

The Intentional Destruction of the National Pandemic Plan

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From Feb 3, 2020, through the post-inauguration transition period in 2021, I had the task of providing almost daily outside scientific considerations to the Executive Office of the President of the United States. This task entailed thousands of hours of unpaid work.¹

From a front-row seat, I watched in disbelief as a small number of senior federal employees defied orders and their oaths, only to join forces with a biased mainstream media and clueless State governors, to systematically ignore and destroy a validated National Pandemic Response Plan that had its origins and testing in 2000,² crafted into its final form in 2005, and updated in 2017.

As early as 2015, the existence of a new coronavirus, analogous to the 2003 SARS virus, was known. The virus, SHCO14-CoV, was capable of jumping directly from bats to humans.³

Yet the alarming level of pandemic unpreparedness did not improve. Most urgently, the U.S. had become dependent on China for the active pharmaceutical ingredients needed to manufacture critical pharmaceuticals. Also, most personal protective equipment was largely manufactured in China.

Americans' lives have been tragically disrupted and permanently altered by the COVID-19 pandemic. Government needs to be held accountable for what went wrong and for the decisions that financially ruined millions of individuals and businesses, crippled the US economy, facilitated the preventable death of more than 600,000 of our citizens, and destroyed confidence in our medical research institutions as well as in government.

Timeline of Events

Beginning of Outbreak

In 2019, "Coronavirus Disease-2019" (COVID-19) broke out in China, with the first *acknowledged* case on Nov 19, 2019. By mid-February 2020, South Korea was using social distancing, case-contact tracing, a drug called chloroquine, and a safer, more effective drug called hydroxychloroquine (HCQ), to control its COVID-19 outbreak. French studies confirmed the Korean data indicating the positive effects of early community outpatient treatment with these drugs.⁴

On Jan 21, 2020, the U.S. announced its first official case of COVID-19, in Washington State.⁵

U.S. Response

On Jan 29, the U.S. COVID-19 Task Force was formed. Its activities were coordinated by HHS Deputy Chief of Staff Brian Harrison, a former Labrador retriever breeder with no medical or public health background, until these responsibilities were transferred to Robert Kadlec, M.D. Dr. Kadlec, a career officer in the U.S. Air Force, was aware of the national pandemic plan and

the need for aggressive early outpatient treatment, treating on suspicion if necessary.

In spite of repeated warnings over 15 years, the local authorities in the New York City mega-region remained significantly unprepared, and one pandemic model, since retracted,⁶ was predicting a COVID catastrophe for the area. A way was urgently needed to rapidly decrease the region's increasing hospitalization and death rates.

Some members of the task force were considering the use of hydroxychloroquine (HCQ) for early home COVID treatment at a cost of 60 cents per tablet, with 11 tablets forming a short five-day course of therapy. By March 2020, there were 10 peer-reviewed studies and seven observational reports of effective physician-supervised early HCQ administration with no adverse cardiac effects. Patients would still become ill for a few days, but the majority would avoid hospitalization if treated early with HCQ.

Although the U.S. system for COVID testing was broken, physicians could still make a provisional diagnosis based on symptoms, history, and clinical suspicion. HCQ was FDA-approved for other conditions, and the physician-directed outpatient use of HCQ would dramatically reduce hospital overloading. Drug safety was not a concern. It was proven safe even for pregnant women and nursing mothers. Adverse cardiac effects were not a major factor in the billions of HCQ doses given for other medical conditions in the past.⁷

The Office of Trade and Manufacturing Policy (OTMP) was able to acquire 62 million doses of chloroquine and HCQ before both China and India shut off their exports of these drugs to the US.

On Mar 23, Rick Bright, Ph.D., Health and Human Services (HHS) Deputy Assistant Secretary for Preparedness and Director of the Biomedical Advanced Research and Development Authority (BARDA), received notice that HHS Secretary Alex Azar directed him to establish an Expanded Access Investigational New Drug (IND) authorization for HCQ through BARDA. This would have legitimized use of the drug stored in the Strategic National Stockpile for treatment of COVID-19 outside a hospital setting.

