FDA obstruction: Patients die, while Trump gets the blame

In a recent *Washington Post* op-ed, seven former FDA commissioners claimed that the agency has lost credibility with the public, and they blamed it on President Trump.

Jumping on the same bandwagon, an editorial in the once-venerable *New England Journal of Medicine* accused the president of "failing at every step" to stop the COVID-19 pandemic, thus enabling more than 220,000 deaths to date.

In reality, these charges are driven by craven politics and Big Pharma conflicts of interest. They divert attention from the FDA's despicable efforts to block access to effective and inexpensive generic medications. Foremost among these is hydroxychloroquine.

Let's take this in steps.

First, who is bringing these charges? The seven commissioners include David Kessler — adviser for the Biden campaign; Scott Gottlieb — board of directors of Pfizer and consultant to many pharmaceutical companies; Mark McClellan — board of directors of Johnson &

Johnson; Robert Califf — extensive ties with many of the largest pharmaceutical companies; Andrew von Eschenbach — board of directors of the biotech company BioTime and director of Viamet Pharmaceuticals; and Jane Henney — who has served on the board of directors of AstraZeneca.

Many of these companies manufacture patented COVID-19 vaccines and medications. These products are in direct competition with generic, low-cost drugs that FDA has been asked to approve for outpatient COVID-19 use, but that it has refused.

Not to be outdone, the *New England Journal of Medicine* editorial was led by Deputy Editor Lindsey Baden, who disclosed that he is involved in COVID-19 vaccine clinical trial work conducted in collaboration with the National Institutes of Health, COVID-19 Vaccine Prevention Network, and Crucell/Janssen, Moderna, the Gates Foundation, and the Ragon Institute.

Baden is also chair of the Antimicrobial Drug Advisory Committee of the FDA. Not only is Baden, because of his role with the FDA, motivated to deflect blame from the agency, but he appears to be incentivized financially to tilt the COVID-19 response away from inexpensive generic medications and toward patented and massively profitable vaccines.

The reality is that the FDA has undermined its own

credibility, and it has done so brazenly in plain sight. No president was needed for that, as I'll explain.

As background, one must understand that COVID-19 patients are typically hospitalized because they have developed a severe and life-threatening pneumonia, one that fills the lungs with inflammatory debris and causes abnormal blood clotting in the lungs and small blood vessels. This advanced and dangerous condition, often described as acute respiratory distress syndrome, or ARDS, is entirely different from early "outpatient" (that is, outside the hospital) manifestations of COVID-19, which typically consist of a self-limiting, flu-like illness. We are thus speaking of two very different groups of patients. This distinction between COVID-19 outpatient and inpatient, of course, is well known to the FDA.

And yet, on July 1, the FDA posted on its website a large, black-letter warning against using hydroxychloroquine, or HCQ, to treat outpatients: "FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting." The FDA justified this warning — stated on the website, just beneath the warning itself — by referring to safety concerns among hospitalized patients.

The FDA does not mention the crucial distinction between evidence for outpatients and inpatients. It does not mention the large body of evidence that HCQ is safe when used in COVID-19 outpatients. It does not mention that HCQ is currently being used safely by millions of

outpatients with lupus and other rheumatological conditions. Nor does the FDA mention that HCQ has been safely used worldwide by hundreds of millions of persons, equaling tens of billions of doses, over more than half a century.

And finally, the FDA does not mention that it has no data showing adverse events in outpatient use. In short, among relatively healthy outpatients, HCQ has amassed one of the deepest and most extensive safety records of any drug in history, and the FDA's warning implication of general harm is an outright lie.

On Aug. 18, Republican Sens. Ron Johnson, Ted Cruz, and Mike Lee sent a letter to FDA Commissioner Stephen Hahn asking the FDA to justify its public warning. After a seven-week delay, the FDA gave a vacuous non-response that contained no data on outpatient adverse events. Yet, the black-letter warning remains on the FDA website. That warning has caused state medical and pharmacy licensing boards to block physicians and patients from obtaining HCQ, and it has caused large health systems, medical groups, individual doctors, and other care providers to shun HCQ altogether.

Why is this important? There is extensive evidence that HCQ, when used within 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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