

# White Paper on Hydroxychloroquine

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## Synopsis:

This white paper is to draw the reader's attention to the indisputable safety of hydroxychloroquine (HCQ), an analog of the same quinine found in tree barks that George Washington used to protect his troops. The modern version has been FDA approved for 65 years, has shown remarkable efficacy against SARS-CoV-2 and its use is being wrongly restricted despite the immediate danger to the American people and the rest of the world.

We speak in support of immediately reversing the massive, irresponsible disinformation campaign that is literally preventing doctors from dispensing HCQ, advocating as well that it be made available over the counter in the United States. This is logistically easy to do in a manner that ensures the supply and appropriate dispensation.

## Introduction:

The purpose of this white paper is to dispassionately present the evidence regarding the safety and efficacy of hydroxychloroquine and determine its proper role in the current pandemic.

## General Consensus that Hydroxychloroquine is Safe

Hydroxychloroquine (HCQ) has been FDA approved for over 65 years and has been used billions of times throughout the entire world without restriction. For many decades it has been given to: pregnant women, breastfeeding women, children, elderly patients, immune compromised patients and healthy persons.

In the USA it is used most often in three situations: systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and as malaria prophylaxis for travelers. These three situations happen to represent three different types of populations.

Patients with SLE are immune compromised.

Patients with RA are elderly.

Travelers are younger and typically healthy.

Although all doctors can and do prescribe HCQ, because it is most commonly used for SLE and RA, **rheumatology** specialists are the physicians in America who prescribe it the most. Although it is in the safest category of medication and it is virtually always safely used, the two most common possible complications fall under the specialty of **cardiology** and **ophthalmology**.

So let us see what these three types of specialties say.

## What do the Rheumatologists Say?

The physicians who prescribe HCQ the most are **rheumatologists**. Patients who need HCQ typically are on the medication for years or decades. Therefore rheumatologists have extensive experience with this medication. They make decisions daily regarding this medication. They decide who can get the medication, is safe or unsafe, how much to give, how often to dose, when to increase/decrease the dose, what testing if any should be done prior to starting the medication, can the medicine be taken with other medicines, when to stop the medication, what the side effects are. To help them with such decisions, rheumatologists can check with their professional society: American College of Rheumatology (ACR.)

The ACR website:

Hydroxychloroquine typically is very well tolerated. Serious side effects are rare. The most common side effects are nausea and diarrhea, which often improve with time. Less common side effects include rash, changes in skin pigment (such as darkening or dark spots), hair changes, and muscle weakness. Rarely, hydroxychloroquine can lead to anemia in some individuals. This can happen in individuals with a condition known as G6PD deficiency or porphyria.

In rare cases, hydroxychloroquine can cause visual changes or loss of vision. Such vision problems are more likely to occur in individuals taking high doses for many years, in individuals 60 years or older, those with significant kidney or liver disease, and those with underlying retinal disease. At the recommended dose, development of visual problems due to the medication is rare. It is recommended that you have an eye exam within the first year of use, then repeat every 1 to 5 years based on current guidelines.

Additional rare reports of changes in the heart rhythm have been reported with the use of hydroxychloroquine, particularly in combination with other medications. While monitoring for this risk is not typical in the office setting, it has been indicated in hospitalized and critically ill patients to evaluate for interactions with other medications.<sup>1</sup>

In other words the professional society of the physicians who prescribe this drug the most, for years have said the following:

1. serious side effects are rare
2. visual changes can happen in people taking high doses for years
3. heart rhythm changes are so uncommon that there is no monitoring pre-use

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<sup>1</sup> <https://www.rheumatology.org/Portals/0/Files/Hydroxychloroquine-Plaquenil-Fact-Sheet.pdf?ver=2020-04-30-154904-073>

In an interview with Dr. Mehmet Oz, prominent Los Angeles rheumatologist, Professor of Medicine, Associate Director of the Rheumatology Dept. Cedars Sinai Medical Center Dr. Daniel Wallace said the following:<sup>2</sup>

Dr. Oz: Is HCQ safe?

A: In 42 years of clinical practice I've treated several thousand lupus patients and I would like to emphasize that all rheumatologists have a great deal of experience with this drug. Regarding safety, since it came out 70 years ago, several million patients have taken the drug. There have not been any reported deaths from using this agent as monotherapy or taken only by itself.

Dr. Oz: Q: arrhythmia, heart issues?

A: It is a problem with CQ, which is its first cousin. And it *was* a problem with HCQ in the 1950's and 1960's when doctors were using 2-3x its usual dose. In the current recommended dose it really does not occur. 400 mg/day.

### What do the Cardiologists Say?

Next let us consider the alleged complication that has dominated the news, which is a potential heart problem. Those specialists are cardiologists. Heart rhythm problems are so rare with HCQ that it is common practice not to do an EKG prior to starting the medication. It's the opposite of the truth to claim that there is a heart risk when the specialty professional organization denies that, and when it is not what has been done for decades prior to this pandemic. In addition, the American Heart Association has demonstrated it is safe during Covid-19, which will be discussed below.<sup>3</sup>

Prominent Los Angeles cardiologist Dr. Daniel Wohlgernter states:

Over the last 30 years I have had several hundred patient visits specifically to discuss the toxicity of hydroxychloroquine. During that time, not a single patient has been taken off of this drug for cardiac toxicity.<sup>4</sup>

The largest meta analysis published in 2018, revealed only 50 cardiac deaths attributed to hydroxychloroquine in 60 plus years.<sup>5</sup>

The largest database analysis that examined this issue stated the following:

The results on the risk of severe adverse events associated with short-term (1 month) HCQ treatment as proposed for COVID-19 therapy are reassuring, with

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<sup>2</sup> [https://www.youtube.com/watch?v=htyCEeq\\_YVI](https://www.youtube.com/watch?v=htyCEeq_YVI)

<sup>3</sup> <https://www.ahajournals.org/doi/10.1161/CIRCEP.120.008662>

<sup>4</sup> <http://www.santamonicacardiology.com/wohlgernter.php>

<sup>5</sup> [https://pubmed.ncbi.nlm.nih.gov/29858838/?from\\_term=Hydroxychloroquine+and+cardiac&from\\_pos=1](https://pubmed.ncbi.nlm.nih.gov/29858838/?from_term=Hydroxychloroquine+and+cardiac&from_pos=1)

no excess risk of any of the considered safety outcomes compared to an equivalent therapy.<sup>6</sup>

### What do the Ophthalmologists Say?

In an interview with Laura Ingraham, Dr. Richard Urso, ophthalmologist said this:

I have had several thousand patient visits to specifically discuss the toxicity of this drug over my last 30 years. It's a super safe drug. It's safer than Tylenol, aspirin, Motrin.<sup>7</sup>

There is no visual risk for short courses of HCQ. No one ever even suggests such a thing. The people who use HCQ for a short period of time are travelers. Even the CDC website does not suggest an eye exam. Rheumatologists and ophthalmologists who are familiar with the rare visual problems all say the same thing. There is a rare risk of retinopathy that is possible when a patient has been on the medication for many years. The risk of retinal toxicity at five years of continuous use is zero. The risk of retinal toxicity at ten years of continuous use is 1%. It gets higher after ten years of continuous use.”<sup>8</sup>

Toxicity can be seen in the macula and electrical conduction of the heart, after years of use. Typically patients who have ingested 1/2 to 1 kilo in their lifetime become more susceptible to these issues. Over a short-term course it is never seen.<sup>9</sup>

To put the amount that is needed to even possibly be at risk for retinopathy in perspective, that is many years of using daily.

### Safety Studies

It is self-evident that HCQ is safe from the fact that it has been FDA approved for 65 years and has been used many billions of times all over the world and it is over the counter in most of the world, certainly pre-2020. It is the #1 most used medication in India, the second most populous nation on the planet with 1.3 billion people. If an American travels to a location where malaria is endemic, per the CDC, they would start HCQ before they left for their trip. There has never been an allegation that HCQ is not safe until 2020.

The only allegations of HCQ not being safe relate to a potential heart problem. The media has stated this so often that many people, including physicians, think there is a potential heart problem. However the evidence is overwhelming that HCQ is very low risk.

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<sup>6</sup> <https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v2>

<sup>7</sup> Dr. Richard Urso, ophthalmologist on Laura Ingraham July 10, 2020.

