, PharmDA

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CC: United States Senate Committee on Health, Education, Labor and Pensions and Dr. Chaudhry.

The purpose of this letter is to inform you that both the medical community and the general public understand that your letter dated 12/13/2021 to the Federation of State Medical Boards is both misleading and dangerous, as it will lead to a continuation of harmful medical practices and the denial of early, aggressive treatments that have been shown to reduce morbidity and mortality associated with disease that results from the infection by the SARS-CoV-2 virus.

The public finds your letter to be misguided and spurious, to the point of nearly appearing erratic.

Your counterfactual letter claims that your position is based on a concern that, “using ivermectin products in preventing or treating COVID-19 may pose risks to patient health or lead to delays in getting effective treatment of COVID-19.”

And yet, the standard of care for patients who test positive for the SARS-CoV-2 virus is to tell patients to go home and wait until they are sick enough to require emergency medical care. This, of course, causes patients to become incubators of the SARS-CoV-2 virus and the source of new variants.

Your letter poses ivermectin in a position of competition with other treatments; in fact, no available treatments are in competition with ivermectin, and each has their own risks and weak support; persons who receive monoclonal antibodies may experience worsening COVID-19 if provided too late, and Remdesivir only shows a marginal reduction in absolute risk of hospitalization and no change in length of hospital stay. Patients being given Remdesivir and their families are not provided with a list of side effects as required under U.S. and state laws governing informed consent, including that once hospitalized with severe COVID-19, no alternative treatment options other than Remdesivir, oxygen and mechanical ventilation will be considered by the attending medical staff other than palliative care.

It is worth pausing to reflect that there were no studies supporting the safety and efficacy of mechanical ventilation in COVID-19 before it was adopted by hospitals across the United States, and the fact that the allopathic medical community continues to treat severe COVID-19 primarily as pneumonia rather than an immunologic vascular disease show a lack of leadership by FDA, NIH and CDC. Others have stepped in to fill the leadership gap. These experts should be consulted at the earliest possible date, and include Dr. Pierre Kory, Dr. Peter McCollough, Dr. Paul Marek, and Dr. Harvey Risch, among others.

Your letter incorrectly asserts that "currently available data do not show that ivermectin is safe or effective for the prevention or treatment of COVID-19". Your letter, however, fails to mention or cite the massive number of studies available that demonstrate a reduction in hospitalizations and deaths associated with SARS-CoV-2 infection via early treatments, including ivermectin. This omission shows an unmistakably callous disregard for scientific evidence in the formation of your policy position.

In fact, the totality of the relevant studies has been laid out for you (and for all of the medical community and the public) at c19early.com since March 2021, and ivmmeta.com since December 2020. The peer-reviewed studies are also available to you via the National Library of Medicine (National Center for Biotechnology Information) via the URL pubmed.gov.

The resource c19early.com includes a database of all ivermectin COVID-19 studies to date. They report:

"There are currently 138 studies, 90 of which are peer-reviewed, 73 with results comparing treatment and control groups. FLCCC provides treatment recommendations. (Four) recently added studies include: Shimizu, Mustafa, Jamir and Kerr Behl. Ivermectin has been officially adopted for early

treatment in all or part of 23 countries (39 including non-government medical organizations).”

The real-time meta-analysis at ivmmeta.com has provided continuously updated meta-analysis of 73 studies and reports that these studies collectively show:

“Statistically significant improvements are seen for mortality, ventilation, ICU admission, hospitalization, recovery, cases, and viral clearance. All remain significant after exclusions. 48 studies from 44 independent teams in 20 different countries show statistically significant improvements in isolation (37 primary outcome, 34 most serious outcome).

Meta-analysis using the most serious outcome shows 66% [53-76%] and 83% [74-89%] improvement for early treatment and prophylaxis, with similar results after exclusion based sensitivity analysis (excluding all GMK/BBC team studies), for primary outcomes, for peer-reviewed studies, and for RCTs.

Results are very robust – in worst case exclusion sensitivity analysis 59 of 73 studies must be excluded to avoid finding statistically significant efficacy.”

Your reckless letter has ignored a massive amount of science.

Your organization has a history of granting EUA approval, and an unusual full FDA approval for one re-named EUA vaccine based on “studies” that are “published” by vaccine manufacturers as press releases that make claims that are so specious they must include, per the U.S. SEC, “forward-looking statements” to protect the vaccine manufacturers from charges of misleading investors. Your organization has granted EUA status for COVID-19 vaccines on the mere promise of data, and has ignored the faults in studies allegedly supporting the safety and efficacy of COVID-19 vaccines.

The animal studies conducted on the question of antibody-

dependent disease enhancement were used by FDA to grant EUA status for the Moderna and Pfizer vaccine without independent peer-review, the sample sizes were too small to be reliable; the companies used the wrong animals, and Pfizer left out an outlier animal.

The public is well aware of the favoritism firmly entrenched in your organization for drugs and biologics from large Pharmaceutical corporations, and that the FDA has been captured by entities with massive financial interests. The public is willing to accept an explanation of your personal incompetence if necessary to avoid the issue of fraud.

Therefore, I am writing to you in the hope that there is some thread of compassion left in you as a human being to please retract your letter and similar communications from the US FDA, such as your letter to the National Association of Boards of Pharmacy and the guidance (i.e., "Letter to Stakeholders") posted 04/10/2020.

Federal policies that influence public health and medical practices must be based on a firm understanding of the totality of the science on any issue before a position is taken or communicated. Your office has exhibited a totality of abject failure in this regard. I am therefore asking physician colleagues and the general public to act, by co-signing this letter by adding their names in the comments, to put the U.S. FDA on notice regarding the risk and danger their positions on early aggressive treatments of COVID-19 as they pose a threat to public health and the welfare of patients across the United States and its territories.

We are collectively requesting your personal and immediate retraction of the letter, or your resignation for gross incompetence, or both – whichever step you feel in your heart is most appropriate for your gross and unacceptable mishandling of this most important matter.

We are asking Dr. Chaudhry to look into the matter of whether the FDA has, in fact, considered the available scientific evidence on the matter of ivermectin and COVID-19 prevention and treatment. As a physician, he must understand that the totality of evidence provided by available studies show the opposite of harm.

Dr. Chaudhry's protest signature on this letter is specifically requested.

Sincerely,

James Lyons-Weiler, PhD

The Institute for Pure and Applied Knowledge

USA

This letter can be copied, pasted and forwarded to Dr. Chaudhry at hchaudhry@fsmb.org.