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Written by **Elizabeth Lee Vliet, M.D.** on May 7, 2020

A Tale of Two Drugs: Money vs. Medical Wisdom

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At the Presidential Briefing on Apr 30, Dr. Anthony Fauci announced early results, prior to peer-review, of one clinical trial using remdesivir, an intravenous (IV) *experimental antiviral medicine* in patients hospitalized with COVID-19. At the "warp speed" currently in vogue for the Fauci-led push to a new vaccine, the *very next day* the FDA issued an Emergency Use Authorization (EAU) for remdesivir to be used in seriously ill hospitalized patients. To announce the emergency approval, President Trump met with the CEO of the drug's manufacturer, Gilead Sciences, in the Oval Office.

Such rapid authorization is quite unusual with the FDA. Unlike the experimental remdesivir with *no prior FDA approval*, hydroxychloroquine (HCQ) required *two months* from reports of successful use in China and South Korea to get the Mar 28 FDA EUA for use in hospitalized COVID-19 patients. HCQ was approved in 1955 for malaria, and later for lupus and rheumatoid arthritis. Over the last 65 years, hundreds of millions of prescriptions have been written for HCQ worldwide.

The EUA for HCQ did not, however, expand its availability but imposed restrictions to prevent non-hospitalized patients from accessing the government's stockpile of the drug. Democrat Governors Cuomo (NY), Sisolak (NV), and Whitmer (MI), then imposed restrictive orders on outpatient use, and all but four states have followed their lead.

In decades of widespread use, HCQ has an impressive safety record. Irregular heart rhythm or damage to the retina occur rarely, usually with high doses used long term. FDA shows only 62 cardiac deaths attributed to HCQ out of more than 50 *million* prescriptions, or 0.000124 percent (1.2 out of each 1 million Rx). Rheumatology guidelines for lupus and rheumatoid arthritis do not even require baseline electrocardiograms before prescribing HCQ, since the risk is minimal.

Approximately $70 million in U.S. taxpayer funding began Gilead's partnership with the U.S. Army, Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH) to develop remdesivir. Initially for treating Ebola, it failed to show benefit and was shelved. If remdesivir is used to treat COVID-19, Gilead shareholders, not the taxpayers, will profit.

Early results of the first clinical trial of remdesivir against placebo in coronavirus were announced at the White House Apr 30, and showed modest benefits, according to *The New York Times*. Surviving patients given remdesivir were discharged 4 days sooner than patients given placebo, though no criteria were given for determining improvement. Death rates were not significantly different. About 25 percent of patients receiving remdesivir had potentially severe side effects, including multiple organ dysfunction, septic shock, acute kidney injury, and low blood pressure. Another 23% showed evidence on lab tests of liver damage.

Gilead's own press release revealed the side effect of acute respiratory failure in 6 percent of patients

in the remdesivir 5-day treatment group, and 10.7 percent of patients in the 10-day treatment group, clearly ominous findings with a drug designed to treat respiratory failure caused by COVID-19.

Dr. Steven Nissen, Cleveland Clinic cardiologist who has conducted dozens of clinical trials, explained to *The New York Times*: *"The disclosure of trial results in a political setting, before peer review or publication, is very unusual. Scientists will need to see figures on harms associated with the drug in order to assess its benefits…. This is too important to be handled in such a sloppy fashion."*

Dr. Michele Barry, a global health expert at Stanford University, expressed concern about Dr. Fauci's overly enthusiastic praise for remdesivir: *"It is unusual to call a drug the 'standard of care' until peer review of data and publication, and before studies have shown benefit in mortality."*

The leading communicable disease specialist in France, Professor Didier Raoult, asked about another odd aspect of the remdesivir trial: *"Could Anthony Fauci explain why the investigators of the NIAID remdesivir trial did change the primary outcome during the course of the project?"* Death as the primary outcome was moved to a secondary outcome, and days to recovery became the primary trial outcome. Changing the primary outcome before trial results are completed is highly unusual and suggests "*p-hacking*"—manipulating the data to get a statistically significant "*p* value."

In contrast, the multi-country compilation of evidence on HCQ and azithromycin in treatment of COVID-19 (updated Apr 27, 2020) has consistently shown that these older medicines prevent infections, significantly reduce severity of illness, reduce viral load and duration of infectivity, reduce number of hospitalizations, reduce ventilator use, and markedly reduce deaths. The data is far beyond "anecodotal," as Dr. Fauci dismissively called it.

Money appears to be trumping medical wisdom in the recent enthusiasm for remdesivir based on just one study with modest results. One naturally wonders whether this may have anything to do with the fact that the "world's largest asset manager," BlackRock, owns the largest share of all Gilead stock at 8.4%. BlackRock's influence in Washington, D.C., is legendary, and it recently was awarded the financial crown jewel of administering the Federal Reserve's $4.5 Trillion COVID-19 loan bail-out program.

Is someone stacking the deck in Gilead's favor? Nineof the experts on the NIH COVID-19 Panel recommending treatment options have disclosed financial support from Gilead. Why did these nine experts not recuse themselves? Did financial conflicts of interest affect the recommendation *against* HCQ, the older, safer, cheaper medicine, and *for* use of remdesivir, the new, expensive experimental medicine, based on weak, not-yet-peer-reviewed evidence?

HCQ has been off patent for decades, is available from a dozen U.S. generic manufacturers, and is also produced in China, India, Israel, and other countries. HCQ costs the patient on average *less than $10* (range 37-63 cents per tablet), for the usual 5-7 day course of treatment. Remdesivir costs upwards of $1,000 per dose, plus the added costs of having to be hospitalized to receive it.

In addition to HCQ's low cost, major pharmaceutical companies (Novartis, Bayer, Teva, and others) have *donated nearly 50 million doses* to the Strategic National Stockpile. Tragically for Americans sick with COVID-19, most of this medicine still sits in warehouses because state governments are interfering with its use in outpatients when it has greatest effect.

Patients' lives are being sacrificed on the altar of financial interests and elite D.C. powerbrokers instead of being entrusted to the judgment of patients' own physicians. We are witnessing the deadly consequences of bureaucrats and governors practicing medicine.

Money over medical wisdom, and politics above patients: two viruses more lethal than COVID-19.