Single Point Failure III: Disinformation & Transparent Conflicts Contribute To The Deaths Of Over 500,000 Innocent Americans

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. I watched in disbelief from a front-row seat as a small number of senior federal employees destroyed the National Pandemic Plan.

In Part Two of the *Single Point Failure* paper *(pub, 27 May 2021; PCEN MEDIA INC)*, I outlined the initial role played by Dr. Anthony Fauci MD in the failure to acknowledge a role for the drug Hydroxychloroquine (HCQ) for the outpatient treatment of early COVID-19 patients. In Part Three, I pose the question of why would Dr. Fauci and senior medical authorities, as well as some of the world's most prestigious medical journals and global public health bodies, ignore the science behind HCQ in favor of a new, poorly tested, and a highly experimental drug called Remdesivir.

This highly expensive drug must be given intravenously in hospital over five days and hence, is not suitable for controlling the spread of COVID-19 through local communities. In addition, Remdesivir would later be discredited as an ineffective hospital drug treatment by the World Health Organization (WHO). The resulting continued explosive spread of COVID-19 lead to inappropriate lockdowns, massive unemployment, a massive increase in U.S. debt, and over a half-million largely preventable COVID-19 deaths in the United States.

The Death of Hydroxychloroquine

The U.S. pandemic progressed from the first *recognized* COVID-19 case on 19 January 2020 into an expanding national epidemic. By 28 March 2020, the drug HCQ became widely used for both COVID-19 outpatients and hospital inpatients.

However, it seemed that for every batch of positive research papers published on HCQ efficacy, there seemed to be a negative HCQ paper rushed into print involving a faulty late-phase hospital study showing either no effect or a harmful effect of the drug in COVID-19 patients.

Following the publication of two faulty studies involving Veterans Affairs data and patients in Brazil, news outlets such as CNN, the Washington Post, The New York Times, and MSNBC began making repeated uninformed claims that HCQ was an ineffective drug that caused dangerous and even fatal cardiac problems.

On 12 April 2021, Dr. Janet Woodcock, MD, transitioned from her role as Director of Center for Drug Evaluation and Research at the FDA to *Principal Medical Advisor* to the FDA Commissioner Dr. Steven Hahn. With training in Rheumatology, Dr. Woodcock would have been aware of HCQ's excellent safety record. However, she was against the outpatient use of HCQ for COVID even though there were no serious cardiac safety concerns with the outpatient use of this drug when used for other medical conditions.

On 24 April 2020, the FDA issued a "black box" safety warning for HCQ, stating that the drug should only be used on hospitalized patients because of cardiac safety concerns. It disapproved of any outpatient use of HCQ. [1]

However, all of the published negative papers on HCQ had major flaws and should never have made it through the peer-review process. For example, one major negative study in the prestigious journal "The Lancet" had used fabricated data and had to be withdrawn, but not before one of the editors at The Lancet had written a scathing political editorial on President Trump.

Behind the scenes, the senior editors of some of the more prestigious journals had privately complained they were forced to publish these flawed studies. [2] Forced by who? China? The FDA? The pharmaceutical companies? A combination of each?

Within days of publication of the fraudulent Lancet paper, a clueless Dr. Anthony Fauci, the de facto voice of the COVID-19 Task Force and Director of the National Institute of Allergy and Infectious Diseases (NIAID), declared on the CNN news channel that **"The scientific data is quite evident now about the lack of efficacy [of Hydroxychloroquine]."** [2]

Dr. Fauci had either not studied the paper, had a serious conflict of interest, or was the most incompetent medical scientist on the COVID-19 Task Force. Furthermore, the Lancet data was not derived from a Randomized Controlled Clinical Trial (RCT). However, based on his own repeated statements concerning Hydroxychloroquine, an RCT was the only type of clinical study that Dr. Fauci was willing to accept.

The resulting negative massive media wave against HCQ created a panic among the world governments and private physicians alike. As a result, large clinical trials testing HCQ for COVID-19 were temporarily suspended by the World Health Organization (WHO), the U.K. government regulatory agency, and the French government. In addition, the FDA in the U.S. would soon withdraw its EUA for HCQ.

