Stephen M. Hahn M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

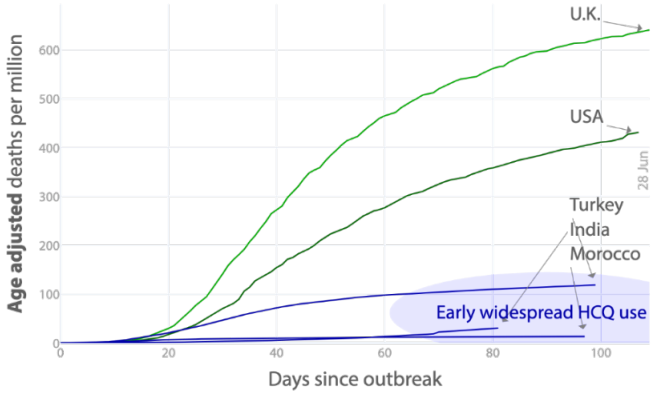
RE: Support for the Request for Emergency Use Authorization of Hydroxychloroquine for Ambulatory Prophylaxis and Treatment of COVID-19

Dr. Hahn,

The current "NIH-FDA doctrine" is for COVID-infected patients to wait in home quarantine until they develop a shortness of breath and are hospitalized before they can receive hydroxychloroquine treatment. This doctrine is a failure. It has resulted in significant, unnecessary mortality and the overwhelming of hospital Intensive Care Units. It is not a concept of the 2017 National Pandemic Plan for Respiratory Viruses, and it does not help patients be medicated while they are still within the narrow treatment window for this drug.

It is unrealistic to believe that a continuation of this doctrine will have any practical effect in halting the epidemiological spread and significantly reducing the mortality rate of COVID-19.

In contrast to the United States and the UK, other countries have initiated an aggressive program of early outpatient treatment of COVID-19 using hydroxychloroquine and have brought or are bringing their national pandemic under control. These include Costa Rica, UAE, S. Korea, Israel, South Africa, Chile, Turkey. India, Brazil and China.



The last hope for some degree of COVID-19 control within the US lies with the initiation of physician-directed hydroxychloroquine outpatient drug therapy, given within the first 7-days of patient symptoms, as well as the prophylactic use of hydroxychloroquine in high-risk Health Care Workers (HCW) and in a very low-dose pre-exposure role for individuals with a high number of daily inter-personal contacts if there are no contraindications. This is supported by emerging data from India and elsewhere.

On April 6, 2020, an international team of scientists and doctors met to review the data on hydroxychloroquine use in more than 130,000 patients. They reaffirmed that hydroxychloroquine was a safe FDA-approved drug. When administered at the doses used for diseases like

rheumatoid arthritis and lupus, there are no serious side effects. Further evidence to the safety of HCQ comes from the 2020 North American Consortium of Hydroxychloroquine RCT for Prevention of COVID-19: *"Since March 17, 2020, a total of 1966 participants have been enrolled across the 7 RCTs. DSMB and independent review events were collected from these RCTs. To date, there have been no SAE, no deaths related to hydroxychloroquine. No study participant has required hospitalization due to the drug. There have been no significant adverse cardiovascular events."*

It is time to return the practice of medicine to trained physicians, and away from dysfunctional agencies influenced by the opinions of the mainstream media and non-peer reviewed papers, not medical science. A recent meta-analysis of 20 available reports, including 105,040 patients by Million M, Gautret P, Colson P, et al. (in press) shows that hydroxychloroquine and its related compounds, improve clinical outcomes and reduce mortality by a factor of 3 in COVID-19 patients. This is reaffirmed by over 50 research reports during the last 5 months. Cardiac events have not been a factor in early-use patients not on supplemental oxygen. The recent publication of the Ford study involved 2662 patients and while not an outpatient study, it provides the best "early treatment" assessment of hydroxychloroquine for the US management of COVID to date.

At a statistically significant level, early-use hydroxychloroquine alone was associated with a 51 % reduction in the mortality rate of COVID patients receiving an early five-day course of hydroxychloroquine.

A new Request for Emergency Use Authorization for hydroxychloroquine has been sent to the FDA by the physicians running the clinical trials of this safe drug at the Ford System in Detroit.

Scope of Authorization Requested

- Allow Physicians to prescribe HCQ, with or without antibiotic additions, after assessment of indications, contraindications and under reasonable dosages based on their clinical judgement.
- Continue studies evaluating HCQ for pre, post and early treatment of HCQ to be supported without the need for IND requirement limiting the potential for studies to be initiated.
- A program of prophylactic HCQ should be initiated for all Health Care Workers that wish this and that do not have contraindications.
- Healthcare professionals added to case-contact tracing teams should be allowed to administer Hydroxychloroquine if requested to close contacts of infected patients.
- Hydroxychloroquine prophylaxis should be offered to all individuals in close contact with others during their normal daily activities, to include bus drivers, police, fire, EMS, first responders and other high-risk groups.

This open letter supports this FDA EUA Request and is signed by clinicians, medical researchers, statisticians, and ethicists.