On Mar 24, Janet Woodcock, M.D., then-FDA Director of the Center for Drug Evaluation and Research and now FDA acting commissioner, quickly reached out to Rick Bright. In place of obtaining an IND as directed by his superiors, she advised Bright to submit an application for an Emergency Use Authorization (EUA) for hydroxychloroquine instead. This is curious because Dr. Woodcock was an internal medicine specialist with subspecialty training in rheumatology. Consequently, she would have been quite familiar with the extraordinary safety profile of HCQ when given to hundreds of thousands of lupus, scleroderma, and rheumatoid arthritis patients for more than 50 years.

In the whistleblower complaint that he filed after President Trump removed him from his position, Rick Bright states his concern was the risk of irregular heart rhythm fatalities in patients taking HCQ. Bright, however, is not a physician and lacks training in cardiology and human pathology. He seemed unaware that millions of patients had been taking HCQ for other conditions over the years, in much higher doses and for longer periods of time than the short five-day course of therapy proposed for early COVID-19 treatment. He also seemed unaware that evidence was building that in some patients, the COVID virus was attacking the heart. His job when brought into BARDA by the Obama Administration was to improve U.S. domestic vaccine production capability.

In legal documents Bright admits to insubordination to multiple layers of leadership including the White House, HHS Secretary Azar, and Robert Kadlec, M.D., Assistant HHS Secretary for Preparedness and Readiness. Instead of expanding access, the EUA proposed by Woodcock was a “compromise” position, “to rein in HHS leadership’s initial campaign to make HCQ available to the public outside of a hospital setting.”^{8, p 43}

Although not authorized to speak to the press, Bright then reached out to biased media outlets to express his inaccurate belief that chloroquine and HCQ were dangerous drugs.⁸ By the time President Trump revealed that he had taken HCQ, Bright had already primed the mainstream media to over-react to any negative reports on the drug, including reports that were grossly inaccurate or not even peer-reviewed.

On Mar 28, the FDA issued its EUA for HCQ to be used by licensed health care providers to treat hospitalized patients with confirmed COVID-19. With delayed laboratory testing, this ensured that only late-phase patients with serious established pathologies would receive the drug. The issued EUA stated that “hospitalized patients were likely to have a greater prospect of benefit (compared to ambulatory patients with mild illness).”⁹ In reality, the published data showed that the exact opposite was true.

Despite the EUA, private physicians in the New York Megaregion and elsewhere began using HCQ on their COVID outpatients as an “early” off-label treatment with great success. In contrast, hospital doctors began using HCQ to treat what were essentially late-stage patients already suffering from shortness of breath. The clinical results were as predicted, with a suboptimal effect in these late patients in whom no drug was likely to show much effect.

In mid-April, two deeply flawed, non-peer-reviewed, unpublished papers were put onto a pre-print internet server. These papers had not been accepted for publication by any medical journal. One described a Veterans Administration database and the other was a Brazilian study involving unjustifiable toxic doses of chloroquine given to late-stage patients. Both papers indicated fatal effects of HCQ and chloroquine when used in COVID-19. Although quickly refuted by physicians, the Rick Bright-primed mainstream media created a feeding frenzy over these two flawed studies, while accusing President Trump of promoting dangerous drugs.¹⁰

On May 1, FDA issued a formal caution against HCQ, stating it should only be taken in the hospital because of “serious heart rhythm problems.”¹¹ The FDA did not mention that the virus itself was affecting the heart in 15 percent of cases and irregular/fatal cardiac rhythms were occurring in COVID-19

patients who had never once taken HCQ.¹² The virus was clearly affecting the heart.

Based on FDA’s advice, many doctors became afraid to prescribe the drug. Use of HCQ by private U.S. physicians for early COVID-19 outpatients plummeted. Yet, as shown in India and parts of Europe and Brazil, use of HCQ was critical to bringing the COVID pandemic under some degree of control.

COVID positive outpatients in the U.S. were now told to quarantine at home without medication until they became short of breath and required hospitalization. Once in the hospital they might be given HCQ, which would now not work to its maximum effect because their infections were too far advanced. This lethal FDA proclamation would now assure that a surge of viral cases would overwhelm U.S. hospitals, and entire families would be infected, further promoting viral spread, as quickly happened.

