



SPECIAL REPORT

The \$20 Solution to Coronavirus: 'Anecdotal Evidence' Is a Life-Saver



by GEORGE PARRY

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Over the weekend, the Food and Drug Administration (FDA) issued an emergency authorization for the use of hydroxychloroquine (HCQ) and chloroquine (CQ) to treat hospitalized COVID-19 patients. Simultaneously, the Department of Health and Human Services (HHS)

announced that Sandoz has donated 30 million doses of HCQ and Bayer one million doses of CQ to the Strategic National Stockpile. According to HHS, these drugs will be “distributed and prescribed by doctors to hospitalized teen and adult patients with COVID-19, as appropriate, when a clinical trial is not available.”

The effect of the FDA’s emergency authorization is unclear. The FDA regulates the manner in which manufacturers of pharmaceuticals may advertise and sell their products. If, after testing and clinical trials, the FDA approves a drug for a particular use, then the manufacturer may market it for that purpose and no other.

The FDA, however, does not set the standard of care for physicians and does not regulate the practice of medicine. That is why, even before the FDA’s “emergency authorization,” physicians have been free to make “off-label” (non-FDA approved) use of HCQ and CQ to treat COVID-19 patients.

Following clinical trials in China, South Korea, and France that demonstrated the efficacy of treating and likely preventing COVID-19 infections with HCQ alone or in combination with azithromycin, President Trump expressed to the media optimism about HCQ being a potential “game changer” in the fight to defeat the pandemic. But, at that same press briefing, Dr. Anthony Fauci seemed to throw cold water on Trump’s enthusiasm. In answer to a reporter’s question, Fauci stated that although there was “anecdotal evidence” that HCQ was effective in treating and preventing COVID-19 infections, controlled clinical trials of the drug were still necessary before any definite conclusions could be reached.

Since then, “anecdotal evidence” has become the mantra of the mainstream media, who, in their eagerness to portray Trump as a snake oil salesman

offering false hope to a panicked nation, have dismissed the use of HCQ and CQ as an unproven, speculative proposition.

But to the undoubted dismay of the media and all those who hope the pandemic will destroy Trump's presidency, that pesky "anecdotal evidence" supporting the use of HCQ and CQ to successfully treat and possibly prevent COVID-19 infections continues to grow at an exponential rate.

For example, in a follow-up of its previously reported study recommending the use of HCQ and azithromycin to treat COVID-19 cases, researchers in France and Vietnam under the leadership of world-renowned infectious disease expert Professor Didier Raoult, the head of the Institut Hospitalo-Universitaire (IHU) Méditerranée Infection in Marseille, have reported another clinical trial in which that drug combination cured 79 out of 80 patients. Noting that "adverse events were rare and minor," the researchers summarized their findings as follows:

In conclusion, we confirm the efficacy of hydroxychloroquine associated with azithromycin in the treatment of COVID-19 and its potential effectiveness in the early impairment of contagiousness. Given the urgent therapeutic need to manage this disease with effective and safe drugs and given the negligible cost of both hydroxychloroquine and azithromycin, we believe that other teams should urgently evaluate this therapeutic strategy both to avoid the spread of the disease and to treat patients before severe irreversible respiratory complications take hold.

As this report was issued, India's Ministry of Health and Family Welfare issued a directive declaring that

Whereas, the Central Government is satisfied that the drug 'Hydroxychloroquine' is essential to meet the requirements of emergency arising due to pandemic COVID-19 and in the public interest, it is necessary and expedient to regulate and restrict the sale and distribution of the drug "Hydroxychloroquine" ... (Emphasis added.)

Based on this finding, India has banned the export of HCQ and is recommending that health-care workers take HCQ prophylactically to avoid becoming infected while treating COVID-19 patients.

Similarly, Belgium and Bahrain are reporting that their hospitals are using HCQ to successfully treat COVID-19 patients. According to the Bahrain News Agency, the head of Bahrain's National Taskforce for Combatting COVID-19 reports that HCQ has had a "profound impact" when used to treat COVID-19 patients. And Belgium has established a "strategic reserve" of HCQ to treat as many as 22,000 COVID-19 patients on an "off-label" basis.

