Behind the clinical test of hydroxychloroquine in Detroit

Kevin Reed
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On April 2, Democratic Mayor of Detroit Mike Duggan announced a 3,000-person clinical trial of the anti-malarial drug hydroxychloroquine (HCQ) at the Henry Ford Health System, the first of its kind in the US. According to news reports at the time, Mayor Duggan made a personal plea to the federal government for approval of the trial.

The volunteer enrollment period for the clinical trial took place from April 9-15. The "randomized, doubled-blinded study" called "Will Hydroxychloroquine Impede or Prevent COVID-19" (WHIP COVID-19) involves the voluntary eight-week participation of health care workers, EMS workers and bus drivers who are being exposed to the coronavirus on the job each day.

Further details published on the clinicaltrials.gov website shows that the status of the WHIP COVID-19 trial remains at the "recruitment" stage with the final data collection of the study set for June 30.

The published description of the study says, "Once they provide a blood sample, the study subjects will receive vials with unidentified, specific pills to take over the next eight weeks: a once-a-week dose of hydroxychloroquine, a once-a-day dose, or a placebo (a pill that looks like the medication, but does not contain any medication or other active ingredients)." Participants do not know which group they are in.

In announcing the trial, Mayor Duggan said, "If this works out, we'll save the lives of first responders around the world." Although he did not spell out who he meant by "we," it is clear that Duggan—who was the president and CEO of the Detroit Medical Center from 2004 to 2012 before becoming mayor in 2014—was working closely with officials in the Trump administration, the FDA and the Detroit corporate medical establishment in raising expectations about HCQ.

As a report in the *Michigan Chronicle* revealed, "Mayor Duggan has been in constant contact with the commissioner of the FDA, Dr. Stephen Hahn, since the idea of the medical trial was put into motion 10 days ago. Duggan notes that this is one of the fastest conceived medical trials ever and applauds Henry Ford Health Systems and the FDA."

Ever since President Trump went to the podium at the March 19 White House press briefing and said of HCQ, "I feel good about it. That's all it is, just a feeling, you know, smart guy. I feel good about it," it has been clear that something other than ensuring the public's health has been the motivating interest in the drug at the highest levels of the US government.

What neither Trump nor Duggan has mentioned is that a bottle of 50 hydroxychloroquine pills generally costs about $40. If everyone in the city starts taking it in an attempt to stave of the pandemic, it will provide a $27 million windfall to whatever company sells it. If everyone in the country takes it, that translates to $13 billion in revenue, even before prices are inevitably jacked up in the face of rising demand.

Clearly, the $1.5 trillion global pharmaceutical industry recognizes an enormous business opportunity is to be realized by developing treatment drugs and a vaccine for COVID-19. Billions of dollars are being invested by companies such as Pfizer, Johnson & Johnson and Moderna for a coronavirus vaccine in anticipation of hundreds of billions in profits if their company finds a cure.

There are currently 70 candidates in development internationally with the timeline for a vaccine set by researchers at somewhere between one year and 18 months from now. This projection is optimistic, given that the previous record to develop a vaccine is four years (the mumps vaccine in 1967), and there has yet to be a successful coronavirus vaccine for SARS (2002) or MERS (2012) because funding dried up before research could be completed.

"A year to 18 months would be absolutely unprecedented," said Peter Hotez, dean at Baylor University's National School of Tropical Medicine, to *National Geographic*. "Maybe with the new technology, maybe with throwing enough money on it, that'll happen. But we have to be really careful about those time estimates."

Since vaccine development is a longterm project, coming up with a coronavirus "wonder drug" in the meantime would provide the ruling elite with a medical justification to force a rapid return to work against the advice of epidemiologists and public health experts during the pandemic. In the case of HCQ, it would be a windfall for the companies such as Novartis and Sanofi that currently manufacture it under the product name Plaquenil for the treatment of malaria and lupus.

However, recent reports are that coronavirus patients taking HCQ died in greater numbers than those who did not and that they may be at risk of a sudden cardiac failure. This could have an impact on ongoing clinical testing of the drug that has been recklessly promoted by President Trump and others as a cure for COVID-19.

On April 20, the preliminary results of research by the National Institutes of Health (NIH) and the University of Virginia of 368 Veterans Health Administration coronavirus patients taking hydroxychloroquine were published. The scientists analyzed the medical records of male veterans with confirmed cases of the coronavirus who died or were discharged by April 11.

Of those in the study who had COVID-19 and were given the same level of care, 11 percent who did not take the drug died, while 28 percent of those who did take the drug suffered a fatal complication. In addition to the death rates, the results also showed that patients who were given HCQ were no less likely to need a ventilator in their treatment for the virus.

Working at Columbia VA Health Care System in South Carolina, the University of South Carolina and the University of Virginia, the researchers wrote, "An association of increased overall mortality was identified in patients treated with hydroxychloroquine alone. These findings highlight the importance of awaiting the results of ongoing prospective, randomized, controlled studies before widespread adoption of these drugs."

Additionally, on April 21, a panel of experts at NIH recommended against the use of HCQ, along with the antibiotic azithromycin in coronavirus patients outside of clinical trials. The NIH panelists wrote that the use of the two drugs in combination increases the risk of sudden cardiac death.