<sup>8</sup> Dr. Daniel Wallace, rheumatologist on Dr. Oz April 8, 2020

[https://www.youtube.com/watch?v=htyCEeq\\_YVI](https://www.youtube.com/watch?v=htyCEeq_YVI)

<sup>9</sup> Dr. Richard Urso, ophthalmologist on Laura Ingraham July 10, 2020

I. In the largest study to date on the subject, HCQ has been shown to not increase heart (cardiac) risk.<sup>10</sup> This study was across a multinational, distributed database network. It studied all the data for 20 years, from January 9, 2000 – 2020 on patients who were prescribed HCQ. The study had two goals: to understand the safety of HCQ by itself and its safety when paired with the antibiotic azithromycin. This paper was authored by scientists from 33 countries and companies across the world.

The paper is titled “Safety of hydroxychloroquine, alone and in combination with azithromycin, in light of rapid widespread use for COVID-19: a multinational, network cohort and self-controlled case series study.” In plain English, the authors found that over a twenty-year period, looking at almost one million patients, those taking HCQ did not have an increased risk of heart problems. It says:

This is the largest ever analysis of the safety of such treatments worldwide, examining over 900,000 HCQ and more than 300,000 HCQ + azithromycin users respectively. The results on the risk of serious adverse events associated with short-term (1 month) HCQ treatment as proposed for COVID-19 therapy are reassuring, with no excess risk of any of the considered safety outcomes compared to an equivalent therapy.

II. The FDA database shows a total of 640 deaths attributable to HCQ over fifty years. To put this in context “Each year the FDA receives over one million adverse event reports associated with the use of drug products” “This concerns the entirety of HCQ use over more than 50 years of data, likely millions of uses and of longer-term use than the five days recommended for Covid-19 treatment.”<sup>11</sup> The 640 deaths represented 0.034% of all the deaths (1,910,212) attributable to medications.

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<sup>10</sup> <https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v2>. The authors include scientists from: University of Oxford, Fundacio Institut Universitari per a la recerca a l'Atencio Primaria de Salut Jordi Gol I Gurina, University of Sao Paulo, Massachusetts General Hospital, King Saud University, Harvard School of Public Health, Department of Veterans Affairs, University of Utah School of Medicine, University of Zagreb School of Medicine, Columbia University Medical Center, Islamic University of Gaza, New York Presbyterian Hospital, National Institute for Health and Care UK, University of New Mexico Health Sciences Center, Erasmus Medical Center, Vanderbilt University, University of Arizona College of Medicine, University of Dundee Scotland, Institute of Medicine Sweden, Ajou University South Korea, National University of Singapore, UCLA, Shanghai University of Traditional Chinese Medicine, Peking Union Medical College, University of Melbourne, Janssen Research, Real World Solution, Actelion Pharmaceuticals, Real-World Evidence Spain, AstraZeneca, RTI Health Solutions, Bayer Pharmaceuticals

<sup>11</sup> US Food & Drug Administration. FDA Adverse Events Reporting System (FAERS) Public Dashboard. <https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis>

III. The CDC has an information sheet about HCQ. That sheet includes the following questions/answers.<sup>12</sup>

Q: Who can take hydroxychloroquine?

A: Hydroxychloroquine can be prescribed to adults and children of all ages. It can also be safely taken by pregnant women and nursing mothers.

Q: Who should not take hydroxychloroquine?

A: People with psoriasis should not take hydroxychloroquine.

Q: How should I take hydroxychloroquine?

A: Both adults and children should take one dose of hydroxychloroquine per week starting at least one week before traveling... They should take one dose per week while there, and for four consecutive weeks after leaving. **The weekly dosage for adults in 400 mg.**

Q: What are the potential side effects of hydroxychloroquine?

A: Hydroxychloroquine is a relatively well tolerated medicine. The most common adverse reactions reported are stomach pain, nausea, vomiting, and headache. These side effects can often be lessened by taking hydroxychloroquine with food. Hydroxychloroquine may also cause itching in some people.

Q: How long is it safe to use hydroxychloroquine?

A: CDC has no limits on the use of hydroxychloroquine for the prevention of malaria. When hydroxychloroquine is used at higher doses for many years, a rare eye condition called retinopathy has occurred. People who take hydroxychloroquine for more than five years should get regular eye exams.

IV. It is well established that there is no scientific basis for the claim that HCQ is risky on its own. The only credible theory as to why there has even been a concern, is that since the beginning, possible treatment options of COVID-19 have always included HCQ in *combination* with the antibiotic azithromycin. Because each medication independently can cause the same rare heart rhythm disturbance, there has been an academic concern whether the two drugs could be risky when taken together. The particular heart rhythm problem is called “QT prolongation” and it is a known side effect of hundreds of drugs. If the “QT prolongation” is severe it can lead to a fatal rhythm problem called Torsades de Pointes. Even though it is rare, this has been alleged to be of serious and frequent enough concern that people should not use HCQ for Covid-19. The American Heart Association has now answered this specific question. (April 29, 2020)

In the largest reported cohort of coronavirus disease 2019 to date treated with chloroquine/hydroxychloroquine +/- azithromycin, **no** instances of Torsades de Pointes or arrhythmogenic death were reported.<sup>13</sup>

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<sup>12</sup> <https://www.cdc.gov/parasites/malaria/index.html>

<sup>13</sup> <https://www.ahajournals.org/doi/10.1161/CIRCEP.120.008662>

In plain English: Taking HCQ even in combination with the antibiotic azithromycin does not cause an increased risk of fatal heart rhythm problems.

The most comprehensive study on the subject was authored by Dr. Harvey Risch, MD, PhD, Professor of Epidemiology at Yale School of Public Health, and published in affiliation with the Johns Hopkins Bloomberg School of Public Health.<sup>14</sup> Dr. Risch who has 39,779 citations on Google Scholar, reviewed five outpatient studies, and shows with specificity how the results have been misinterpreted, misstated and misreported. He notes the following.

1. When examining the data on safety, Dr. Risch notes that early evidence of safety was being ignored. “Lack of any cardiac arrhythmia events in the 405 Zelenko patients or the 1061 Marseilles patients or the 412 Brazil patients.”

2. When examining the data on safety, Dr. Risch demonstrates that the negative conclusions drawn by various professional organizations are not based upon science. “It is unclear why the FDA, NIH, and cardiology societies made their [negative] recommendations about HCQ+AZM use now, when the Oxford study analyzed 323,122 users of HCQ+AZ ... that the combination of HCQ+AZ has been in widespread standard-of-care use in the US and elsewhere for decades ... this use predominantly in older adults with multiple comorbidities, with no such strident warnings about the use given during that time.”<sup>15</sup>

## **Efficacy**

There are only two things that must be considered regarding a medication: is it safe and does it work? HCQ is amongst the safest of all prescription drugs in USA and that is why across much of the world it is sold over the counter. And at a time when the world has become seized with panic over a virus without a specific cure, the question of effectiveness is almost moot. If a drug is safe and might work, and if there are no other options, we must try it.

The safety record of HCQ is indisputable. But now seven months into the pandemic there is overwhelming evidence accumulating that HCQ is also *effective* for Covid-19. There are dozens of studies demonstrating its effectiveness from all around the world. From China to France to Saudi Arabia to Iran to Italy to India to New York City to Michigan to Brazil. This is not surprising. As far back as, chloroquine (CQ) the first cousin of HCQ and previously known to be effective against SARS-CoV-1, was stated by China to be a treatment for Covid-19.