On Jun 15, following two more flawed late-use studies (one later retracted by the *Lancet* for fraudulent data), and amid another fake mainstream media storm, FDA wrote an error-filled letter revoking its issued EUA for HCQ.¹³

Lacking any FDA-authorized outpatient treatment, COVID-19 patients continued to die from cardiac events without any exposure to HCQ. FDA never realized or acknowledged that the cardiac events were being caused by the virus.

A year later, the pandemic is still out of control. In contrast, numerous countries like India (population 1.2 billion), with their early-use HCQ policy, have kept their infection rates under some control and their total deaths less than half those of the U.S. with a much smaller population (333 million). The totality of published research and operational experience with HCQ to date indicates that HCQ is highly effective for early COVID-19 treatment and can significantly prevent hospitalization. Adverse cardiac effects are not and never were a major issue with the early use of this drug for the outpatient treatment of COVID-19.

By July 2020, seven controlled, well-conducted clinical studies had been done in Brazil (1353 patients); France (425 nursing-home and clinic patients); New Jersey (1,247 outpatients); Andorra (100 long-term care patients); and Saudi Arabia (7,892 patients). All these studies used the premise of the early treatment of high-risk mortality COVID outpatients, and all showed 50 percent or greater reductions in hospitalizations and deaths. Not a single fatal cardiac arrhythmia was attributable to HCQ in more than 11,000 outpatient outcomes.¹⁴

In addition, a summary analysis of five randomized controlled clinical trials, involving 5,577 patients in the United States and Spain, also found that outpatient use of HCQ for early treatment of COVID-19 significantly reduced the composite of hospitalization and death.¹⁵

Again, adverse cardiac events were not a factor.

Within four weeks, the single act of admitted insubordinate action by Rick Bright, Ph.D., promoted by Janet Woodcock, M.D., combined with the actions of a biased, ignorant mainstream media, served to trigger destruction of the core foundation of the National Pandemic Plan, which was based on early outpatient antiviral drug treatment until a safe effective vaccine could be developed.

The promised vaccine was the only outpatient method, aside from the failed lockdowns, officially favored to control the

epidemic. Of note, Dr. Woodcock has had to recuse herself from any decisions on vaccines because of her conflicts of interest. She also serves on the editorial board of the *New England Journal of Medicine*, which refused to publish the groundbreaking June 2020 study showing that early HCQ hospital use is associated with a 51 percent reduction in mortality.¹⁶ These results were quickly reproduced by a Mount Sinai Hospital study and by a later Spanish study, which showed a 66 percent reduction in COVID mortality.¹⁷

Negative media reports, including widespread coverage of the *Lancet* study that had to be retracted for fraud, destroyed efforts to recruit patients in ongoing studies.

By Apr 21, 2021, 232 studies had nonetheless been reported, involving 3,706 scientists and 358,764 patients, showing significant (64 percent) improvement in outcomes when treatment was begun early. Results and meta-analyses, with links to original papers, are compiled at hcqmeta.com. Government agencies, however, choose to reference only a handful of negative studies, all of which are flawed. If an existing safe effective drug treatment for an infectious disease is available, then an EUA for an experimental vaccine cannot be issued.¹⁸ Thus, acknowledgment of the favorable studies would block the emergency use of vaccines even before the results of studies scheduled for completion at the end of 2022 can be known.

Conclusions

All Americans need to have clear answers to the factors and decisions that transpired from February to September 2020 concerning the decision for the issue and withdraw of the EUA for hydroxychloroquine, resulting in the single-point failure of the National Pandemic Plan. This should include a demand for congressional testimony from Rick Bright, Ph.D., Janet Woodcock, M.D., and the senior editor of the *New England Journal of Medicine*. About 640,000 Americans are dead, the majority of whom might have been saved, and there must be accountability.

We must also review the political influences and conflicts of interest within the Food and Drug Administration and Centers for Disease Control and Prevention, and the need for a drastic reorganization of both entities.

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