**Testimony before the U.S. Senate Committee on Homeland Security and Government Oversight**
**December 8, 2020**
**Jane M. Orient, M.D.**

Thank you Chairman Johnson, ranking member Peters, and committee members, for allowing me to present the plea of practicing physicians for early and prophylactic home treatment for COVID-19. We urge you to exercise your oversight function over federal agencies that are effectively blocking treatment that could prevent 100,000 needless deaths and stop the crippling fear and the destruction of millions of livelihoods.

On Aug 18, Sen. Ron Johnson, Sen. Mike Lee, and Sen. Ted Cruz asked FDA to "provide any studies and data that informed the FDA's apparent determination that giving HCQ [hydroxychloroquine] or CQ [chloroquine] to infected outpatients within seven days from the onset of symptoms, under a doctor's supervision, will have no clinical effect and may be harmful to the patient."

FDA's tardy response provided no references pertaining to the question. The only logical conclusion is that FDA's extremely influential determination was ***without foundation***.

FDA Commissioner Stephen Hahn has stated, correctly, that FDA has no authority to regulate the practice of medicine and that doctors have the right to prescribe approved drugs for "off-label" uses. But as AAPS has shown in its lawsuit against the FDA, state agencies have used the FDA's language as the basis of regulations to block or forbid prescribing or dispensing HCQ.

In March, HHS Secretary Azar asked BARDA (Biomedical Advanced Research and Development Authority) for a Nationwide Expanded Access Investigational New Drug (IND) protocol for CQ and HCQ in the Strategic National Stockpile. This would have legitimized these drugs for the treatment of COVID-19 outside of a hospital setting based on a physician's judgment. Instead, influential officials transformed the request into an Emergency Use Authorization (EUA) only for hospitalized patients who did not have access to a clinical trial. Instead of *expanding* access, the EUA *restricted* it to patients least likely to benefit. Later, FDA withdrew the EUA, further impeding HCQ use. HHS is presumably still hoarding more than 50 million doses of HCQ in the Strategic Stockpile.

At its interim meeting, the American Medical Association refused to rescind its unprecedented statement calling for physicians to stop prescribing HCQ and CQ for COVID-19 until sufficient evidence becomes available to conclusively illustrate that benefit outweighs harm. Yet, 192 studies (126 peer-reviewed) have been compiled on HCQ, with all showing some benefit when used early, in contrast to the handful of studies on remdesivir or monoclonal antibodies. More than 65 years of experience in hundreds of millions of patients have demonstrated safety—HCQ is safer than most over-the-counter drugs. However, organized medicine and academic physicians such as Dr. Ashish Jha have stated that the evidence is insufficiently "scientific," not meeting the "gold standard" of the randomized controlled trial (RCT).

In fact, most published guidelines rely on lower orders of evidence, and studies with appropriately analyzed data give results identical to RCTs. RCTs are themselves not infallible, as they can be designed to succeed, or to fail. Researchers in two HCQ trials even used toxic or lethal doses. Publication in the most prestigious journals does not assure reliability. Huge

studies that used probably fabricated data, with flaws undetected by peer reviewers or editors, were rushed into publication and had to be retracted by *Lancet* and *NEJM*—not quickly enough to prevent their significant misleading effect.

RCTs are useful for testing, but not for making discoveries, which are often serendipitous. The smallpox vaccine was discovered because GPs were sharing observations ("anecdotes") at the pub. (Farmers who had had cowpox didn't seem to get smallpox.) Or they may result from study of basic science and patient observation. Today's standard treatment of Wegener granulomatosis is based on a 1973 article of nonrandomized patients given cyclophosphamide and steroids—by Dr. Anthony Fauci.

Today's top-down, authority-based "standard of care" for early COVID, promulgated in NIH guidelines, is therapeutic nihilism (except for the new addition of expensive, largely unavailable monoclonal antibodies). This is shocking and unprecedented, but in today's litigious environment, doctors who follow the SOC are protected. Those who dare prescribe HCQ could be fired, removed from insurance panels, investigated, or even delicensed.

Patients nationwide call AAPS in search of a doctor who will treat them. One patient told me he had had his wife drive him all the way to Dallas when all the doctors he knew in Tucson refused to prescribe HCQ. His severe symptoms were relieved within hours.

Doctors report that they can't get HCQ for their nursing home patients.

Quarantines, masks, and lockdowns are not backed by RCTs. They have not stopped the pandemic and are unsustainable. Vaccines are touted as a great hope, but have not been shown to prevent contagion.

What is needed NOW is effective early treatment for COVID-19. HCQ and other safe, long-used agents could be immediately available if government stopped blocking access and deterring use.