OP ED: FDA DELAYS ON HCQ OUTPATIENT APPROVAL ARE CAUSING DEATHS DAILY

By Elizabeth Lee Vliet, M.D.

20,000 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 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 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.

Author/Contributor short bio:

- Dr. Vliet has been a leader in patient centered, individualized medical care. Since 1986, she has practiced medicine independent of insurance contracts that interfere with patient-physician relationships and decision-making. Dr. Vliet focus is medical freedom and free market approaches to healthcare. Dr. Vliet is the founder of Vive Life Center and Hormone Health Strategies with medical practices in Tucson AZ and Dallas TX, specializing in preventive and climacteric medicine with an integrated approach to evaluation and treatment of women and men with complex medical and hormonal 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 in men and women, and is recognized in the US as a motivational speaker in health and wellness and a powerful patient advocate, proponent of free market approaches to lower healthcare costs. Dr. Vliet is the recipient of Voice of Women Award from Arizona Foundation for Women in recognition of her pioneering advocacy for the overlooked hormone connections in women's health.
- Dr. Vliet's consumer health books include: *It's My Ovaries, Stupid; Screaming To Be Heard: Hormonal Connections Women Suspect-- And Doctors STILL Ignore; Women, Weight and Hormones; The Savvy Woman's Guide to PCOS, The Savvy Woman's Guide to Great Sex, Strength, and Stamina.*
- Dr. Vliet is a past Director of the Association of American Physicians and Surgeons (AAPS), a member of the AAPS Editorial Writing Team on healthcare reform, and a member of International Menopause Society and the International Society for The Study of the Aging Male (ISSAM). She received her M.D. degree and internship in Internal Medicine at Eastern Virginia Medical School, and completed specialty training at Johns Hopkins Hospital. She earned her B.S. and Master's degrees from the College of William and Mary in Virginia.
- Dr. Vliet has appeared on FOX NEWS, Cavuto, Stuart Varney Show, Fox and Friends, Sean Hannity and many nationally syndicated radio shows across the country as well as presented hundreds of Healthcare Town Halls addressing the economic and medical impact of the 2010 healthcare law and free market reforms, as well as seminars and radio shows on healthcare reform, Men's Health and Women's Health.

- Dr. Vliet speaks as an independent physician, not as an official spokesperson for any organization or political party. Dr. Vliet has no financial ties to any health care system or health insurance plan. Her allegiance and advocacy is to and for patients.

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