In a videotaped interview (https://www.youtube.com/watch?v=ZYgiCALEdpE), a former French Health Minister provided insight into how repeated flawed negative HCQ studies managed to become published in prestigious medical journals. He revealed that the editors of both *The Lancet* and the *U.S. New England Journal of Medicine* expressed their exasperation, citing the pressures put on them by pharmaceutical companies. Each of the editors used the word *"criminal"* to describe this erosion of science. [3]

On 4 June 2020, the fraudulent Lancet paper was quietly retracted. However, the damage was done. **On 15 June 2020**, the FDA wrote an error-filled letter that revoked its issued Emergency Use Authorization (EUA) for HCQ. [4] Basing its decision on the minority of negative HCQ studies done on late-phase hospitalized COVID patients, a small FDA panel (mainly pharmacists) determined that that HCQ was unlikely to be effective in treating COVID-19 and that it could cause fatal heart problems. **The FDA never mentioned that the COVID virus was attacking the heart and that fatal heart problems were occurring in COVID patients that had never taken HCQ.** [5]

The FDA withdrawal letter and its supporting annex were "junk science" with gross errors, the failure to discuss positive HCQ results, the referencing of non-peer-reviewed research papers, over-reaching and unsupported statements, poor statistics, and incorrect interpretations of data. Thus, the FDA letter was a travesty of science. Moreover, it was an intentional biased effort by the FDA to block HCQ.

In contrast, by the end of July 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. These studies involved the early treatment of high-risk COVID outpatients, and all showed 50% or higher reductions in hospitalization and death. **Not a single fatal heart problem was attributable to HCQ in over 11,000 outpatient outcomes.** [6] | [7]

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. [8]
Again, adverse cardiac events were not a factor.

From 15 June 2020 until today, the U.S. has lacked any FDA authorized outpatient treatment for COVID-19, and HCQ is no longer used in a hospitalized patients who c***ontinued to die from cardiac events without any exposure to HCQ.*** In addition, the FDA never acknowledged that the COVID virus itself was causing abnormal cardiac events.

In a later *Zoom* meeting that I attended, Dr. Fauci represented the *supposedly independent* COVID-19 Treatment Panel he had helped create. He attempted to defend the FDA's actions for its refusal to reinstate the Emergency Use Authorization for Hydroxychloroquine. The request had been based on the successful *early-use* hospital HCQ trial by the Ford Group in Detroit, the Mt Sinai Hospital, and a large Spanish study showing a 66% decreased mortality in early use hospitalized patients. [9] | [10]

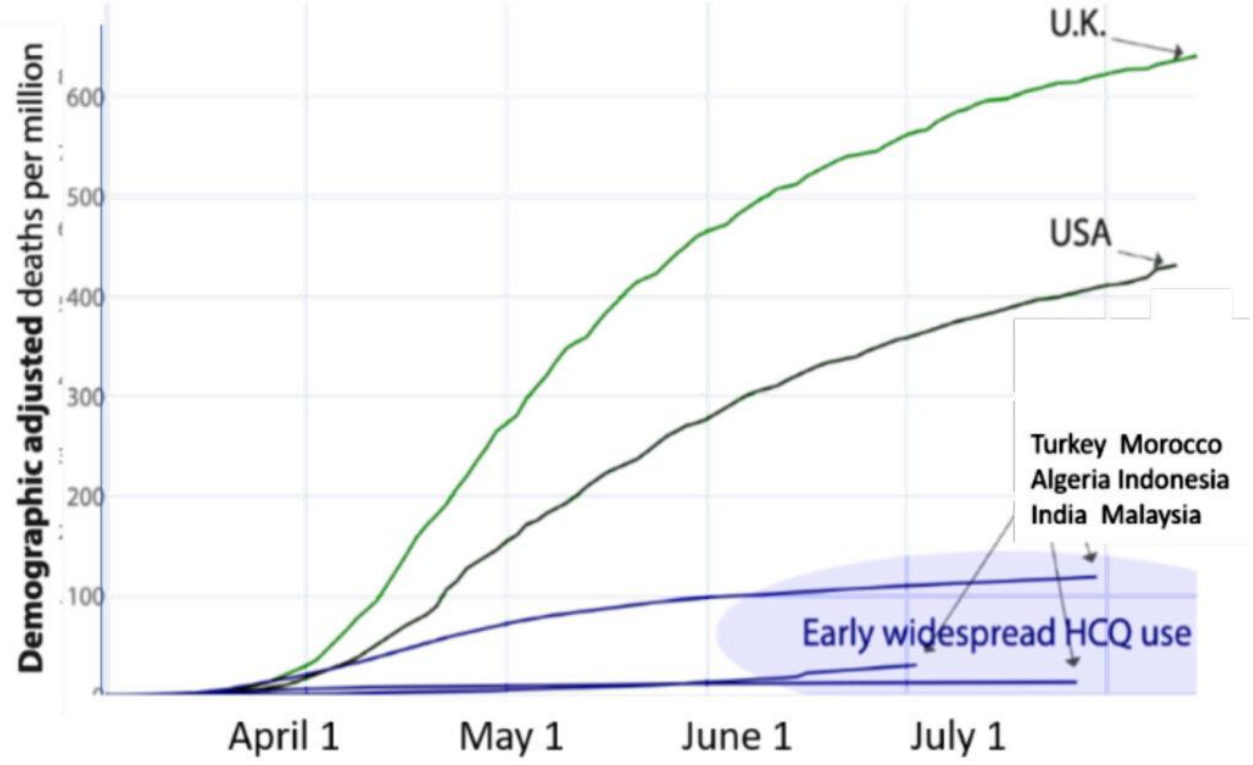
In response, Dr. Fauci presented *"proof"* that early use HCQ did not work, based on five flawed, negatively critiqued, small-size, so-called *"early-use"* research papers. However, when analyzed properly, two of these flawed papers show a positive effect for HCQ administration; two papers were worthless small-sample-size, late-use studies, and a *fifth paper had not even been peer-reviewed which meant it represented nothing*.