- February 19, 2020 China: “The drug [chloroquine] is recommended to be included in the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National

<sup>14</sup> <https://www.aspph.org/yale-dr-harvey-risch-wins-50000-ruth-leff-siegel-award/>

<sup>15</sup> <https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v2>



Health Commission of the People's Republic of China for the treatment of COVID-10 infection in larger populations in the future.”<sup>16</sup>

- March 4, 2020: France: “The first results obtained from more than 100 patients show the superiority of chloroquine compared with treatment of the control group in terms of reduction of exacerbation of pneumonia, duration of symptoms and delay of viral clearance all in the absence of severe side effects.”<sup>17</sup>

- March 20, 2020: New York: 1450 patients. 1045 mild and not requiring meds (all recovered), 405 treated with HCQ + AZM + Zinc of which six were hospitalized and two died.<sup>18</sup>

- March 22, 2020: India: The country of India recommends HCQ prophylaxis broadly.<sup>19</sup>

- March 22, 2020: China: “Among patients with Covid-19, HCQ could significantly shorten time to complete recovery and promote the absorption of pneumonia.”<sup>20</sup>

- April 11, 2020: France: All patients [treated with HCQ + AZM] improved clinically except [two]... A rapid fall of nasopharyngeal viral load was noted. ... Patients were able to be rapidly discharged from IDU [Infectious Disease Unit]... ”<sup>21</sup>

- April 13, 2020: NY: 54 long-term care/nursing home patients received HCQ+ Doxycycline and only 5.6% died. (this population can have >50% mortality)<sup>22 23</sup>

- April 17, 2020: Brazil: Of 636 symptomatic high-risk outpatients, only 1.9% of those treated needed hospitalization vs., 5.4% of the untreated.<sup>24</sup>

- April 21, 2020: 16 countries: “The difference in dynamics of daily deaths is so striking that we believe that the urgency context commands presenting the analysis ... ”<sup>25 26</sup>

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<sup>16</sup> [https://www.jstage.jst.go.jp/article/bst/14/1/14\\_2020.01047/\\_article](https://www.jstage.jst.go.jp/article/bst/14/1/14_2020.01047/_article)

<sup>17</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135139/>

<sup>18</sup> <https://academic.oup.com/aje/article/doi/10.1093/aje/kwaa093/5847586>

<sup>19</sup> <https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinaphylaxisforSARSCoV2infection.pdf>

<sup>20</sup> <https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v3>

<sup>21</sup> <https://www.sciencedirect.com/science/article/pii/S1477893920301319>

<sup>22</sup> ABC News. <https://abc7ny.com/coronavirus-treatment-long-island-news-nassau-county/6093072/>

<sup>23</sup> <https://pubmed.ncbi.nlm.nih.gov/32418114/>

<sup>24</sup> <https://pgibertie.files.wordpress.com/2020/04/2020.04.15-journal-manuscript-final.pdf>

<sup>25</sup> [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3575899](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3575899)

<sup>26</sup> <https://www.medrxiv.org/content/10.1101/2020.04.18.20063875v2>

- April 24, 2020: Iran: Hydroxychloroquine ...can be potential treatment options.<sup>27</sup>
- April 30, 2020: Saudi Arabia: “Chloroquine and hydroxychloroquine have antiviral characteristics in vitro. The findings support the hypotheses that these drugs have efficacy in the treatment of COvid-19.”<sup>28</sup>
- May 15, 2020: China: We found that fatalities are 18.8% in the HCQ group, significantly lower than 47.4% in the non-HCQ group. These data demonstrate that addition of HCQ on top of the basic treatments is highly effective in reducing the fatality of critically ill patients of Covid-19 through attenuation of inflammatory cytokine storm. Therefore, HCQ should be prescribed as a part of treatment for critically ill Covid-19 patients, with possible outcome of saving lives.<sup>29</sup>
- May 16, 2020: France: 1061 Covid-positive patients treated with HCQ+AZM “no cardiac toxicity was observed” and “good clinical outcome and virological cure were seen in 92%.”<sup>30</sup>
- June 6, 2020: France: “In conclusion, a meta-analysis of publicly available clinical reports demonstrates that chloroquine ... reduces mortality by a factor 3 in patients infected with Covid-19.”<sup>31</sup>
- June 20, 2020: India: “Consumption of four or more maintenance doses of HCQ was associated with a significant decline in the odds of getting infected... This study provides actionable information for policymakers to protect healthcare workers at the forefront of Covid-19 response.”<sup>32 33</sup>
- June 29, 2020: Portugal: The odds ration of [Covid-19] infection in patient with chronic treatment with HCQ is half.<sup>34</sup>
- June 29, 2020: Detroit: “In this multi-hospital assessment, when controlling for Covid-19 risk factors, treatment with HCQ alone and in combination with AZM was associated with reduction in Covid-19 mortality.”<sup>35</sup>

<sup>27</sup> [https://www.researchgate.net/publication/341197843\\_COVID-19\\_in\\_Iran\\_a\\_comprehensive\\_investigation\\_from\\_exposure\\_to\\_treatment\\_outcomes](https://www.researchgate.net/publication/341197843_COVID-19_in_Iran_a_comprehensive_investigation_from_exposure_to_treatment_outcomes)

<sup>28</sup> <https://www.europeanreview.org/wp/wp-content/uploads/4539-4547.pdf>

<sup>29</sup> <https://pubmed.ncbi.nlm.nih.gov/32418114/>

<sup>30</sup> <https://www.mediterranee-infection.com/wp-content/uploads/2020/04/MS.pdf>

<sup>31</sup> <https://www.sciencedirect.com/science/article/pii/S2052297520300615?via%3Dihub>

<sup>32</sup> [http://www.ijmr.org.in/article.asp?issn=0971-](http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee)

[5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee](http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee)

<sup>33</sup> <https://www.ncbi.nlm.nih.gov/research/coronavirus/publication/32611916>

<sup>34</sup> <https://www.medrxiv.org/content/10.1101/2020.06.26.20056507v1>

<sup>35</sup> <https://www.ijidonline.com/action/showPdf?pii=S1201-9712%2820%2930534-8>

- June 30, 2020: NYC: 6493 patients who had laboratory confirmed Covid-19 with clinical outcomes between March 13-April 17, 2020 who were seen in 8 hospitals and 400 clinics in the NYC metropolitan area. “Hydroxychloroquine use was associated with decreased mortality.”<sup>36</sup>
- July 3, 2020: NY: Covid-positive patients treated with HCQ + AZM + Zinc vs. untreated.<sup>37</sup>
  - hospitalized: treated 2.8% vs. untreated 15.4%
  - death: treated 0.7% vs. untreated 3.5%
  - No cardiac side effects
  - 5x less all-cause deaths
- August 20, 2020: NJ: 1274 outpatients with documented SARS-CoV-2 found HCQ exposure cut hospitalization from 31% to 21% and cut mortality in half and no HCQ patient had arrhythmia-event.<sup>38</sup>

As discussed in the Safety section, the most comprehensive study on the subject was authored by Dr. Harvey Risch, MD, PhD, Professor of Epidemiology at Yale School of Public Health, and published in affiliation with the Johns Hopkins Bloomberg School of Public Health.<sup>39</sup> He notes the following.

1. When examining data on efficacy, Dr. Risch notes that the French studies were routinely disparaged as not being randomized, controlled and double-blinded. (Although that is the gold standard in research, it is of course impossible in the beginning stages of investigating a new disease.) However Dr. Risch notes that the results were so stunning as to far outweigh that issue. “The first study of HCQ + AZM showed a 50x benefit vs. standard of care. This is such an enormous difference that it cannot be ignored despite lack of randomization.”<sup>40</sup>
2. When examining data on efficacy, Dr. Risch notes that **evidence against HCQ when it is used alone is irrelevant, as it has been known since Feb-March that HCQ must be used in combination therapy.**<sup>41</sup>

<sup>36</sup> <https://link.springer.com/article/10.1007/s11606-020-05983-z>

<sup>37</sup> <https://www.preprints.org/manuscript/202007.0025/v1>

<sup>38</sup> <https://www.medrxiv.org/content/10.1101/2020.08.20.20178772v1.full.pdf>

<sup>39</sup> <https://www.aspph.org/yale-dr-harvey-risch-wins-50000-ruth-leff-siegel-award/>

<sup>40</sup> Gautret P, Lagier J-C, Parola P, et al. Hydroxychloroquine and azithromycin as a treatment of Covid-19: results of an open-label non-randomized clinical trial. Int J Antimicrob Agent 2020 Mar 17. <https://pubmed.ncbi.nlm.nih.gov/32205204/>

<sup>41</sup> [https://stopcovid19.today/wp-content/uploads/2020/04/COVID\\_19\\_RAPPORT\\_ETUDE\\_RETROSPECTIVE\\_CLINIQUE\\_ET\\_THERAPEUTIQUE\\_200430.pdf](https://stopcovid19.today/wp-content/uploads/2020/04/COVID_19_RAPPORT_ETUDE_RETROSPECTIVE_CLINIQUE_ET_THERAPEUTIQUE_200430.pdf)

## Four Levels of Obfuscation Used to Disparage This Remedy

### Corruption of the Scientific Journals

It is well known that **The Lancet** and **The New England Journal of Medicine** (NEJM) had to retract their studies. It was well documented in a series published in The Guardian starting with the headline: “The Lancet has made one of the biggest retractions in modern history. How could this happen?”<sup>42</sup> The sheer number and magnitude of the things that went wrong or missing are too enormous to attribute to mere incompetence.

