

Dr. McCullough Senate Testimony

Thank you Chairman Johnson, Ranking Member Peters, and the members of the Committee for the opportunity to speak to you today about the need for more government attention and support for the early treatment of COVID-19.

As we sit here today the COVID-19 outbreak has the greatest number of currently infected persons, highest hospital census, and all epidemic curves are pointing straight up. We face public panic, hospital over-runs, and significantly higher mortality in the months to come. The highly contagious infection starts out like a cold and takes about two weeks to either resolve or worsen into serious pneumonia. Thus, urgent pandemic response can be viewed as having four pillars as shown on the first chart: the four pillars are: Contagion Control; Early Home Treatment; Late Stage Treatment; and Vaccination. To date, we have tragically ignored the second pillar, Early Treatment, so I am glad today's hearing is focused on it.

Doctors and researchers around the world have learned much about the virus from more than 75,000 scientific reports and 54 million cases where the disease process in three phases is shown on the second chart: first phase is early viral replication, followed by the second phase cytokine storm and the third phase blood clotting. They have innovated with the use of established medications used in various combinations to lessen the intensity and duration of symptoms, cut hospitalizations, and avoid death. I led a team of US and Italian physicians to synthesize what had been learned from this progress and published the first sequenced multidrug protocol for early COVID-19 at home in the August 7 issue of the *American Journal of Medicine*.

What inspired me and my physician colleagues was the need for an immediate compassionate response. Patients wait in fear at home after testing positive, logically thinking they would face a terrifying hospitalization, isolation, and at worst--death. Innovative and courageous physicians knew they had to rapidly use clinical judgment and learn from all sources of evidence to come up with a treatment plan for at-home patients. Protocols focussed on newly diagnosed COVID-19 patients at high risk for hospitalization and death and used over the counter supplements and available generic medications. Telemedicine became the backbone of monitoring, helping track symptoms and adjust treatment.

Our paper drew considerable attention and became a beacon for more innovation and rapid research that have led to subsequent refinement and application to practice.

Unfortunately, the government has not always been very supportive of practicing physicians. Regulatory barriers have blocked access to generic drugs in at-home treatment protocols, and as a result, doctors have been forced to create endless workarounds to get medicine quickly before the virus spirals out of control in their vulnerable patients. Government agencies and medical organizations have admonished doctors for responding to COVID-19 patients outside of the hospital and have actively discouraged attempts to treat patients. Sadly, this has resulted in few patients getting early treatment and no chance of avoiding a hospitalization.

Astonishingly, The National Institutes of Health, in its October 9, 2020, COVID-19 Treatment Guidelines directs doctors to let even high-risk COVID-19 patients, sicken at home for two weeks or

more, and when finally gasping and choking for air, place them in hospital isolation. NIH says that a COVID-19 patient may receive their first medical treatment only if oxygen is given. While the NIH, agency representatives, and academicians stand behind this document as “best science” many practicing physicians, patients, and community leaders view this as medically irresponsible and humanely unconscionable.

I have managed COVID-19 over the spectrum of illness, and I can tell you that I would never allow a high-risk COVID-19 patient to go without treatment, become progressively panicked and unable to breathe, and force them to the hospital, possibly never to see their loved ones again. By the time a patient is that sick, the chances of lung, heart, and organ damage is far too high. Hospital administered medications cannot save all the patients or stop the torrent of hospital complications. Administration of intravenous drugs at earlier stages of COVID exposes others to the virus and is not scalable. The use of oral sequenced multi-drug treatment at home as a national strategy has a reasonable chance of success with acceptable safety. Competent physicians and providers who are called by their patients should be supported by all stakeholders in their efforts to provide compassionate care, reduce the spread of infection, and avoid hospitalization and death.

In summary, I urge the Committee to ask all responsible government agencies to prioritize an “early treatment initiative.” I believe this is the only viable strategy to avoid catastrophic loss of life before natural immunity and vaccination can bring this crisis to a close.