There is something seriously wrong when a panel of supposedly distinguished scientists is so desperate that they play word semantics and attempt to use non-peer-reviewed papers to support their inaccurate conclusions when the global

data paints a much different picture from what they are stating. It is made worse when a later meta-analysis of these five papers indicates a positive effect for HCQ administration.

The United States and the United Kingdom failed to promote early community outpatient treatment with HCQ. In contrast, numerous countries like India *(population 1.2 billion-plus)*, with their early use HCQ policy, kept their daily COVID deaths under a large degree of control during the first two waves of the COVID-19 pandemic, and their total deaths under half that of the U.S. *(total population only 320 million)*.

HCQ is used in Costa Rica, the UAE, South Korea, Chile, Turkey, Algeria, Morocco, Greece, India, parts of Brazil, and China. [11]



April 1 to 1 July 2020 Countries that have used outpatient HCQ aggressively as part of their pandemic strategy have kept their death rates under some degree of control. (c19study.com)

Countries that have stopped their use of HCQ or allowed large mass gatherings to resume (like India recently) have seen a resurgence in their local COVID

infection rates. A year later, the pandemic is still out of control in some areas, with over 600,000 total deaths in the U.S. alone.

Dr. Fauci constantly admonishes Americans that they must *"follow the science"*. In this respect, the "*Emperor has no clothes"*. However, the totality of published research and operational experience with HCQ to date indicates that HCQ is highly effective for early outpatient COVID-19 treatment and that it can significantly prevent hospitalization.

Adverse cardiac effects are not and never were a major issue with the early use of HCQ for the outpatient treatment of COVID-19.

The question is not *"Does early Hydroxychloroquine work in COVID-19?"*. The question is, *"Have the actions of Dr. Anthony Fauci and the FDA Department formerly run by Dr. Janet Woodcock, concerning Hydroxychloroquine been incompetent….or have they been willful?"*. [12]

- Note: On 8 September, the FDA Commissioner Stephen Hahn openly admitted during a radio interview that some studies do indeed "suggest a benefit" for using Hydroxychloroquine for COVID-19 infections. [13]

- Note: Dr. Janet Woodcock, MD, is now the temporary FDA Commissioner under the Biden Administration ***after recusing herself from any decisions on COVID vaccines because of her stated conflicts of interest*** in this area.

Transparent Conflicts?

Americans deserve a reasonable answer as to why the FDA issued the drug *Remdesivir* a EUA based essentially only on manufacturer-supplied "new" evidence during the 2020 portion of the COVID crisis. However, it failed to reauthorize the EUA for Hydroxychloroquine, despite overwhelming evidence of its effect in early use COVID cases. (WHO would later determine Remdesivir to be an ineffective drug). [14]

The timeline for all this is interesting.

On 28 March 2020, the FDA issued an EUA for HCQ. Throughout April, numerous studies showing the efficacy of HCQ were published.