Significantly, Richard Bright, director of the Biomedical Advanced Research and Development Authority in HHS, issued a statement on April 22 that he had been removed from his post the day before because he insisted that the government spend funds on safe and scientifically verified solutions.

Bright pointed specifically to political influence behind the promotion of HCQ. “I am speaking out because to combat this deadly virus, science—not politics or cronyism—has to lead the way.” He continued, noting that this just one effort, “to fund potentially dangerous drugs promoted by those with political connections.”

It is no accident that the first major clinical trial of HCQ has been carried out in Detroit. The city and the state house some of the most impoverished and desperate sections of the working class, largely seen as disposable by the pharmaceutical companies, corporate medical services, the FDA, the White House, and the local Democratic Party. This is after all the state which includes the lead-poisoned population of Flint.

Numerous media reports in the Detroit area in late March showed that local doctors had been giving HCQ to COVID-19 patients for weeks prior to its approval by the Food and Drug Administration (FDA). A report in *MLive.com* said that Dr. Marcus Zervos, division head of infectious diseases at Henry Ford Hospital in Detroit, had been prescribing HCQ to “a majority of COVID-19 patients” as far back as March 10 and a “hospital spokesperson said that 800 patients have been treated with hydroxychloroquine this month.”

On March 24, a strongly worded letter from the Michigan Department of Licensing and Regulatory Affairs (LARA) to “Licensed Prescribers and Dispensers” that the department had received “multiple allegations of Michigan physicians inappropriately prescribing hydroxychloroquine or chloroquine to themselves, family, friends, and/or coworkers without a legitimate medical purpose.”

The letter went on to say that these drugs had not been proven scientifically or medically to treat COVID-19 and that “Reports of this conduct will be evaluated and may be further investigated for administrative action.”

Within days of the LARA letter, Democratic Michigan Governor Gretchen Whitmer openly opposed efforts to stop the unauthorized prescription of HCQ by medical professionals, saying, “We want to ensure that doctors have the ability to prescribe these medicines.” Whitmer claimed her primary concern was that doctors were hoarding the drug, which is also needed for those with prescriptions for treatment of other conditions, such as lupus.

On March 28, the FDA issued an emergency approval for the use of the drug without proof of its effectiveness. The letter from Denise M. Hinton, FDA chief scientist, said, “It is reasonable to believe that” HCQ may be effective in treating COVID-19 and that the potential benefits of the drug “outweigh the known and potential risks of such products.”

The next day, the US Department of Health and Human Services (HHS) accepted 30 million doses of the drug from Sandoz, a division of the Swiss-based pharmaceutical manufacturer Novartis. An HHS statement said, “companies may donate additional doses, and companies have ramped up production to provide additional supplies of the medication to the commercial market.”

It also became apparent during the White House press briefing of April 5 that there was a quid pro quo involved in the exchange between Mayor Duggan and the Trump administration. This was revealed by Vice President Mike Pence when he said that Mayor Duggan “was so grateful to the FDA, not only for approving the Henry Ford Hospital tests that will be exploring hydroxychloroquine, but also for the rapid approval of the 15-minute test.”

In other words, in exchange for promoting the HCQ clinical trial at Henry Ford Health System, Duggan was given access to 15-minute test kits for Detroit police, EMS workers and fire fighters. As Pence explained, Duggan “told me that he was able to use the 15-minute test this weekend to test 150 first responders, who had been sidelined because they’d been exposed to the coronavirus. They all got the 15-minute tests. They’re all back in the line of duty.”

Once the trial had been approved, it was necessary to launch a public relations campaign directed at overcoming skepticism that HCQ is a legitimate candidate for treatment of the coronavirus. Such a campaign was launched on Monday, April 6, with a widely reported statement from Democratic State Representative Karen Whitsett praising both HCQ and President Trump personally.

Speaking to the local media, Whitsett said she had been prescribed HCQ by her doctor after exhibiting symptoms of COVID-19, and once she tested positive on March 31 she took the medication and was rapidly cured. Appearing on *Fox News* with Laura Ingraham, Whitsett said, “If President Trump had not talked about this, it would not be something that’s accessible. … My husband was able to pick up the prescription that night, and I was better within a couple of hours.”

The following day, when asked about a plan to track the potential side effects of HQC during the White House briefing, Trump picked up on the Whitsett story without mentioning her by name, “Four hours later, she awoke and she said, ‘I feel better.’ And then shortly thereafter, she felt great. This a woman that thought she was going to die. It’s … I mean, she’s a Democrat representative, a highly respected woman, African American woman.”

Of course, this is not the only terrible medical recommendation provided by the American president. Last Thursday he urged people to inject themselves with disinfectant and sources of ultraviolet light, both of which are potentially fatal pieces of advice.

The rush to find a coronavirus cure, however, could in the end prove even more deadly if dangerous drug treatments, such as hydroxychloroquine, become public policy. Whatever promise a given drug may or may not show, established procedures and the basic rights of the public must not be run roughshod over by political and corporate interests. Workers must demand the best practices of medicine and science so that a highly-touted “cure” does not kill them.