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Doctors, Not Politicians, Ought To Decide Whether Off-Label Drug Use of Hydroxychloroquine Is Appropriate for COVID-19 Patients

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As he often does, President Donald Trump uttered an untruth at a March 13 White House coronavirus task force briefing. The president claimed the drugs chloroquine and hydroxychloroquine, used for decades to treat malaria and connective tissue diseases, had been approved by the Food and Drug Administration (FDA) to treat COVID-19 and could be a "game changer" in the battle to defeat the virus.

Trump's understanding of the FDA approval process was wrong—the drugs had not yet been approved to treat COVID-19—and his declaration of the drugs' effectiveness was premature. But partisan animus toward the president ignited a firestorm of criticism from commentators and political leaders disproportionate to these inaccuracies that has in some states already prevented coronavirus patients from getting off-label drug prescriptions which might help them recover.

As a physician in clinical practice for more than 35 years, what I know about the drugs' effectiveness I got from reading the medical literature. What I've seen about hydroxychloroquine makes me cautiously optimistic. Doctors should not be prohibited from using their best clinical judgment and recommending it to patients—especially considering the fact that these drugs have been around for a long time, which means we are familiar with their risks and complications. The government should stay out of this and let clinicians practice medicine, provided they get their patients' informed consent. Patients have a fundamental right to try drugs they think may save their lives. Doctors they consult must be free to give patients their best advice, unencumbered by government overseers.

Unfortunately, after Trump's pronouncement, the governors of Nevada, Michigan, and New York issued executive orders restricting how doctors can use hydroxychloroquine to treat patients with COVID-19. *The Washington Post* published disparaging remarks about the drugs' potential while *The New Yorker* accused Trump of "coronavirus quackery," which rested on the fact that Dr. Anthony Fauci of the coronavirus task force had stated, "the answer is no," when asked by a reporter if he can claim hydroxychloroquine is an effective treatment for COVID-19.

I can understand Fauci's response. In fact, I would be surprised if he had responded otherwise. Administrative physicians usually don't declare drugs effective for the treatment of conditions if randomized controlled studies have not yet been done. To clinicians in the field, however, it's an entirely different matter.

The FDA allows doctors to prescribe drugs off-label all the time. Once the FDA approves a drug for use for the specific condition for which it was developed, there are no restrictions on "off-label" use, or clinicians using that drug to treat other conditions. Much of what clinicians read in the peer-reviewed scientific literature are clinical studies and case reports of off-label uses of various FDA-approved drugs to treat various conditions. Clinicians then use that information, along with their own clinical experience and judgment, and knowledge of their patients' individual risks and potential benefits, when attending to their patients. In this way, roughly one in five prescriptions written by U.S. clinicians are off-label. At the April 4 coronavirus task force briefing, FDA Commissioner Dr. Stephen Hahn said, in answer to a question about off-label prescribing, "As a doctor, we do this all the time."

In fact, many medical advances start out this way. Physicians learn of observational studies about the successful off-label use of a drug. Clinical situations develop in which it makes sense for them to see if it helps their patients. They then report their results. Enough anecdotal reports accumulate for the drug to gain acceptance for a particular off-label use. That off-label use of the drug may gain mainstream acceptance but it may take years before the FDA is convinced by randomized controlled studies to add that use to the list of approved uses on the drug label. Aspirin is a well-known example, since it had been used off-label to prevent recurrent stroke or heart attack for many years before the FDA finally approved that use.

While Trump made false statements about hydroxychloroquine and chloroquine, the fact remains that several reports from reputable quarters suggest the drugs may reduce the severity of infection.

Researchers in Marseilles, France, reported successful results with hydroxychloroquine and azithromycin in a small 20-patient sample in early March. A follow-up study with 80 patients published three weeks later showed similar promising results. Doctors in hospitals in Kansas, China, and South Korea have all reported successfully using hydroxychloroquine to treat their patients. (Other studies, out of China and France, suggest the drug might not be very useful at treating COVID-19.)

Critics fail to appreciate that medicine is both an art and a science. Clinicians must often apply imprecise scientific knowledge to variable human predicaments. The intrusion into the practice of medicine by governors and other politicians who are not trained in medicine, yet have the hubris to tell physicians how and what they may use to treat their patients, threatens the integrity of the medical profession, and indirectly imperils patients.

This is not new. It began a few years ago when politicians started dictating, in statute, the medical management of pain. That practice continues despite admonition by the Centers for Disease Control and Prevention that politicians are misinterpreting and misapplying the CDC's

own pain management guidelines. This has led to patients being undertreated for pain and doctors being afraid to properly treat them. Now governors are dictating what drugs clinicians may use to treat a viral infection. Will they next dictate what drugs should be used to treat high cholesterol? Or hypertension? Or diabetes?

As a scientifically disciplined physician, I cannot say with any degree of certainty if hydroxychloroquine or chloroquine are effective to treat COVID-19. I can only state that early observational studies show some promise.

If I got COVID-19 and was having a rough time of it, I would ask for one of these drugs to be used on me. I wouldn't want to take the drugs if I had a mild case because the risk of an adverse drug reaction might not be outweighed by the risk of succumbing to the infection. And if I have patients suffering from a severe case of the infection, possibly even facing death, I am ethically bound to inform them of the possible benefits of the drugs, as well as the risks, and offer it to them.

I understand that doctors should study the research carefully and be cautious about recommending new treatments to patients. And patients should ask questions and practice due diligence before accepting their doctors' advice. But the decision-making process belongs to them, not to detached bureaucrats and politicians.

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