On 1 May 2020, the FDA issued an EUA for *Remdesivir* for use in severely ill coronavirus patients. At the same time, it issued a caution against HCQ stating it should only be taken in the hospital or as part of a formal study due to reports of *"serious heart rhythm problems."* However, it made no mention that COVID viral infections were damaging the heart, and heart damage can cause cardiac rhythm problems.

On 16 May 2020, the Ford Group in Detroit submitted its early-hospital-use HCQ paper showing a major effect with a 51% reduced COVID-19 mortality when given to early hospitalized patients. **Unfortunately, the New England Journal of Medicine had rejected this pioneering study. *Without accusation, it is noted that Dr. Janet Woodcock at the FDA was on the editorial board of this journal at the time.***

On 23 May 2020, the Ford HCQ paper was then submitted to the International Journal of Infectious disease. The Journal accepted the study for publication but stated they *"wanted to wait a few weeks until they published it"*. No reason for this was given, but they alluded to the controversy it would generate.

On 15 June 2020, the FDA revoked Hydroxychloroquine's EUA claiming the drug did not affect and was harmful **in all** COVID-19 infected patients. [15]

A few hours later, on the same day, the FDA released a warning that laboratory studies indicated that HCQ chemically inactivated Remdesivir and that the two drugs should never be administered together. [16]

On 29 June 2020, Dr. Fauci recommended a 1.6 billion dollar purchase of *Remdesivir* from Gilead Sciences even though the clinical trials of the drug had not been completed ***and the first Chinese study showed the drug to have toxic side effects with little effect on mortality.***

The decision to devote so much time, effort, and money to Remdesivir was one of Dr. Fauci's most tragic mistakes, and he has made many. The drug was going to take over six months to manufacture in sufficient quantities. In the meantime, the inappropriate FDA ban on HCQ would mean that thousands of Americans would die a preventable death.

A recent study published in the *Journal of Virus Eradication* attempted to analyze the cost of manufacturing Remdesivir. The authors looked at the chemical synthesis of the drug and concluded that a 10-day course for one person would cost $9, allowing for a 20 percent loss during formulation, plus the cost of the vials, a profit margin, and tax. [18]

On 29 June 2020, the California-based drugmaker Gilead Sciences announced its pricing plans for Remdesivir, stating the treatment would cost $520 per dose for U.S. private insurance companies and $390 per dose for the U.S. government. A five-day treatment using the drug would entail six vials. The total charged to hospitals for patients with private insurance in the U.S. will be $3,120. For those under U.S. government health programs, the total will be $2,340 per patient. [19]

In contrast, the cost for HCQ is 60 cents a tablet, and a treatment dose requires 11 tablets.

On 2 July 2020, the Henry Ford HCQ paper showed that patient treatment immediately on hospital admission with Hydroxychloroquine cut the death rate by 51% in hospitalized COVID patients without any heart-related side-effects. This was soon followed by papers from Mt. Sinai and Spain confirming these results in their studies, which involved several thousand patients and showed strong evidence of benefit in COVID-19, with no harmful cardiac or other serious side effects. **The journal had sat on this critical pioneering paper for a month during a global pandemic.**

On 6 July 2020, The Ford System's request for a **new** EUA for an early-use ambulatory outpatient clinical study using HCQ arrived at the FDA. It would be denied on 10 August 2020.

On 10 July 2020, following the disastrous Chinese clinical trial of *Remdesivir*, the results for the **new Remdesivir trial** were announced. Dr. Fauci rushed to the television cameras to declare the drug was the new standard of care for COVID patients. However, unfortunately, there was no reduction in inpatient mortality, only a reduction in the length of hospital stays for survivors.

The ban on HCQ use in hospitals by the FDA and a ban on drug use by the state Governors in Michigan and other states, combined with the media-generated fear of the drug, made private physicians afraid to prescribe HCQ in COVID

outpatients. As a result, with only an intermittent supply of Remdesivir during the summer of 2020, many hospitalized patients would now receive **no antiviral drug at all, *and they would die*.**

It was heart rendering. In March, I contacted hospital nurses to monitor hospitals' situation in intensive care units in cities with large, low-resource, low-income disadvantaged communities. This included Detroit-Michigan and Gary-Indiana, which my previous research had indicated would suffer the worst. In the White House, ICU nurses were now phoning me in tears, asking in desperation how they could get more Remdesivir. Unfortunately, it would take time for the supplies of Remdesivir to be adequate.