But far and away the widespread off-label use by physicians in the United States of HCQ alone or in combination with other FDA-approved drugs to successfully treat COVID-19 cases has produced the most stunning and powerful "anecdotal evidence." This has resulted in major hospitals such as Michigan's Henry Ford Hospital and the University of Michigan Hospital publishing COVID-19 treatment protocols that include the use of HCQ. This is happening across the nation, and physicians are using HCQ either alone or in combination with azithromycin to successfully treat COVID-19 patients.

Consider, for instance, the overwhelmingly positive patient outcomes that have been achieved by Dr. Vladmir (Zev) Zelenko, a New York physician.

By letter dated March 23, 2020, Dr. Zelenko reported to the Israel Ministry of Health that he and his team had used a combination of HCQ, azithromycin, and zinc to successfully treat 500 high-risk COVID-19 patients. He reported “ZERO deaths, ZERO hospitalizations, and ZERO intubations [ventilator uses]” and “no serious negative side effects” caused by the drug protocol.

In his letter, Dr. Zelenko wrote, “I would like to thank President Trump for approving Hydroxychloroquine for use against this virus.”

Here is Dr. Zelenko’s letter:

B"H

Dr. Vladimir (Zev) Zelenko
Board Certified Family Practitioner
501 Rt 208, Monroe, NY 10950
845-238-0000

3/23/20

To the Israel Ministry of Health:

My name is Dr. Zev Zelenko and I practice medicine in Monroe, NY. For the last 16 years, I have cared for approximately 75% of the adult population of Kiryas Joel, which is a chassidic enclave of approximately thirty five thousand people.

As of today, 65% of the Covid-19 test results have been positive. If extrapolated to the entire community, mostly likely more than twenty thousand people are infected at the present time. The average age of the residents of Kiryas Joel is around fifteen years old. I estimate that there are around 1500 patients that fall into the high risk category (i.e. >60, immunocompromised, comorbidities, etc).

I have developed the following treatment protocol for the outpatient setting:

- 1- Any patient with shortness of breath, regardless of age, I will treat.
- 2- Any HIGH RISK patient with even mild symptoms, I will treat.
- 3- I do not treat young and low risk patients unless they have shortness of breath.

I would like to thank President Trump for approving Hydroxychloroquine for use against this virus.

My treatment regimen is as follows:

- 1- Hydroxychloroquine 200mg one pill twice a day for 5 days
- 2- Azithromycin 500mg one pill a day for 5 days
- 3- Zinc sulfate 220mg one pill a day for 5 days

The rationale for my treatment plan is as follows. I combined the data available from China and South Korea with the recent study published from France. We know that hydroxychloroquine helps Zinc enter the cell. We know that Zinc slows viral replication within

the cell. Regarding the use of azithromycin, I postulate that it probably prevents secondary bacterial infections, but I am not sure. These three drugs are well known and usually well tolerated, hence the risk to the patient is low.

My team has treated, since last Thursday, approximately 350 patients in Kiryas Joel, and I have treated around 150 patients in Monsey, NY and New York City. I can definitively report that we have had ZERO deaths, ZERO hospitalizations, and ZERO intubations in Kiryas Joel since Thursday. I medically advise the Kiryas Joel Hatzolah and I am fully aware of their data. To the best of my knowledge, the 150 patients that I have treated outside of Kiryas Joel are doing well, thank G-d. I have not seen any serious negative side effects. I have seen around 10% of patients with nausea and diarrhea from the medication.

In summary, my recommendation is to initiate treatment in the outpatient setting, as soon as possible, in the appropriate patient. It seems to prevent acute respiratory distress syndrome (ARDS) and the need for respiratory support.

With much respect,

Dr. Zev Zelenko

cc: President Donald J. Trump; Mr. Mark Meadows, Chief of Staff

Subsequently, Dr. Zelenko appeared on Rudy Giuliani's televised podcast "Common Sense" to report that, as of March 29, 2020, he and his team had treated hundreds of high-risk COVID-19 patients with no deaths, no

intubations, and only three hospitalizations. (According to a tweet by Giuliani, the actual number of patients by that date was 699.)

In the podcast, Giuliani conducted a lawyerly but friendly deposition of Dr. Zelenko, whose answers were astounding. He stated that, by using a “cocktail” of HCQ, azithromycin, and zinc in an outpatient setting “as soon as possible,” none of his patients have died, been intubated, or treated in an ICU. Three patients have been hospitalized with pneumonia without intubation or ICU care and are doing well.