The data upon which these studies were based were so ridiculously erroneous that it only took two weeks for an eagle-eyed physician to publicly demand an explanation.<sup>43</sup> What’s incredible is that the editors of these esteemed journals still have a job – that is how utterly incredible the supposed data underlying the studies was. The company that “gathered” the alleged data (Surgisphere) is now wiped clean from the Internet.

The Lancet and The NEJM have at least been exposed, but the third premier journal, as yet unexposed, is the **Journal of the American Medical Association** (JAMA.) While the first two journals published fraudulent studies, the JAMA study seems criminal in its utter disregard for human life.

The worldwide fallout from these three journals was fast and furious:

USA Today:

“Coronavirus Patients who took HCQ had higher risk of death, study shows.”<sup>44</sup>

The World Health Organization ordered nations to stop using HCQ and CQ,<sup>45</sup> WHO Chief Tedros suspended trials being held in hundreds of hospitals across the world,<sup>46</sup>

The EU governments France, Italy, and Belgium banned HCQ for Covid-19 trials,<sup>47</sup>

Worldwide ridicule was heaped upon the President of the United States.<sup>48 49</sup>

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<sup>42</sup> <https://www.theguardian.com/commentisfree/2020/jun/05/lancet-had-to-do-one-of-the-biggest-retractions-in-modern-history-how-could-this-happen>

<sup>43</sup> [https://www.youtube.com/watch?v=4HYK5pL2Z\\_s](https://www.youtube.com/watch?v=4HYK5pL2Z_s)

<sup>44</sup> <https://www.usatoday.com/story/news/health/2020/05/22/covid-19-study-links-hydroxychloroquine-higher-risk-death/5244664002/>

<sup>45</sup> <https://www.reuters.com/article/us-health-coronavirus-indonesia-chloroqu/exclusive-indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it-idUSKBN23227L>

<sup>46</sup> <https://medicalxpress.com/news/2020-05-trial-hydroxychloroquine-covid-treatment.html>

<sup>47</sup> <https://www.reuters.com/article/health-coronavirus-hydroxychloroquine-fr/eu-governments-ban-malaria-drug-for-covid-19-trial-paused-as-safety-fears-grow-idUSKBN2340A6>

<sup>48</sup> <https://www.nytimes.com/2020/05/18/us/politics/trump-hydroxychloroquine-covid-coronavirus.html>

<sup>49</sup> <https://www.nytimes.com/2020/05/22/health/malaria-drug-trump-coronavirus.html>

One can speculate how it is possible that the #1, #2, and #3 most famous medical journals in the world have jointly, erroneously, and virtually simultaneously, condemned HCQ/CQ. Here is one theory.

Dr. Dousty-Blazy, the former French Health Minister, Under Secretary General of UN, and candidate for Director of WHO has publicly stated that The Lancet and the NEJM Editors admit to being pressured by pharmaceutical companies to publish certain results.

The Lancet's boss ... said ... the pharmaceutical companies are so financially powerful today and are able to use such methodologies as to have us accept papers which ... in reality manage to conclude what they want ... I have been doing research for 20 years of my life. I never thought the boss of The Lancet could say that. And the boss of the NEJM too. He even said it was 'criminal.'<sup>50</sup>

In the case of the JAMA study, the scientists gave up to 2.5x lethal dosage of the medication.<sup>51</sup> Unsurprisingly so many patients died they halted the study early. They also cherry-picked patients and had no proof that there was the standard ethics oversight of the study. JAMA knew of these problems and published the study anyway. Various scientists have demanded its retraction, and even now, with civil and *criminal* investigations into these deaths, the study is still is not retracted. And the headlines around this study blame the drug, not the fact that old, sick, hospitalized, compromised patients were given toxic dosages of a drug.

This is a mockery. These journals did not publish science, but instead published fiction or evidence of a crime.

### **Corruption of the Media**

In addition to the corruption of the Journals we must note the widespread disinformation campaign as regards this safe and effective medication. While we don't blame individual journalists or publishers, in the aggregate, it is breathtaking that the overwhelming news regarding HCQ is positive and yet it is almost impossible to find any good news in the American media.

For example at approximately the same time The Lancet and the NEJM and JAMA published their retracted and possibly criminal studies, one of the oldest and most prestigious Journals in the world, the Indian Journal of Medical Research published very good news regarding HCQ.<sup>52</sup> Few have heard of this study because the mainstream press has ignored it.

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<sup>50</sup> <https://www.youtube.com/watch?v=ZYgiCALEdpE>

<sup>51</sup> <https://jamanetwork.com/journals/jamacardiology/fullarticle/2765631>

<sup>52</sup> <http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee>

Another example is the inexplicable delay in the publication of the Detroit study. This study was completed May 2, 2020.”<sup>53</sup> The Detroit study was not published until just before the July 4<sup>th</sup> Holiday and there was also no pre-publication press conference hinting at the good news. In normal times, a lag of seven weeks would be acceptable, but the Detroit results were showed a half mortality rate and everything regarding Covid-19 era is published at warp speed. Why the delay?

### Censorship of the Public “Town Square”

The clearest example of physician free speech censorship is what happened to James Todaro, MD.<sup>54</sup> Dr. Todaro, who up until these events was a mere private citizen, tweeted his thoughts about HCQ including a link to a public Google doc six days *before* the President endorsed HCQ. Dr. Todaro’s apolitical scientific commentary was his opinion of a scientific study that appeared to be fabricated, despite being published in a world-class journal. It turns out Dr. Todaro was so spot-on *correct*, that the study, which unfortunately had enormous worldwide influence, was *retracted* which is exceedingly rare. But before the public could read Dr. Todaro’s prescient words, the President happened to endorse HCQ, and Google scrubbed the document within hours.

And by scrubbed we mean that Google didn’t want you to think it was *missing*, they wanted you to not know such a thing ever even *existed*. This is how it happens.

First, Dr. Todaro has already learned that he will be censored, so he decides to bypass the censor by not even attempting to get a mainstream news source to publish his story about HCQ. He has accepted that even though his story is exactly the kind of counter-culture story that used to be sought after by journalists, those days are gone.

So Dr. Todaro self-publishes a document that he wrote and puts it out for public view, on a site that calls itself content-neutral: Google. Google claims it is a platform and not a publisher, which is a huge distinction. Platforms are just the vehicle to get the words from point a to point b. Publishers are responsible for content. If Google is a platform, which it represents itself to be, including before Congress, then it should not censor non-salacious content written by a scientist about science.

Censorship is evident for those who wish to see it.

### Excessive & Punitive Regulations at the State Level & “Off-Label” Prescribing

There is obviously a tremendous disinformation campaign going on in the United States of America claiming that HCQ is neither safe nor effective. This is quite remarkable for a medication that has been FDA approved for 65 years and having already been dispensed billions of times all across the world with only 57 serious adverse events (heart) noted by the FDA in their own database over the past fifty years. In many countries it is available over the counter, like aspirin and Tylenol.

<sup>53</sup> <https://www.ijidonline.com/action/showPdf?pii=S1201-9712%2820%2930534-8>

<sup>54</sup> <https://docs.google.com/document/d/1HY50zIjuSIVKltTk5UegfgqdiHN9ehLxLqLES9nwDZ8/e/dit?ts=5f106ac5>

Nonetheless, with the negative pressure being applied, state Governors have ordered, through their state licensing boards that physicians stop using it, and pharmacists stop dispensing it. Their wording is often more cautious, but doctors are told that they could be charged with “unprofessional conduct” (a threat to their license) or be “sanctioned” if they prescribe. First we need to understand how prescriptions have been done for decades.

Once approved by the FDA, any physician can prescribe any prescription medication in the USA, for any reason.<sup>55</sup> This is significant in that a drug is not approved for a specific diagnosis; a drug either makes it through the years-long approval process or it does not. That means a medication can be used “on-label” (the reason it was approved) or “off-label” (other reasons that have never received FDA approval.) It costs a lot of money for the pharmaceutical company to gain another “on-label” use, so once a drug is approved for any use, it is typically used for many reasons. Those additional reasons are called “off-label.”

As a practical matter “off-label” use accounts for about 20% of prescriptions. It is a daily occurrence. For example, it is off-label to give morphine as a pain medication for children. Indomethacin (an anti-inflammatory) was discovered in the 1970’s to work for a specific heart condition in newborns and is the standard of care for that condition (PDA) even though it has *never* been approved for this diagnosis. The very popular anti-nausea drug “Zofran” is given routinely (doctors call it the “bacon” of drugs) for virtually any type of nausea but it only has two very specific on-label indications: post-operative and chemotherapy induced nausea.

Another very common example is aspirin, which is *not* indicated for heart (coronary artery disease) prophylaxis in diabetics and yet it is the formal recommendation and standard practice by cardiologists.<sup>56</sup> It has been estimated that 73% of off-label use had low or no scientific support.<sup>57</sup> Pediatric antidepressant drugs are typically used off-label and are prone to error.<sup>58</sup>

There is a complete disconnect between physicians and everyone else on the subject of off-label use.<sup>59</sup> While almost all members of the public have benefited from “off-label” use of drug, many may not be focused on the distinction between “off-label” and “on-label” usages. This is logical as patients rely on and know physicians are personally and professionally obligated (and subject to much oversight and malpractice litigation), to do what is in the patient’s best interest.

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<sup>55</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/>

<sup>56</sup> Regulating off-label drug use--rethinking the role of the FDA. *Stafford RS N Engl J Med.* 2008 Apr 3; 358(14):1427-9.

<sup>57</sup> Off-label prescribing among office-based physicians. *Radley DC, Finkelstein SN, Stafford RS Arch Intern Med.* 2006 May 8; 166(9):1021-

<sup>58</sup> Pediatric antidepressant medication errors in a national error reporting database. *Rinke ML, Bundy DG, Shore AD, Colantuoni E, Morlock LL, Miller MR J Dev Behav Pediatr.* 2010 Feb-Mar; 31(2):129-36.

<sup>59</sup> <https://www.wsj.com/articles/SB116422408807730936>



Exploiting the public's understandable lack of focus on the non-distinction between off-label and on-label has contributed to the public's confusion regarding HCQ for Covid-19. From the physician's perspective if a drug is FDA approved and safe it is within the physician's armamentarium. And from the physician's perspective, is highly suspect that that rule should change in the middle of a pandemic and without any legislative discussion or regulation whatsoever, let alone sound science to support the same. It has **never** happened that a state has threatened a doctor for prescribing a universally accepted safe generic cheap drug off-label.

Although the states are the entities that empower physicians to prescribe, examples of abusive state actions will be in the next (federal) section because the states commonly blame the FDA (federal) for their newly aggressive regulations. But please note that many doctors have personally attested to the four harms caused by these Governors/State Medical Boards.<sup>60</sup>

1. doctors have been sanctioned, disciplined, interrogated
2. pharmacists have been empowered to over-ride physicians
3. patients get sicker and die
4. physicians self-censoring due to fear of retribution

#### **Misstatements at the Federal (FDA) Level**

Hydroxychloroquine is safe as a matter of fact, as demonstrated above. It is also considered "legally" safe as a matter of law as it is FDA approved for 65 years and doctors have been freely prescribing it in all that time until Covid-19. Contradicting its own policy, we believe for the first time in its history, the FDA has made statements that have caused states to restrict its use. While the right to prescribe is granted by each state, the states are informed by the FDA, and in reliance on the FDA, here are examples of over-reaching by many states.

#### **Arkansas:**<sup>61</sup>

Updated June 16, 2020

The Food and Drug Administration (FDA) has announced the removal of Emergency Use Authorizations (EUA) for chloroquine (CQ) and hydroxychloroquine (HCQ) to treat COVID-19. The announcement follows the FDA's determination that CQ and HCQ are unlikely effective treatments for COVID-19. In addition, the FDA further indicated the potential benefit does not outweigh the potential serious cardiovascular events and other adverse effects that can be caused by CQ and HCQ.<sup>2</sup>

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<sup>60</sup> <https://aapsonline.org/judicial/aaps-v-fda-hcq-6-2-2020.pdf>

<sup>61</sup> <https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-chloroquine>



Based on this information, the Arkansas Department of Health has updated its guidance related to hydroxychloroquine and chloroquine. The utilization of CQ and HCQ for treatment of COVID-19 should be avoided in both outpatient and hospitalized settings. HCQ that has been distributed through the Strategic National Stockpile is no longer authorized under the EUA to treat hospitalized patients for COVID-19, unless they had already started treatments.

Chloroquine and hydroxychloroquine should be administered, prescribed and dispensed for FDA approved medical conditions under supervision of a patient's healthcare provider.

### **California:**<sup>62</sup>

#### Statement Regarding Improper Prescribing of Medications Related to Treatment for Novel Coronavirus (COVID-19)

Several states have recently issued emergency restrictions on how the drugs can be dispensed. Many require that medications be prescribed and dispensed only to patients with a legitimate and current medical condition. Further, the FDA recently issued an Emergency Use Authorization to allow for the use of hydroxychloroquine sulfate and chloroquine phosphate products donated by the Strategic National Stockpile for certain hospitalized patients with COVID-19.

DCA, the Medical Board of California, and the California State Board of Pharmacy remind health care professionals that inappropriately prescribing or dispensing medications constitutes unprofessional conduct in California. Prescribers and pharmacists are obligated to follow the law, standard of care, and professional codes of ethics in serving their patients and public health.

### **Colorado:**<sup>63</sup>

Here are recommendations, first distributed by The American Society of Health-System Pharmacists (ASHP) to its membership, which may serve as a general guide for healthcare professionals regarding the receipt and dispensing of prescriptions for hydroxychloroquine, which can be applied to other COVID-19 investigative medications.

1. Continue to fill prescriptions for existing patients who are being prescribed these medications for FDA-approved indications on chronic therapy.
2. For new prescriptions, prescribers should be cognizant that hydroxychloroquine use in COVID-19 patients is not the standard of care. Pharmacists should verify and document diagnosis with the prescriber or prescriber's agent and limit to a 30-day supply of medication with the drug

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<sup>62</sup> Author has original copy

<sup>63</sup> <https://content.govdelivery.com/accounts/CODORA/bulletins/2833740>

frequently on back order at this time for prescriptions with an FDA-approved indication.

3. Due to limited supply, reserve hydroxychloroquine for patients with known autoimmune disorders and those ill enough to be hospitalized for COVID-19.

Please note that the Colorado State Board of Pharmacy, the Colorado Medical Board and the Colorado Nursing Board have the authority to discipline their corresponding licensees who fail to meet their corresponding generally accepted standards of practice.

### **Connecticut:**<sup>64</sup>

DPH strongly advises against off-label use of hydroxychloroquine and azithromycin in the outpatient setting for COVID-19 prophylaxis or treatment.

### **New Hampshire:**<sup>65</sup>

Chloroquine, hydroxychloroquine, and albuterol inhalers shall be subject to the following controls, restrictions, and rationing: a) Outpatient prescriptions for patients not already established on chloroquine and hydroxychloroquine shall be limited to a 30-day supply. b) No prescriptions of chloroquine or hydroxychloroquine shall be issued or dispensed as prophylaxis treatment for COVID-19. c) Prescribing providers, when issuing a prescription in any form for chloroquine or hydroxychloroquine, must document an indication for all patients, including patients already established on these medications. d) For albuterol inhalers, prescribing providers shall limit prescriptions to one inhaler with up to three refills for all new prescriptions to treat respiratory symptoms of COVID-19. e) For all prescriptions of albuterol inhalers, pharmacists shall conduct a prospective drug utilization review to ensure adherence to asthma controller or maintenance medications, and counsel patients that are non-compliant and over-utilizing rescue inhalers. 2. This Order shall remain in effect until the State of Emergency declared by the Governor is terminated, or this Order is rescinded, whichever shall happen first.

### **New York:**<sup>66</sup>

No pharmacist shall dispense hydroxychloroquine or chloroquine except when written as prescribed for an FDA-approved indication; or as part of a state approved clinical trial related to COVID-19 for a patient who has tested

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<sup>64</sup> <https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Blast-Fax-2020-29-Updated-Guidance-for-COVID-19.pdf?la=en>

<sup>65</sup> <https://www.oplc.nh.gov/pharmacy/documents/dhhs-emergency-order-04-03-2020.pdf>

<sup>66</sup> <https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency>

positive for COVID-19, with such test result documented as part of the prescription. No other experimental or prophylactic use shall be permitted, and any permitted prescription is limited to one fourteen day prescription with no refills.

### **Oregon:<sup>67</sup>**

Updated 6/15/2020

Oregon's pharmacy board put out a new rule on 6/15:

"Prescription orders for chloroquine or hydroxychloroquine for the prevention or treatment of COVID-19 infection may only be dispensed if written for a patient enrolled in a clinical trial by an authorized investigator."

And the board cites the FDA revocation of the EUA:

NEED FOR THE RULE(S): On 6/15/2020, the FDA revoked the emergency use authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible. The agency determined that the legal criteria for issuing an EUA are no longer met. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use. Furthermore, hydroxychloroquine continues to remain on the FDA's drug shortage list.

