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EDITORIAL

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CORONAVIRUS

We're on our own

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The failure of U.S. government scientists in the Trump administration to follow the science around COVID-19 has left the medical community to fend for itself.

The dance is becoming sadly familiar. A possible treatment for COVID-19 is discussed by scientists, a logical plan for testing it is prepared, then the White House applies pressure to announce that it works long before the data are in. Scientists protest, then either U.S. Food and Drug Administration (FDA) Director Stephen Hahn or U.S. Health and Human Services Secretary Alex Azar cracks and agrees to endorse the treatment. Scientists howl again and there is a partial walking back. Confusion reigns. A similar cycle plays out for public health measures, like closing schools or wearing masks, with Robert Redfield, Director of the U.S. Centers for Disease Control and Prevention–guidance is posted and then changed. More confusion is sown. We now know that Redfield, Azar, and Hahn are not capable of, or willing to, stand up to President Trump. The medical science community must stop this dance as we get closer to rolling out a vaccine for COVID-19 because we now know that we won't get any help from the federal government. We're on our own.

Before fast forwarding to last week's debacle on plasma from convalescing COVID-19 patients, here's a recap of the Trump administration's prior mishaps on COVID-19 treatments. The harbinger of these sagas is the hydroxychloroquine fiasco. In listing drugs that might help with COVID-19, it was logical to add hydroxychloroquine to the list because of its action against some viruses in vitro. Early studies were vague and shady in various ways, but eventually a picture emerged that it didn't work. All along the way, President Trump hawked the medicine as a 'game-changer' that would end the pandemic. FDA Director Hahn caved and granted an Emergency Use Authorization (EUA) on March 30, thereby allowing its medical application without the agency's full approval for use in COVID-19. After millions of dollars were wasted on new studies to prove that the drug was not effective against COVID-19, Hahn finally retracted the EUA on June 15. Trump continued to promote the drug, causing conservative physicians to continue to use it and Trump supporters to demand it. In the meantime, patients who needed hydroxychloroquine for approved indications had trouble getting their normal refills.

Trump's goal was not to deliver a miracle cure, but to paint science into the same corner with his other enemies – academia, the media, coastal elites. When the medical science community said "No" to hydroxychloroquine, politicians retaliated by accusing scientists of taking away hope for people. More importantly, this allowed politicians to use their digital misinformation machine to sow confusion. Confusion is the fuel of Trump's political strategy machine, and it was further enhanced by Hahn's EUA, which he then reversed.

Which brings me to convalescent plasma. This is a measure that many scientists think has promise and may likely meet reasonable standards. Nevertheless, when FDA's EUA for convalescent plasma suddenly showed up on the treatment radar, NIH scientists Anthony Fauci and Francis Collins strongly objected and tried to slow things down. Then Fauci went in for surgery on his vocal cords, and the White House Coronavirus Task Force rushed to resurrect the EUA, announcing it in a breathless press conference as a major breakthrough. This is hardly the case, and in the press conference, Hahn completely botched the statistics. He tried to walk back his statements after scientists cried out from outside the FDA, and probably from inside the agency as well. Hahn also fired chief spokesperson Emily Miller only 11 days after she was hired. But the damage was done. Trump got what he wanted–more confusion, chaos, and scientists debating details that the public doesn't understand.

Now we see the buildup to similar battles about COVID-19 vaccines. Already, the FDA has set a meeting for October 22 of its Vaccines and Related Biological Products Advisory Committee to discuss vaccine progress. The clinical trials on candidate vaccines are still only about halfway enrolled with volunteers. Assuming it takes until the end of September to finish enrollment, and because both of the fastest-moving clinical trials require subjects to receive a second shot 3 to 4 weeks after the first, there likely won't be a lot of news on October 22. It's impossible to imagine full approval for a vaccine next month. There will probably be another meeting to discuss progress and another breathless press conference to announce that things are looking good. It will be highly ironic

for the Trump administration to thank and compliment the scientists that it has spent months undermining, but that cognitive dissonance has long been accepted or ignored.

But what if the October 22 meeting leads to something far more dangerous: A premature EUA for a vaccine? Trump has already denigrated FDA scientists as part of a 'deep state' conspiracy to harm him politically, and White House Chief of Staff Mark Meadows has acknowledged that the administration wants the FDA to 'feel the heat.' It's a biological fact that the vaccine won't be proven effective until enough volunteers in the control arm have become infected. Only then will we be able to say whether those in the vaccinated group were protected. So, what exactly is the conspiracy supposed to be? That FDA scientists would somehow drag their feet in analyzing the data, jeopardizing lives to affect the November election results—surely not even Trump can really believe this. The Trump administration just wants to turn up the heat on Hahn. The administration knows that Hahn caved on two EUAs already after it pressured him, so why not try it again? He could rashly announce an EUA on October 22 and if there's a problem, deal with it after the presidential election on November 3.

Peter Marks, Director of the FDA Center for Biologics Evaluation and Research, should be the primary decision-maker on the vaccine. Marks, who enjoys an outstanding reputation among scientists built over many years, says he would resign if asked to approve a vaccine that he deemed premature. And administration officials are confirming that stance for the time being. But should we feel confident after Hahn's gymnastics on convalescent plasma? Probably not.

I have written in recent weeks that we should continue to support Hahn and his colleagues as long as we think they'll stay strong on the vaccine. The convalescent plasma episode has convinced me that we can't count on him any longer. Scientists at the National Institutes of Health are exhausted from walking on eggshells for six months trying to dodge the administration's political lunges, and Hahn, Redfield, and Azar have shown that they don't have the courage to stand up to President Trump.

It shouldn't be this way. We're supposed to have an FDA to make sure that only scientifically validated medicine is approved. But with no reason to trust that the U.S. government scientists can stay strong, the only choice is for the medical community itself to vow that only a safe and effective vaccine will be prescribed. This is no small challenge. I get mail and comments on social media from physicians who support President Trump and say that I'm too negative and deprive people of hope, and that medical science is too self-absorbed and disconnected from real problems in the clinics. If Trump gets excited about a vaccine and gets an EUA from Hahn, it will be hard to stop physicians from getting it for their patients. Physicians and their professional societies are starting to speak up. The American Association of Medical Colleges (AAMC) has been strong on full FDA approval for a COVID-19 vaccine rather than an EUA and will hopefully have some control on the rollout of a vaccine that has not received full FDA approval at academic medical centers. I asked Heather Pierce, Senior Director for Science Policy and Regulatory Counsel at the AAMC, about this. "When the FDA is free from political interference and gets good data," she said, "it makes good decisions, but the EUA mechanism has been shown to be more susceptible to interference and should not be used for a vaccine."

I'm grateful for these voices, but we don't have the federal safety net we've always had. We're truly on our own.

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