

the first five days of symptom onset, produces a sharp and statistically significant reduction in hospitalization and mortality. Seven controlled, well-conducted clinical studies show this: 636 outpatients in São Paulo, Brazil; 199 clinic patients in Marseille, France; 717 patients across a large HMO network in Brazil; 226 nursing-home patients in Marseille; 1,247 outpatients in New Jersey; 100 long-term care institution patients in Andorra (between France and Spain); and 7,892 patients across Saudi Arabia.

All of these studies pertain to the early treatment of high-risk outpatients, and all showed 50% or higher reductions in hospitalization or death. Not a single fatal cardiac arrhythmia attributable to the HCQ was reported among these thousands of patients. In addition, a new summary analysis of five randomized controlled trials has also shown a statistically significant outpatient benefit, proving the case.

The inability of COVID-19 outpatients to obtain prescriptions for HCQ — a medication that along with zinc, vitamin D, antibiotics, and likely steroids will almost certainly prevent them from hospitalization and death — stems entirely from FDA's refusal to remove its fictional website warning, and its refusal to grant HCQ emergency use authorization in spite of the major evidence of benefit. That evidence is much stronger than that involved in the FDA's approval of convalescent plasma, and especially of its approval of remdesivir, which has now been proven ineffective.

Many or most of the 220,000 deaths in the United States to date could have been prevented by widespread HCQ use that the FDA blocked. It is the FDA that is responsible for these deaths, not the president. It is sheer corrupt hypocrisy, and completely shameful, for past FDA commissioners and for a *New England Journal of Medicine* editor with ties to the FDA to accuse the president of what the FDA itself has done.

It is time to clean up this mess once and for all. The FDA must remove its black-box warning, approve the emergency use authorization for outpatient HCQ use, and let doctors get on with the work of saving lives.

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