It bears repeating that to be FDA approved, a drug has to go through years of testing. To be FDA approved for 65 years is an overwhelming testimonial to a drug's safety and efficacy. There is no need for additional government intrusion.

Only a handful of states let doctors continue to be doctors. Florida did not get involved in the politicization of a drug. Florida spoke loudly and clearly by adding nothing additional to the already massive amounts of drug regulations by the Governor, the state medical board and the state pharmacy board.

### **Why Is HCQ Being Maligned?**

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<sup>67</sup> <https://secure.sos.state.or.us/oard/viewReceiptPDF.action?filingRsn=44884>

COVID-19 is an acronym for SARS-CoV-2. It is so named because it turns out there was a SARS-CoV-1. Reading the scientific literature related to the first SARS is so eerily similar that excerpts are copy/pasted on the next page. In 2002 there was a new coronavirus, originating in China, which rapidly spread to dozens of countries, within a few months, leading to worldwide efforts to contain it. The scientists discovered that CQ had a strong antiviral effect on this SARS-CoV virus, whether the CQ was used before or after infection. It was concluded that CQ had both prophylactic and therapeutic use.

The study “Chloroquine is a Potent Inhibitor of SARS Coronavirus Infection and Spread” by Vincent, Bergeron, Benjannet, et. al., was published by the official publication of the National Institutes of Health when Dr. Fauci was NIH Director.<sup>68</sup> Given that CQ was demonstrated to be very effective against a 78% identical coronavirus less than 15 years ago during a very similar situation, it is very curious that there was a multinational effort to restrict it starting in mid-January. (CQ is a precursor to the more modern HCQ. We now use HCQ in the USA. But studies of CQ are as reliable as studies of HCQ.)

On January 13, 2020 France quietly changed the status of HCQ from its years long over-the-counter status to “List II poisonous substance.”<sup>69</sup> This was an unprecedented demotion. And in the USA: “Dr. Anthony Fauci said Wednesday that data shows HCQ is not an effective agent for the coronavirus, disputing use of the drug to fight the deadly virus even as President Donald Trump touts it as a potential cure.”<sup>70</sup>

It is unclear when Dr. Fauci came to believe the opposite of what the NIH published when he was the NIH Director. What we do know is that 70,000-100,000 excess American lives have been lost due to lack of access to HCQ. So why did a medication that had been over the counter for decades, suddenly but quietly get pulled from the shelves, in the midst of a pandemic, due to a virus that is so similar it shares a name?

It is well known that newly patented drugs can be extremely profitable if there is demand and no other supply. The demand for Gilead’s Remdisivir, which is used **late** in the disease, obviously will plummet if the disease is stopped by HCQ **early**. Remdisivir is sold for \$3200-\$5700 per treatment and the federal government has already purchased all or most of it.<sup>71</sup> The generic HCQ is ~\$10 per treatment.

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<sup>68</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/>

<sup>69</sup> [https://www.legifrance.gouv.fr/jo\\_pdf.do?id=JORFTEXT000041400024](https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000041400024)

<sup>70</sup> <https://www.cnn.com/2020/05/27/politics/anthony-fauci-hydroxychloroquine-trump-cnn/index.html>

<sup>71</sup> [https://omnij.org/Gilead:\\_Twenty\\_one\\_billion\\_reasons\\_to\\_discredit\\_hydroxychloroquine\\_\(ORIGINAL\\_ARTICLE\)](https://omnij.org/Gilead:_Twenty_one_billion_reasons_to_discredit_hydroxychloroquine_(ORIGINAL_ARTICLE))

## Background

Severe acute respiratory syndrome (SARS) is caused by a newly discovered coronavirus (SARS-CoV). No effective prophylactic or post-exposure therapy is currently available.

## Results

We report, however, that chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage. In addition to the well-known functions of chloroquine such as elevations of endosomal pH, the drug appears to interfere with terminal glycosylation of the cellular receptor, angiotensin-converting enzyme 2. This may negatively influence the virus-receptor binding and abrogate the infection, with further ramifications by the elevation of vesicular pH, resulting in the inhibition of infection and spread of SARS CoV at clinically admissible concentrations.

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## Background

Severe acute respiratory syndrome (SARS) is an emerging disease that was first reported in Guangdong Province, China, in late 2002. The disease rapidly spread to at least 30 countries within months of its first appearance, and concerted worldwide efforts led to the identification of the etiological agent as SARS coronavirus (SARS-CoV), a novel member of the family *Coronaviridae* [1]. Complete genome

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## Discussion

We have identified chloroquine as an effective antiviral agent for SARS-CoV in cell culture conditions, as evidenced by its inhibitory effect when the drug was added prior to infection or after the initiation and establishment of infection. The fact that chloroquine exerts an antiviral effect during pre- and post-infection conditions suggest that it is likely to have both prophylactic and therapeutic advantages. Recently, Keyaerts et al. [21] reported the antiviral properties of chloroquine and identified that the drug affects SARS-CoV replication in cell culture, as evidenced by quantitative RT-PCR. Taken together with the findings of Keyaerts et al. [21], our analysis provides further evidence that chloroquine is effective against SARS-CoV Frankfurt and Urbani strains. We have provided evidence that chloroquine is effective in preventing SARS-CoV infection in cell culture if the drug is added to the cells 24 h prior to infection. In addition, chloroquine was significantly effective even when the drug was added 3–5 h after infection, suggesting an antiviral effect even after the establishment of infection. Since similar results were obtained by NH<sub>4</sub>Cl treatment of Vero E6 cells, the underlying mechanism(s) of action of these drugs might be similar.

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## Conclusion

Chloroquine, a relatively safe, effective and cheap drug used for treating many human diseases including malaria, amoebiasis and human immunodeficiency virus is effective in inhibiting the infection and spread of SARS CoV in cell culture. The fact that the drug has significant inhibitory antiviral effect when the susceptible cells were treated either prior to or after infection suggests a possible prophylactic and therapeutic use.

## Implications for the USA if restrictions on HCQ are not lifted immediately.

The safety of HCQ is so well established that it should have been over the counter decades ago, and in fact that is how it is in much of the world. The process to move a medication from prescription to over the counter in America is typically driven by a pharmaceutical company that has a profit motive: is a safe, well-established drug more profitable, at this time, over the counter? That is how drugs such as Zantac, Pepcid, Zyrtec, Allegra, Aleve, Benadryl, Minoxidil and nicotine patches and others came to be over the counter.

HCQ is safe but there's no profit motive to move it to over the counter, as there have been no general usage indication in America. It would languish on the shelves. So it sits in the armamentarium of prescription drugs, and quite frankly, no one gave it much thought prior to this pandemic. However, the landscape has changed, and now there is an urgent impetus to make it readily available to the American people.

It is interesting to note that many over the counter drugs, probably the majority, are less safe than HCQ. For example Tylenol, and aspirin are listed as more risky.<sup>72</sup> Most doctors would attest to the frequent problems people have with Motrin/Ibuprofen/Aleve. Tylenol toxicity is the most common reason for liver transplant in the USA and anti-inflammatories account for an enormous number of GI bleeds/pain/distress.

If the disinformation campaign regarding HCQ weren't so complete, from the scientific journals, to the media, to the state medical boards to the FDA, this would not really matter. Individual physicians who are innovators and early adopters would have moved first, prescribing HCQ off-label, just as physicians already do 20% of the time, and it would have caught on rapidly. However, the disinformation campaign blocked off-label use, and now we are in a pandemic with a safe and effective drug that doctors inclined to prescribe and patients inclined to take, cannot access.

As a result, not only are patients not being treated promptly, effectively, and safely, some patients die. And as the fear of the pandemic has overtaken the virus itself and it is impossible to change public and physician opinion quickly enough to save lives, we must make the medication available to the public directly.

Dr. Harvey Risch, MD, PhD, Professor of Epidemiology at Yale School of Public Health and published in affiliation with the Johns Hopkins Bloomberg School of Public Health.<sup>73</sup> Dr. Risch who has 39,779 citations on Google Scholar, notes that:<sup>74</sup>

“US cumulative deaths through July 15 are 140,000. Had we permitted HCQ use liberally, we would have saved half, 70,000 and it is very possible we could have saved 3/4, 105,000.”