At the same time, roughly 60 million doses of Hydroxychloroquine sat idle in the Strategic National Stockpile. Because of Dr. Fauci and the incompetent FDA, patients continued to die.

Tragically, throughout July and early August, numerous studies in multiple countries were published showing the efficacy of HCQ for COVID-19.

On 20 November 2020, the WHO advises against the use of *Remdesivir* as there is no evidence that the drug improves survival or any other outcome in COVID patients.

It is obvious that something more than incompetence is to blame. Logically, it appears to have been a well-planned and well-executed action to discredit HCQ by the NIAID and the FDA.

A reasonable explanation in support of this theory is that these governmental agencies, the Covid-19 Panel, and Dr. Fauci himself ignored the National Pandemic Plan, were compromised by conflicts of interest and sought to promote the costly and ineffective inpatient drug *Remdesivir*, instead of the effective and inexpensive outpatient HCQ.

Why? It is important to understand that if an FDA-approved drug therapy exists (HCQ) for the treatment of a given viral infection, a new experimental COVID vaccine could not be given an Emergency Use Authorization. [20]

Simply concluded: the discreditation of HCQ was necessary to pave the way for the widespread administration of the experimental mRNA vaccines.

This unconscionable action resulted in the ***PREVENTABLE*** deaths of over half a million Americans and the destruction of the U.S. economy.

The American people deserve an honest explanation.

References

1. FDA cautions against the use of Hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems | FDA
   Updated: Lancet Published a Fraudulent Study: Editor Calls it "Department of Error" – Alliance for Human Research Protection (ahrp.org)

2. https://ahrp.org/the-lancet-published-a-fraudulent-study-editor-calls-it-department-of-error/

3. Lancet Editor Spills the Beans, and Britain's PM Surrenders to the Gates Vaccine Cartel – Alliance for Human Research Protection (ahrp.org)

4. https://www.fda.gov/media/138945/download

5. Can Coronavirus Cause Heart Damage? | Johns Hopkins Medicine

6. Risch H. FDA obstruction: Patients die, while Trump gets the blame. Washingtonexaminer.com. Pub 19 October 2020. Accessed 30 October 2020. https://www.washingtonexaminer.com/opinion/fda-obstruction-patients-die-while-trump-gets-the-blame

7. H. A. Risch. Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately as Key to the Pandemic Crisis Am J Epidemiol. 2020 2 November;189(11):1218-1226.doi: 10.1093/aje/kwaa093.
   https://pubmed.ncbi.nlm.nih.gov/32458969/

8. Ladapo JA, McKinnon JE, McCullough PA, Risch H. Randomized Controlled Trials of early ambulatory Hydroxychloroquine in the prevention of COVID-

19 infection, hospitalization, and death: Meta-analysis. Published 2020. doi:10.1101/2020.09.30.20204693

9. Henry Ford Study https://pubmed.ncbi.nlm.nih.gov/32623082/

10. M. de Novales, F.J.; Ramírez-Olivencia, G.; Estébanez, M.; de Dios et al., Early Hydroxychloroquine Is Associated with an Increase Survival COVID-19 Patients: An Observational Study. (doi:10.20944/preprints202005.0057.v1). https://www.preprints.org/manuscript/202005.0057/v2

11. Covid Analysis, 4 April 2021) https://hcqmeta.com/

12. https://forums.livescience.com/threads/gilead-remdesivir-veklury-and-cdc-nih-covid-19-conflicts-of-interests-how-important-is-this.3360/

13. https://www1.cbn.com/cbnnews/health/2020/july/covid-doc-says-hydroxychloroquine-highly-effective-and-fears-are-overblown-now-fda-chief-admits-it-might-help-nbsp

14. WHO defends conclusion that remdesivir is ineffective against COVID-19 | News | D.W. | 16.10.2020

15. https://www.fda.gov/media/138945/download

16. FDA Warns Against Co-Administering Remdesivir with Hydroxychloroquine or Chloroquine |BioSpace

17. Gilead Sciences Update on Veklury® (Remdesivir) Manufacturing Network

18. AndrewHill J.Wang, J.Levi Journal of Virus Eradication Volume 6, Issue 2, April 2020, Pages 61-69 https://www.sciencedirect.com/science/article/pii/S2055664020300182

19. Coronavirus drug remdesivir to cost $3,120 per patient with private insurance, irking critics – ABC News (go.com)

20. https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained