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How a Single Point Failure Destroyed the National Pandemic Plan

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Introduction

From 3 February 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.

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 [1], crafted into its final form in 2005, and updated in 2017.

In response, the Americans whose lives have been tragically disrupted and permanently altered, need to have an accountability of what went wrong and who was involved in the decisions that financially ruined millions of individuals and businesses, crippled the US economy, facilitated the preventable death of over 500,000 of our citizens, and destroyed all confidence in our medical research institutions and government.

This incompetence and intentional interference in science and medicine must never be allowed to happen again! Congress must, for once, put aside Partisanship.
There needs to be Criminal Justice.
There needs to be ***Medical Justice***.

Timeline of Events

In 2019, “Coronavirus Disease-2019” (COVID-19). broke out in China. By mid-February of 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.[2,3]

The US announced its first official case of COVID-19 on 21 January, 2020. [4] On 29 January, the US COVID-19 Task Force was formed. In spite of repeated warnings over 15 years, the local authorities in the New York City megaregion remained significantly unprepared and one pandemic model was predicting a COVID catastrophe for the area. A way was urgently needed to rapidly decrease the region’s increasing hospitalization and death rates. [5]

In response, some members of the Task Force were considering the use of hydroxychloroquine (HCQ) for early home COVID treatment at a cost of 60¢ per tablet with 11 tablets forming a short 5-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.[6] Patients would still become ill for a few days, but the majority would avoid hospitalization if treated early with HCQ.

Although the US system for COVID testing was broken, physicians could still make a provisional diagnosis based on symptoms, history, and clinical suspicion. Hydroxychloroquine 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]

In 2010, under the Obama Administration, **Dr. Rick Bright, PhD** had been brought into the Biomedical Advanced Research and Development Authority (BARDA). With an emphasis to improve US domestic vaccine production capability, in 2016 he was assigned as a Health and Human Services (HHS) Deputy Assistant Secretary for Preparedness as well as the Director of the BARDA.

On 23 March, Rick Bright received notice that HHS Secretary Azar directed him to establish an Expanded Access Investigational New Drug (IND) authorization for HCQ through BARDA. This would make any of the drug stored in the National Stockpile, legitimized for the treatment of COVID-19 outside of a hospital setting. In emails, Bright expressed indignation over his exclusion from the actual HCQ decision process. [8]

In his Whistleblower Complaint, Rick Bright states his concern was the risk of irregular heart rhythm fatalities in patients taking HCQ. However, Bright was a PhD scientist; he was not a physician and he lacked 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 5-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.

On 24 March, **Dr. Janet Woodcock, MD**, (the FDA's Director of the Center for Drug Evaluation and Research), quickly reached out to advise 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 a physician and 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 over 50 years, often in much higher doses for much longer times than the proposed dosing for early COVID-19 cases.

The issuance of her proposed EUA would predominantly restrict the use of HCQ to hospitalized patients. [7] **Yet the early clinical data showed that HCQ was the most effective in outpatients where it prevented the need for hospitalization in the first place.**

- In a legal document, Rick Bright makes a blatant admission of insubordination to multiple layers of leadership including the White House, HHS Secretary Azar, and Dr. Robert Kadlec, MD, the Assistant HHS Secretary for Preparedness and Readiness.

- Bright states the following in his Whistleblower Complaint: …"instead of a Nationwide Expanded Access IND protocol. Implementing the EUA was a compromise position, to rein in HHS leadership's initial campaign to make the drugs available to the public outside of a hospital setting-" [8 (page 43)]

Unauthorized 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.

The End of Hydroxychloroquine

On 29 March, 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.

Giving HCQ to a hospitalized COVID patient that needed oxygen to stay alive, was not the same as giving the drug to an ambulatory outpatient with an early upper-airway COVID infection in an attempt to stop disease progression.

Bright and Woodcock had over-reached the available data by promoting the use of HCQ for the more-severe late-phase hospitalized patients with well-established COVID-19 lung involvement.

Nevertheless, 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 hydroxychloroquine to treat what were essentially the late-stage patients already suffering from shortness of breath. The clinical results were as predicted, with a suboptimal effect in these late patients where no drug was likely to show much of an effect.