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<sup>72</sup> <https://www.thedenverchannel.com/news/national/these-are-the-50-most-dangerous-drugs-on-the-market>

<sup>73</sup> <https://www.aspph.org/yale-dr-harvey-risch-wins-50000-ruth-leff-siegel-award/>

<sup>74</sup> Interview with the author July 15, 2020



It is relevant that the problem that the USA has with accessing hydroxychloroquine is a first-world problem. Curiously the people who *cannot* get HCQ typically live in first-world democracies. Speaking generally, HCQ or its progenitor CQ, was freely available over the counter in most of the world Africa, Asia, South America, even Canada and Mexico, prior to Covid. Long before President Trump endorsed HCQ on March 20, 2020, the drug was quietly removed from pharmacy shelves in Canada and it was banned outright in France. These two actions were taken in January 2020. It is speculation as to why but one must consider who benefits if HCQ is not accessible.

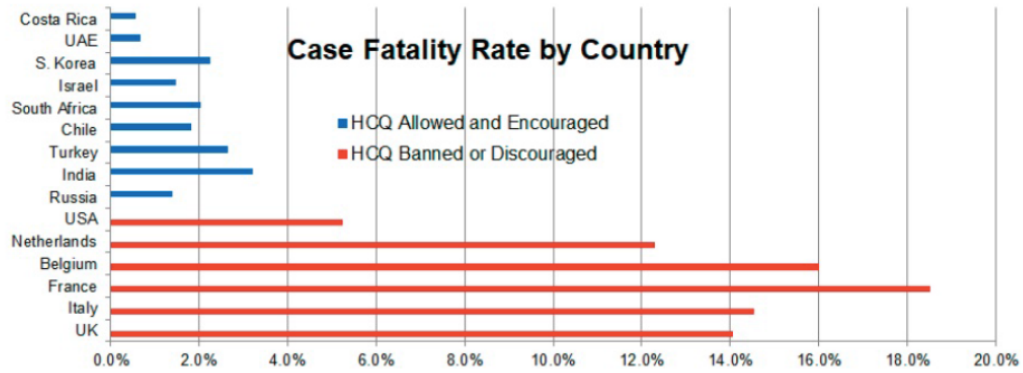
It cannot be overlooked that right now, all over the world, patients who want to buy HCQ simply do. Iran, Costa Rica, Italy, Panama; many others. Here is a photograph of a typical pharmacy in Indonesia taken on July 16, 2020.<sup>75</sup>



No matter the reason, there is an obvious relationship between access to HCQ and mortality rates from Covid-19. While it is true that such a relationship does not prove cause/effect, but it is also true that it would be lunacy to assume no relationship.<sup>76</sup>

<sup>75</sup> @Smackenziekerr July 17, 2020

<sup>76</sup> AAPS vs. FDA <https://aapsonline.org/judicial/aaps-v-fda-hcq-6-2-2020.pdf>



*Id.* ¶ 29.

Country by country data is also available and access to HCQ is strongly linked to lower mortality.<sup>77</sup> We can see that even very poor countries have much lower case fatality rates than wealthy countries, which of course, is typically the opposite of what we would expect of a respiratory disease that could end up in an ICU admission. Kazakhstan, Bangladesh, Senegal, Pakistan, Serbia, Nigeria, Turkey, Ukraine, Honduras ... the list goes on. Wealthier democracies or countries with especially abusive HCQ protocols such as are doing terribly: Ireland, Canada, Spain, The Netherlands, UK, Belgium, France ... Of note, Italy and Spain switched mid-stream and now HCQ is easily available.

<sup>77</sup><https://docs.google.com/spreadsheets/d/14GUXRGzNTV1BUgY6xvpFMfYDTxXvKCUSUrTTlnwwfh8/edit#gid=0>



Country	Mortality i	# of deaths	# of cases	CFR c/d	Deaths per 1 HCQ policy	As of June 21, 2020 - numbers fr
Qatar		94	86488	0.11%		encourages HCQ: Qatar's health minister says country uses HCQ and
Bahrain		60	21,331	0.28%		encourages HCQ: Bahrain among first countries to use Hydroxychloro
Oman		128	28,566	0.45%		encourages HCQ: Oman has approved the antimalaria drug, HCQ, as
Costa Rica		12	2,127	0.56%	2	encourages HCQ use
Belarus		343	57936	0.59%		encourages HCQ: Sandoz will donate potential effective drug for treat
UAE		301	44,533	0.68%	31	encourages HCQ use: UAE says it is successfully treating patients wit
Kazakhstan		118	16779	0.70%		encourages HCQ: Pakistan donated 700,000 chloroquine tablets to Kz
Saudi Arabia		1230	154,233	0.80%		"Saudi Arabia's treatment plan from March which shows HCQ use dat
Bangladesh		1425	108775	1.31%		encourages HCQ: Bangladesh recommends controversial drugs for C
Russia		8002	576,952	1.39%	56	Russia recommended PrEP use of HCQ: Post contact prevention in in
Malaysia		121	8556	1.41%		encourages HCQ: "Malaysia Finds Hydroxychloroquine Can Slow Cov
Senegal		82	5,783	1.42%		encourages HCQ use, Senegal will continue use of HCQ + azithromyc
Israel		305	20,833	1.48%	33	encourages HCQ: PM Netanyahu thanks Modi for donation of HCQ
Chile		4295	236748	1.81%	234	"In Chile, a centralized national Protocol was made in which both Pub
Pakistan		3382	171,666	1.97%		"Pakistan asks India for Hydroxychloroquine to combat coronavirus ou
South Africa		1877	92,881	2.03%	33	"here in South Africa HCQ is used widely for malaria so the last three
Serbia		260	12,803	2.03%		Serbian and Bosnian drugmakers Galenika and Zada Pharmaceutical
Morocco		213	9,839	2.16%		encourages: "Morocco to Receive 8 Million Hydroxychloroquine Table
S. Korea		280	12,421	2.25%	5	encourages HCQ use
Argentina		992	41,204	2.41%		Several reports of patients in Argentina noting they received HCQ
Nigeria		508	19,808	2.55%		"Nigerian authorities say they will continue to use hydroxychloroquine
Turkey		4927	186493	2.64%	59	encouraged HCQ use
Ukraine		994	35,825	2.77%		encourages HCQ use
Honduras		358	12,306	2.91%		"the Honduran government assured that hydroxychloroquine will cont
Peru		7861	251338	3.13%		Peru will continue to use the controversial drug hydroxychloroquine to
Czechia		338	10,448	3.22%		Czech Health Ministry permits temporary use of hydroxychloroquine tc
India		13277	411727	3.22%	10	encourages HCQ use
Colombia		2128	65633	3.24%		"Hydroxychloroquine and Chloroquine Can Be Used to Treat Covid-19
Philippines		1150	29,400	3.91%		Makati Medical Center (MMC) is using Hoq-Az plus zinc and Vitamin C

Egypt		2106	53758	3.92%		Egyptian Health Minister on Hydroxychloroquine: "We put it in the trea
Portugal		1528	38,841	3.93%		Patients in Portugal with Covid-19 can be treated with malaria and ebr
Austria		688	17,323	3.97%		"Malaria drug is used in Austria" hospitalized pts
Poland		1346	31,620	4.26%		Some use in Poland was noted March 13
Brazil		50,058	1,070,139	4.68%		asked US for HCQ late in the process, poor distribution, isolated use
Germany		8961	191,216	4.69%		only 13% of doctors in Germany said they would prescribe HCQ
Iran		9,507	202,584	4.69%		not clear
Denmark	5	600	12,391	4.84%		"hydroxychloroquine in Denmark can only be prescribed by hospital dr
USA		121,980	2,330,578	5.23%	369	blocked HCQ use (a few brave physicians use it), isolated use where :
Japan	6	952	17,799	5.35%		Hydroxychloroquine usage amongst COVID-19 treaters is 7% in Japa
China		4634	83,378	5.56%		didn't know about HCQ initially
Greece		190	3,256	5.84%		Greece has resumed production of chloroquine to treat cases of coron
Switzerland		1956	31,243	6.26%		"hospitalised Covid-19 patients" i.e. too late
Ireland	7	1715	25,374	6.76%		Apparently HCQ was frowned upon in Ireland
Canada	8	8,410	101019	8.33%		very anti-HCQ leadership,
Ecuador	8	4156	49,731	8.36%		At least one city in Ecuador used it reported success
Sweden	9	5053	56,043	9.02%		April 6: Several Swedish Hospitals Have Stopped Using Chloroquine
Spain	10	28322	293018	9.67%	606	Hydroxychloroquine usage amongst COVID-19 treaters is 72% in Spa
Algeria		837	8,324	10.06%		Dr. Idir Bitam reports that in Algeria of 170 people treated with HCQ +
Mexico	12	20,781	175,202	11.86%		very anti-Trump leadership, poor distribution
Netherlands	12	6089	49,502	12.30%	355	some hospitals used HCQ, but early use apparently discouraged, prof
UK	15	42589	303110	14.05%	628	only 13% of UK physicians said they used it
Italy	15	34,610	238,275	14.53%	573	did not initially know about HCQ (eventually adopted in some areas) a
Belgium	15	9,696	60550	16.01%	837	Belgium used HCQ "for the sickest coronavirus patients."
France	18	29,633	160,093	18.51%	454	France banned HCQ;

