COMMENTARY

YOUR GOVERNMENT AT WORK

FDA delays on HCQ cost potentially 16,000 lives this month!

Exclusive: Elizabeth Lee Vliet, M.D., compares hydroxychloroquine effectiveness with remdesivir

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Note: Dr. Vliet is a member of the Association of American Physicians and Surgeons, AAPS.

Twenty thousand more Americans have died while the FDA has delayed, since July 1, a new emergency

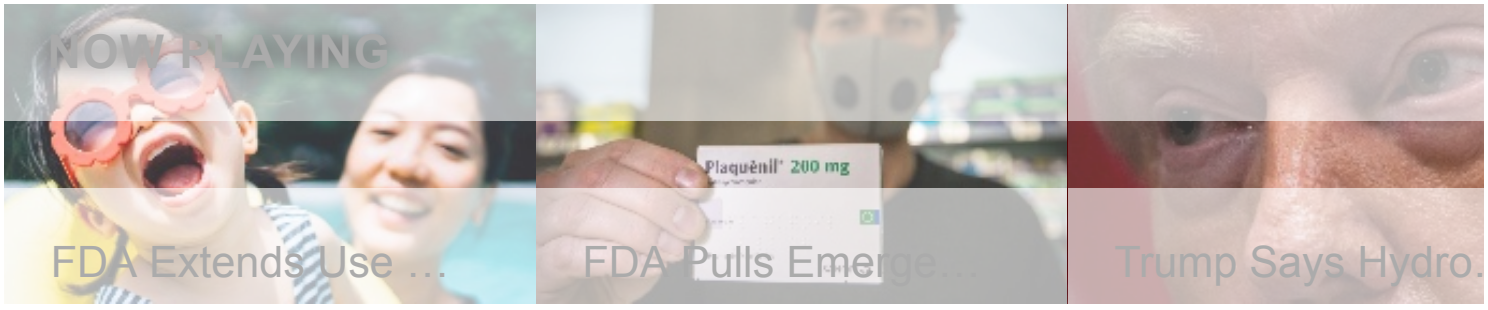
use approval for outpatient use of hydroxychloroquine (HCQ) for COVID-19.

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

seven 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 the 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 p.m. 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. 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 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.

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 keeping 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 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 and 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 distribution of foods, goods and services required to sustain our lives.

Dr. Hahn, America needs you to act NOW.

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Elizabeth Lee Vliet, M.D. is the founder of Vive Life Center independent medical practice in Tucson, Arizona, and Dallas, Texas, specializing in preventive and climacteric medicine with an integrated approach the treatment of women and men with complex medical-endocrine problems from puberty to late life. Dr. Vliet is a 2014 Ellis Island Medal of Honor recipient for her national and international educational efforts in health, wellness, and endocrine aging, recognized in the USA as a powerful patient advocate, and proponent of free market approaches to lower health care costs. Dr. Vliet is a recipient of Voice of Women Award from Arizona Foundation for Women, the author of seven consumer health books and a past Director of the Association of American Physicians and Surgeons (AAPS).