Dr. Zelenko said that, compared to the seasonal flu, COVID-19 is three times more contagious and, for those with risk factors, 10 times more deadly. He estimates that by the end of the year, one-half of all Americans will have COVID-19. He said, however, that it is a “well-established fact” that otherwise healthy COVID-19 patients who are 60 years or younger will be “fine” since their immune systems will be strong enough to deal with the infection. But any of his COVID-19 patients who are 60 or older or with a chronic medical condition or who are immunocompromised, he treats immediately with the “cocktail.”

He derived the mixture of drugs by reviewing a South Korean clinical study in which HCQ was used with zinc to achieve “somewhat successful” but “not too impressive” patient outcomes. He also studied the clinical trial in France in which HCQ and azithromycin were used to achieve “100 % resolution in the lab.” He noted, however, that HCQ and azithromycin are being used in combination in many New York ICUs with “mild to moderate success.” The reason for this is that, by the time patients reach the ICU, many are already suffering from Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19’s destruction of their lung tissue. Even with HCQ and azithromycin, 40 to 50 percent of ICU patients suffering from ARDS will die. In short, he believes that it

is important to treat COVID-19 patients with risk factors as soon as they are diagnosed and well before they reach the ICU.

Drawing on the studies from South Korea and France, he combined HCQ with azithromycin and zinc. Why zinc? Because it interferes with the replication of viruses. Under ordinary circumstances, only a very small percentage of a zinc dose can enter cells. But the HCQ acts as a “canal” by which the zinc enters the cells. Both the HCQ and zinc reduce the amount of virus by interfering with its growth and, accordingly, give the immune system time to overcome the virus before it destroys the lungs. As far as he knows, azithromycin has no impact on the viral load but is effective in suppressing any non-viral pneumonia that may be present.

He stressed that the key to effective treatment is to administer the “cocktail” as soon as COVID-19 is confirmed. As he put it, “Hit the infection hard and early.”

Dr. Zelenko noted that “many doctors” are using his “cocktail” and having similarly positive patient outcomes. Then he added these remarks:

I want to thank the president for approving the use of this drug [HCQ].

He said he had a good feeling about it. And truth is he's very intuitive, and I have the same intuition. I really feel that this is the answer.

If you scale this nationally, the economy will rebound much quicker.

The country will open again. And let me tell you a very important point.

This treatment costs about \$20. That's very important because you can scale that nationally. If every treatment costs \$20,000, that's not so good.

All I'm doing is repurposing old, available drugs which we know their safety profiles, and using them in a unique combination in an outpatient setting.

You can watch the video podcast below. I urge you to watch it from beginning to end:



Now, keep in mind that, according to the mainstream media, all of what you have just read is merely “anecdotal evidence” and that, until further clinical trials have been completed to the satisfaction of the FDA, the off-label use of HCQ alone or in combination with other drugs is simply a medically unproven technique touted by a dishonest President Trump. But, while the media keep tut-tutting and poo-pooing HCQ as so much Trumpian snake oil, physicians like Dr. Zelenko are using it every day across this nation to save lives. Moreover, the anecdotal evidence demonstrates that the majority of high risk COVID-19 patients can be saved by early dosing with HCQ and without tying up hospital and ICU beds or the use of ventilators.

As the nation braces for its medical facilities to be swamped and goes on a wartime footing to erect additional hospital facilities and manufacture personal protective equipment and ventilators in vast, unprecedented numbers, the anecdotal evidence strongly supports the proposition that there is a quicker, far less expensive, and more effective alternative. How about a wartime crash program to increase the production and distribution of the inexpensive and demonstrably safe HCQ so that it may be used *here and now* to save lives on an outpatient basis and to, at the very least, be used prophylactically by our health-care providers and first responders to prevent their contracting COVID-19? Not only would this eliminate the need for building more hospitals and manufacturing massive numbers of ventilators but it would also reduce the exposure of our health-care providers and first responders to COVID-19 and quite likely provide them prophylactic protection from infection.

Oh, did I mention that there is also “anecdotal evidence” that lupus patients who are being treated with HCQ have an almost nonexistent incidence of COVID-19 infections, as do people living in Africa where HCQ tablets are handed out like Pez to prevent malaria? Let me catch my breath, and we’ll talk about that later.

But in the meantime, ask yourselves if there is any good reason why we should delay for one second a nationwide crash program to ramp up production of HCQ and deploy Dr. Zelenko’s \$20 solution and similar effective protocols to defeat the COVID-19 pandemic.

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