The limitation or outright ban on HCQ worldwide has begun to crack. It will soon collapse because the evidence of its safety and efficacy is so overwhelming. The countries that have less flexibility to tolerate fatal policies have already reversed themselves. South of us, Honduras, Panama, Costa Rica have, or earlier had, made HCQ available. Brazil is trying but faces many of the same political problems as the USA. Some countries have started going door to door to facilitate its availability.<sup>78</sup>

In Honduras their national policy now is: “The patient that presents for the first time to a First Level of Care facility, if so, treatment should be started with: Acetaminophen, Hydroxychloroquine 400 every 12 hours, Ivermectin, Azithromycin, Zinc ...”<sup>79</sup>

**Puede que el paciente se presente por primera vez a un Establecimiento del Primer Nivel de Atención, si es así se debe iniciar tratamiento con:**

- Acetaminofén 500mg V.O. c/6 hrs en caso de fiebre.
- Hidroxicloroquina 400 mg V.O. c/12 hrs primer día, luego 400 mg /día x 5 días
- Ivermectina 200 µg/kg día x 5 días.
- Azitromicina 500 mg V.O. /día x 5 días
- Zinc 100 mg V.O. c/día x 5 días.
- Colchicina\* 1 mg V.O primera dosis, luego 0.5 mg V.O c/12 hrs hasta que valores inflamatorios disminuyan por al menos 2 días consecutivos.
- Prednisona 1mg/kg/día V.O x 7 días
- Apixabán\* 5mg V.O. c/12 hrs o Rivaroxabán\* 20 mg V.O. c/día con la comida x 14 días
- Autoaislamiento en el Hogar con vigilancia médica.
- **Pronación voluntaria**

\* Se debe ajustar dosis en pacientes con insuficiencia renal y adultos mayores.

Panama reversed course regarding HCQ and many countries in South and Central America are following suit:<sup>80</sup>

Evaluating new evidence around the therapeutic options for COVID-19, specifically the use of HCQ and the Lancet journal withdrawing its publication on this topic. The Ministry of Health communicates that Circular No. 118-DGSP is null and void, establishing directives for immediate compliance regarding the use of HCQ and / or azithromycin. Leaving the therapeutic option for prescription according to medical criteria. Soon we will be sending a treatment guide for Covid-19 patients.

<sup>78</sup> Conversation author had with Dr. Sanchez, head of FDA Honduras July 10, 2020.

<https://www.arsa.gob.hn/>


<sup>79</sup> Conversation author had with Maria Dolores Aguero Ministra De Relaciones Exteriores July 9, 2020

<sup>80</sup> Dr. Luis Francisco Sucre Mejia – Ministro de Salud

CIRCULAR N°140 - DGSP  
13 de julio de 2020

PARA: Directores Regionales de Salud  
Directores de Hospitales Nacionales  
Directores de Hospitales Regionales  
Directores de Instalaciones de Salud Pública y Privadas

De:

  
DRA. NADJA I. PORCELL IGLESIAS  
Directora General de Salud Pública

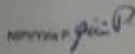


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Evaluando nueva evidencia alrededor de las opciones terapéuticas para COVID-19, específicamente el uso de la hidroxiquina y siendo que la revista Lancet retira su publicación sobre este tema. El Ministerio de Salud comunica que se deja sin efecto la Circular N° 118-DGSP, en la que se establecían directrices de cumplimiento inmediato referente al uso de la hidroxiquina y/o azitromicina. Dejando la opción terapéutica para prescripción según criterio médico.

Próximamente estaremos enviando una guía de tratamiento para pacientes Covid-19.

Atentamente,



c.c. Dr. Luis Francisco Sucre Mejía – Ministro de Salud

In France, HCQ had been sold over the counter for many years, but on January 15, 2020, then Health minister Buzyn reclassified it as “list II of poisonous substances.” Three days after Trump endorsed it, the next Health Minister Veran said that HCQ was only to be used for severely ill hospitalized patients and could not be used early or prophylaxis use. Then two months later he terminated using it at all. All this time, esteemed virologist Professor Raoult continued his clinical trials and in his hospitals the mortality rate was 0.52% compared to the rest of France 19.12%. Because this was so mishandled, resulting in so many unnecessary deaths, the former French Prime Minister and two Ministers of Health are now being criminally investigated.<sup>81</sup>

Former French Prime Minister, health ministers to be investigated for pandemic response” A French court will investigate former French Prime Minister Edouard Philippe and two health ministers following complaints about the government's handling of the coronavirus pandemic, Prosecutor General François Molins said today. Philippe, former Health Minister [Agnès Buzyn](#) and outgoing Health Minister Olivier Véran will have to respond to accusations of abstaining from fighting a disaster.

In The Netherlands, Dr. R. Elens, has filed suit due to his being blocked from prescribing HCQ, which is contrary to his lifelong practice as a physician.<sup>82</sup> He was sanctioned and could face a fine of Euro150,000. He filed this petition to clarify the status of HCQ and will pursue to The Hague if necessary as a crime against humanity.

As in all battles of good vs. evil, when America falters, the world collapses.

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<sup>81</sup> <https://www.politico.eu/article/former-french-pm-health-ministers-to-be-investigated-for-pandemic-response/>

<sup>82</sup> <https://zelfzorgcovid19.nl/wp-content/uploads/2020/06/voornemen-off-label-gebruik.pdf>

## Conclusion:

This white paper is to draw the reader's attention to the indisputable safety of HCQ, remarkable efficacy of HCQ against SARS-CoV-2, and the worldwide political storm that has resulted in its use being restricted. We speak in support of it being made available over the counter in the USA due to the inability of Americans to access it, whether they need it for treatment or to manage their fear.<sup>83</sup>

The virus is known to be asymptomatic or mild the vast majority of the time, but in people with multiple co-morbid conditions, rarely it can be deadly. Because so much was unknown in the beginning, the most cautious approach was taken. However, now that we know the facts, it has proven impossible to dislodge the fear that was implemented.

At this time, disinformation and therefore resultant fear have a firmer grip on Americans than reality. And thus Americans who need a life-saving medication cannot get it either due to their own physicians' reluctance, their pharmacies regulating against the same, their state medical boards threats, the media disinformation, and/or due to certain sectors of the federal government's own anti-HCQ statements.

Some people question if making HCQ over the counter would change anything, as there has been such negative coverage. The answer is like all things in life: there are innovators, early adopters, early majority, late majority and laggards. What has gone wrong in this instance is that innovators and early adopters have been stymied. Once people are free again to make their own choices, they will, and society will normalize over about a month.

Once Americans know they can buy a safe, cheap, generic, life-saving medication, should they need it, calm and rationality can be restored, not just to America, but throughout the world. A person who suffers from an occasional migraine headache but who has the migraine medicine at home or in her pocket, in case she needs it, is a person who feels safe and comfortable going about her daily routine. If she does not have that prescription, she may limit herself a lot or a little, and either way, she is fearful of what is around the corner.

At the very least, the efficacy "assassination" of HCQ must be reversed immediately. Doctors must be able to prescribe HCQ as a treatment and as a prophylaxis. It is absolutely unacceptable that doctors are not being able to communicate responsibly and with compassion with their patients. That must be remedied. Period.

Americans do not need to be afraid. Instead, they need to be empowered. Their physicians should not be prevented from upholding their Hippocratic Oath and healing their patients. Instead, they must be permitted to practice sound and safe medicine. Patients and their doctors must be able to discuss the options for optimal care and treatment and the patient-physician relationship must take precedent.

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<sup>83</sup> [https://www.wsj.com/articles/notable-quotable-fear-for-our-children-11594854726?st=qb7dqvvapgd7s2z&reflink=article\\_email\\_share](https://www.wsj.com/articles/notable-quotable-fear-for-our-children-11594854726?st=qb7dqvvapgd7s2z&reflink=article_email_share)