Cascade of Events

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 Veteran's 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]

Quickly making an inaccurate decision, on 1 May, the 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 made no mention that the virus itself was affecting the heart in 15% of cases and irregular/fatal cardiac rhythms were occurring in COVID-19 patients that had never once taken HCQ. [12] The virus was clearly affecting the heart.

Consequently, the FDA incorrectly advised against any outpatient use of HCQ and many doctors became afraid to prescribe the drug. The use of Hydroxychloroquine by private US physicians for early COVID-19 outpatients plummeted. Yet, as shown in India and parts of Europe and Brazil, the use of HCQ was critical to bringing the COVID pandemic under some degree of control.

COVID positive outpatients in the US were now told to quarantine at home without medication until they became short of breath and required hospitalization. Once in the hospital they would 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 US hospitals and entire families would be infected further promoting viral spread, which of course quickly happened.

Following two more flawed late-use studies (one later retracted by the Lancet for completely fraudulent data), and amid another fake mainstream media storm, the FDA wrote an error-filled "junk science" letter on 15 June revoking its issued EUA for hydroxychloroquine. [13]

From this time on, the US has now lacked any FDA authorized outpatient treatment and COVID-19 patients continued to die from cardiac events without any exposure to HCQ. The 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 with record daily deaths.

In complete 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 under half that of the much smaller population of the US (320 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 it 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.

Within four weeks, the single act of admitted insubordinate action by Rick Bright PhD, promoted by Dr. Janet Woodcock MD, combined with the actions of a biased, ignorant mainstream media, served to trigger the 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.

For over a year now there has been ever growing, extensive, and overwhelming clinical evidence that HCQ, when used within the first five days of symptom onset, produces a sharp and statistically significant reduction in COVID hospitalization and mortality. Adverse cardiac events are not a factor.

By July of 2020, seven controlled, well-conducted clinical studies had been conducted in Brazil (1353 patients); France (425 nursing-home and clinic patients); New Jersey (1,247 outpatients); Andorra (100 long-term care patients); and 7,892 patients across Saudi Arabia. All of these studies used the premise of the early treatment of high-risk mortality COVID outpatients, and all showed 50% or higher reductions in hospitalization and death. Not a single fatal cardiac arrhythmia was attributable to HCQ in over 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.

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Summary

The evidence and legal testimony of Rick Bright indicates that his decisions and insubordinate actions together with the actions of Janet Woodcock MD at the FDA, incorrectly limited the use of Hydroxychloroquine to hospitalized late-phase patients. This created a single point failure for the entire National Pandemic Plan. The negligence of some members of the COVID-19 Task Force in responding to the science concerning HCQ (Dr. Fauci) and the eager participation of the biased mainstream media in this is a matter, is a matter on record. [16]

The preventable death of tens of thousands of Americans and the destruction of the US economy is the end result.

A recent analysis published on April 4, 2021 shows that HCQ is highly effective for COVID-19 when used early, based on a real-time metaanalysis of 232 clinical studies. [17]

HCQ for Covid-19

232 trials, 3,706 scientists, 358,764 patients
65% improvement in 26 early treatments trials – RR 0.35 [0.25-0.50]
72% improvement in 11 early treatment mortality results – RR 0.28 [0.18-0.43]
49% improvement in 6 early treatment RCT results – RR 0.51 [0.32-0.82]
23% improvement in 158 late treatment trials – RR 0.77 [0.71-0.83]
28% improvement in 29 randomized controlled trials – RR 0.72 [0.57-0.90]

Recent Summary of Results for oral HCQ use in COVID-19 April 4, 2021 [17]

After blaming the Trump Administration for the failure of the US pandemic response, Rick Bright, PhD has taken a senior position in pandemic preparedness at the prestigious Rockefeller Institute.

Dr. Janet Woodcock, MD is now the temporary FDA Commissioner under the Biden Administration **after recusing herself from any decisions on vaccines because of her conflicts of interest in this area.** She also serves on the editorial board of the prestigious New England Journal of Medicine which **refused to publish the ground-breaking June 2020 study showing that early HCQ hospital use is associated with a 51% reduction in mortality.** These results were quickly reproduced by a Mt Sinai study and by a later Spanish study which showed a 66% reduction in COVID mortality. [17,18,19]

Americans demand an explanation for these decisions that have affected millions, both in the US and overseas. This must be openly investigated, and an accountability established.

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