



Written by [Elizabeth Lee Vliet, M.D.](#) on July 28, 2020

## FDA Delays on HCQ Outpatient Approval Are Causing Deaths Daily

[Twenty thousand more Americans have died](#) while the FDA has delayed since July 1 a new emergency-use approval for outpatient use of hydroxychloroquine (HCQ) for COVID-19.

On July, 1 Henry Ford Hospital physicians and researchers in Detroit filed an urgent request to FDA Commissioner Dr. Stephen Hahn for a [new outpatient Emergency Use Authorization \(EUA\)](#) for FDA approval of HCQ to be used in early treatment for COVID-19. [Baylor Scott & White Heart and Vascular Institute in Dallas](#) issued an urgent appeal supporting the Henry Ford EUA application, based on their clinical study of prophylactic use of HCQ in their own medical workers. Baylor cardiologists emphasized there were no adverse cardiac outcomes in their own or the Ford study.

[Henry Ford's new clinical trial](#) found an impressive *51% reduction in deaths* if HCQ was begun within 24 hours of admission to hospital. An outpatient primary care study by [Dr. Vladimir Zelenko](#), using HCQ, azithromycin, and zinc given within less than 7 days of COVID-19 symptoms, showed approximately *80% decrease in deaths*, and less than 1% of his patients needed to be admitted to hospital. These U.S. early intervention studies' extraordinary results show how many lives can be saved with *early* HCQ treatment.

If the FDA had acted quickly on the Henry Ford and Baylor approval request for HCQ, we can reasonably consider that *16,000 lives could have been saved* since July 1.

EUA applications do not *have* to take long to approve, when well-documented rationale and supporting research is presented as Henry Ford team and Baylor cardiologists did.

HCQ is already an FDA-approved drug, unlike remdesivir, which had almost an immediate compassionate use authorization granted that has now been expanded for early use despite severe side effects. The former director of the FDA subagency BARDA, Rick Bright, Ph.D., submitted an EUA for HCQ approval for *hospital* use at 11:30 pm on March 28, 2020.

Dr. Hahn's approval was granted a little after midnight, March 29, 2020. *Approval in about 30 minutes.* We have been waiting almost *30 days* for Dr. Hahn to issue approval of the Henry Ford EUA application for outpatient use. Dr. Hahn has stated that we need more data. Henry Ford and Baylor doctors have already provided research documentation stronger than in Rick Bright's March application, and included current COVID-19 studies from the U.S. and other countries. What amount of "[data](#)" will ever





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satisfy Dr. Hahn?

Let *THIS sink in*: [Laboratory studies published by the National Institutes of Health 15 years ago \(2005\)](#) showed potent antiviral effects of chloroquine against SARS-CoV-1 to block the infection at the earliest stage. Anthony Fauci, who was working at NIH at that time, has to have known for the last 15-18 years that chloroquine and hydroxychloroquine are effective against SARS-Co-V-1, which shares 79% of the viral genome with SARS-CoV-2, the cause of COVID-19 disease.

It is appalling that so many more Americans have died, while the *physician* who is head of the FDA has dawdled on approving HCQ for an urgent new use in this pandemic. Dr. Hahn knows full well the 65-year track record of safety worldwide in [patients of all ages, all ethnic groups, and even pregnant women and nursing mothers](#).

Doctors who are treating COVID-19 patients see lives being saved by cheap, safe, FDA-approved medicines — hydroxychloroquine, azithromycin, doxycycline.

It is crucial to start HCQ *early*, during days 1-7 of symptoms, for these key reasons:

- *Early* treatment is when HCQ works best *two ways*: to *stop viral entry* into our cells, and *block the virus from multiplying* using the cell's machinery.
- The viral load explodes by day 6, and then can trigger an exaggerated inflammatory response called Cytokine Storm, which severely damages critical organs: lungs, kidneys, heart, brain, liver and intestines. This severe complication doesn't occur in all COVID-19 patients, but often is fatal when it does.
- *Early* treatment keeps infected people from spreading the virus to others.
- *Early* treatment is crucial to keep people out of hospitals and off ventilators.
- *Availability of early treatment* is urgently needed to safely re-open businesses, schools, and churches, and help relieve public anxiety and fear.

Front-line doctors have been pleading with the FDA and State officials since March to open access to early treatment with HCQ. The supply of HCQ has been ramped up to handle its use in early treatment of COVID. The Strategic National Stockpile has millions of doses deteriorating in government warehouses that are not being distributed because doctors are prevented from prescribing for outpatients with COVID-19. FDA's misleading statements about HCQ have led to dangerous, unprecedented restrictions on physicians' off-label prescribing rights imposed by state governors, medical boards and pharmacy boards.

Generic HCQ with azithromycin or doxycycline plus zinc is taken by mouth. Total treatment cost is about \$25-\$30 cash price for the 5-7 day course used in COVID-19.

Remdesivir must be given intravenously to patients *in hospital*, at a cost of about \$3,500. Its serious side effects include respiratory failure, the very condition it is supposed to treat. It has shown limited success: It shortened hospital stays by only 4 days and has not been clearly shown to reduce deaths.

Baylor's study showing *prophylactic* benefits for hospital workers is profoundly important, not only for front-line medical workers, but also for law-enforcement officers, paramedics, clergy, dentists/dental hygienists, truck drivers, food-processing workers, teachers, behavioral health professionals, factory and grocery store workers, flight attendants, and many others.

HCQ is a [safe, effective outpatient treatment](#) we have NOW. Physicians and patients need freedom to



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use it. Delays waiting for the “magic bullet” of a vaccine inevitably mean more deaths. Even IF we have a vaccine that works, we *still need therapeutics*, such as HCQ.

Testing is inaccurate and often unavailable, and HCQ dispensing must not be limited to persons with a positive test. Such limits also prevent prophylactic use. Governors and other officials must not be allowed to arbitrarily restrict life-saving HCQ treatment.

Continued shutdowns of businesses, schools, churches, and mandatory mask edicts [are not controlling the epidemic](#). Meanwhile, these orders have eroded our constitutional freedoms, and devastated our economic, psychological, physical, and spiritual well-being.

Dr. Hahn’s FDA is costing more lives with its delay in removing the obstructions it created to prescribing safe, effective early HCQ treatment: deaths directly from COVID-19 and indirectly by destroying livelihoods and distributions of foods, goods, and services required to sustain our lives.

Dr. Hahn, America needs you to act NOW.



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