On July 6, a team of doctors from Henry Ford Hospital, supported by physicians from Baylor University Medical Center, submitted an urgent request to the Food and Drug Administration (FDA) to reauthorize use of hydroxychloroquine (HCQ) for early treatment of COVID-19. Since that day, more than 25,000 more Americans have died from the virus as COVID-19 continues to burn through communities across America. If the results of a recent Henry Ford Hospital study are accurate, at least half of these patients might have been saved by HCQ.

Since the pandemic from China first hit America with brute force early in March, it has become apparent to physicians that the medicine works best when — as with any anti-infective agent — it is given early in the course of the infection. Moreover, hospitalization can be avoided if treatment starts within the first day of symptoms.

While HCQ alone has been found by numerous studies to reduce mortality rates, severity of symptoms, and length of hospital stays, it also can be combined with zinc and either azithromycin or doxycycline, followed by corticosteroids (prednisone, dexamethasone), and in some cases anticoagulants — all working together for improved outcomes. For each one of these drugs, there is both a good scientific rationale and either early clinical trials completed or planned with sufficient promise.

Of these drugs, only HCQ was singled out as a political football early in spring — right after President Trump urged the medical community to consider HCQ. At the time, one of Trump's top medical advisers, Dr. Anthony Fauci, stated that if a COVID-19 patient were under his care, he would use HCQ, preferably in a clinical trial protocol. Fauci, however, has since backed away from that statement and his opposition has become a rallying cry of the left-leaning mainstream media's "Hydroxy Hysteria."

The politicization of HCQ is an ongoing tragedy. The Federal Emergency Management Agency (FEMA) has more than 60 million HCQ tablets sitting in its warehouses. Absent a new Emergency Use Authorization, FEMA cannot ship this valuable medicine for appropriate "off-label" treatment of COVID-19 patients. Nor can hospitals or clinics easily recruit patients for the kind of randomized clinical trials needed to ultimately settle the question of how HCQ might best be used in the fight against COVID-19. Should it be purely in early treatment, as a prophylactic for health care workers or senior home patients at risk, in outpatient versus hospital settings, or in other settings?

Positive HCQ studies have been dismissed in medical journal editorials as "flawed" because they were "observational" rather than randomized. The few randomized trials of HCQ reported to date have been a debacle because of the failure to distinguish clearly between early treatment (one to seven days after the onset of symptoms), when the medicine should work, versus later treatment, when it is unlikely to help. To make matters worse, in a classic

"statistical type two error," many of the preventive and early illness trials of HCQ changed primary endpoints, reduced sample sizes, and became unable to see the benefit of HCQ, if indeed it was there.

For example, the University of Minnesota, in a collaboration with other centers, published randomized prevention and early treatment trials. While both trials were stopped early and thereby had small samples, both made definitive claims that HCQ was not effective. However, careful review of their data shows just the opposite — numerically (but not statistically significant) lower numbers of infections and hospitalizations in those who were randomized to HCQ.

Further clouding the issue, the National Institutes of Health opened an outpatient trial of HCQ and azithromycin in May but closed it in June, stating they could not recruit subjects into the study. This was a highly disingenuous claim, given the overwhelming numbers of COVID-19 patients desperate for treatment.

My own conclusion from a review of the literature is that HCQ has not failed the randomized trials, but researchers have failed HCQ. Many doctors who understand the science and the threats to validity in the HCQ literature continue to prescribe HCQ appropriately "off-label" to COVID-19 victims at home, in senior centers, and early in the hospital. The Association of American Physicians and Surgeons is suing the FDA for access to HCQ.

In thinking carefully about all the negative news that you may have heard about HCQ, keep in mind this drug has been used in the U.S. since 1955. It has a completely established safety record for lupus, rheumatoid arthritis, and malaria prevention and treatment. Prescribed under a physician's good judgment, it is unlikely to cause harm.

So how did HCQ become considered dangerous? The first false safety concerns arose early in the pandemic in reports that doctors prescribed HCQ not in an early treatment setting at the first sign of symptoms but rather in a late-stage setting to more severely ill patients in the hospital. This form of treatment bias — that is, giving medicine to the sickest before death — created a false association between HCQ and mortality. Unfortunately, the mainstream media picked up on these reports and did great damage by promulgating a false narrative without understanding the epidemiological underpinning of confounding by indication.

In what would be a death blow to public trust of HCQ, the prestigious Lancet journal published a massive worldwide study that purported to show excessive deaths in patients treated across six continents — only to have the paper later retracted. The New England Journal of Medicine had a similar unprecedented retraction — more evidence of HCQ becoming a political football in medical science. While the studies were fraudulent and discredited within a few weeks, the media coverage, and earlier flawed studies, led both the

FDA and World Health Organization (WHO) to withdraw endorsements of the drug for COVID-19 treatment.

Gates Foundation invests in $3 COVID-19 vaccine for poorer countries

Two cats test positive for coronavirus in Texas

We now know, based on the large New York and Detroit experiences at Ford and Mt. Sinai hospitals, that HCQ is safe. To date, there has not been a single credible report that the medication increases the risk of death in COVID-19 patients when prescribed by competent physicians who understand its safety profile.

It is time for the FDA and state medical boards to support the use of HCQ in conjunction with other commonly used drugs — steroids and antithrombotics — against COVID-19, treated early at home to help avoid hospitalization and death. As President Trump has said, what have you got to lose by reinstating an Emergency Use Authorization? As to what might be gained, appropriate research and prescription (combined with other medications) could spare hundreds of thousands of hospitalizations and save tens of thousands of American lives.

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