Testimony of Pierre Kory, MD
Homeland Security Committee Meeting: Focus on Early Treatment of COVID-19
December 8, 2020

I want to begin by thanking Senator Johnson and the Committee for this critically needed effort to bring attention to the importance and need for effective early treatment approaches to COVID-19. I am speaking today not only as an individual physician, but also on behalf of my non-profit organization, the Front-Line COVID-19 Critical Care Alliance, made up of some of the most highly published and well-known critical care experts in the world with almost 2,000 peer -reviewed publications in the medical literature as well as over 100 years of bedside clinical experience in ICU's around the country.

Although we, like many, are extremely encouraged by the apparent successes in developing effective vaccines, we also are dismayed at the near complete absence of guidance and research on effective early, at-home, or preventative treatment options apart from vaccines, a reality we find unconscionable. Our hospitals are overflowing with over 100,000 COVID-19 patients admitted, and new record deaths are reported each passing day. It will take months for the vaccine to be distributed to the general public and further time to have sufficient impact in this crisis, so we are here to stress the need for effective early treatment. My organization of critical care specialists have spent the almost nine months tirelessly reviewing the scientific literature to gain insight into this virus and the disease process and to develop effective treatment protocols. All the while, we were working long hours in Intensive Care Units full of COVID patients. I was proud to testify in front of the committee about our MATH+ Hospital Treatment Protocol in May which I would like to mention has had nearly every single component of its combination therapies validated in clinical studies and our paper detailing and reporting on the impacts of the treatment protocol will be published within days in the Journal of Critical Care Medicine.

And so, it is with great pride as well as significant optimism, that I am here to report that our group, led by Professor Paul E. Marik, has developed a highly effective protocol for preventing and early treatment of COVID-19. In the last 3-4 months, emerging publications provide conclusive data on the profound efficacy of the anti-parasite, anti-viral drug, anti-inflammatory agent called ivermectin in all stages of the disease. Our protocol was created only recently, after we identified these data. Nearly all studies are demonstrating the therapeutic potency and safety of ivermectin in preventing transmission and progression of illness in nearly all who take the drug.

Before proceeding, I want to bring attention to two critical deficits in our national treatment response that has made this hearing necessary in the first place. Besides the early interest and research into hydroxychloroquine, we can find no other significant efforts to research the use of any other already existing, safe, low-cost therapeutic agents. Seemingly the only research and treatment focus that we have observed on a national scale is with novel or high-cost pharmaceutically engineered products such as remdesivir, monoclonal antibodies, tocilizumab, with all such therapies costing thousands of dollars. This is consistent with conclusions drawn by a physician consulting to Congress about Covid-19 when she concluded, "There is a pervasive problem on the Hill with how we prove the value of a low cost treatment." Another barrier has been the censorship of all of our attempts at disseminating critical scientific

information on facebook and other social media with our pages repeatedly being blocked. Finally, we believe the lack of clinical experts on the existing task forces is further hindering progress on identifying effective therapeutics. We can identify almost no members with any similarities to the skill set, clinical knowledge base, and patient care experience to our group of expert clinicians. Existing members all seem to be either physician leaders of large health care organizations or have research backgrounds. Although many must have had some bedside experience in the care of patients in their careers, there seem to be almost none that have been at the bedside of COVID- 19 patients in any appreciable fashion during this pandemic. Expert clinician panels such as ours have large amounts of valuable insights and wisdom and we are extremely pleased to share our recent discovery of the immense potency of Ivermectin in COVID-19.

Ivermectin is highly safe, widely available, and low cost. Its discovery was awarded the Nobel Prize in medicine, and is already included on the WHO's "World's List of Essential Medicines." We now have data from over 20 well-designed clinical studies, ten of them randomized, controlled trials, with every study consistently reporting large magnitude and statistically significant benefits in decreasing transmission rates, shortening recovery times, decreasing hospitalizations, or large reductions in deaths. This clinical data is also supported by multiple basic science, in-vitro and animal studies. Our manuscript, completed one week ago, is already out of date due to the near daily emergence of new, positive ivermectin studies. The manuscript has been posted on the medical pre-print server OSF (Open Science Foundation) and can be downloaded here https://osf.io/wx3zn/ or on our organization's website, www.flccc.net. A more updated meta-analysis and review authored by a group of Ph.D. researchers and scientists includes all ivermectin studies as of December 4th, 2020 and can be found on the c19study.com website here: https://ivmmeta.com/

These data show that ivermectin is effectively a "miracle drug" against COVID-19. The magnitude of the effect is similar to its Nobel prize-worthy historical impacts against parasitic disease across many parts of the globe. It should be noted that that Merck, the pharmaceutical company whose scientists helped discover ivermectin, has from the first availability of the drug, donated hundreds of millions of doses for free to support the WHO parasite eradication programs. We believe a similar initiative is needed to eradicate the globe from the scourge of COVID-19. Our group held a press conference this past Friday, December 4th at the United Memorial Medical Center in Houston, issuing a "Call to Action." We made a formal request to our national and global health care agencies and leaders to rapidly assess the growing scientific evidence on ivermectin and update treatment guidelines accordingly. We noted that the last treatment recommendation on ivermectin is from August 27th where on the NIH website, they recommended that ivermectin only be used in clinical trials and they based that recommendation as "expert opinion" only given the lack of clinical studies at the time. There is now a wealth of studies reporting efficacy of ivermectin. In that press conference, we called for a rapid and updated review of this evidence in the hopes a treatment recommendation could be made and thus saving many thousands of lives, quickly. The press conference was broadcast via the Associated Press and Univision to nearly every country globally. The Health Ministry of the Government of Uganda is currently reviewing our manuscript with the intent of incorporating our treatment protocol into a national treatment guideline. It is now 48 hours later and, although it has been shared widely, we have not heard from:

- Any national news radio, newspaper or television station.
- Any single member of any U.S health care agency.
- One notable exception is the interest shown by the Health Ministry of the Government of Uganda as they are currently reviewing our manuscript with the intent of incorporating our treatment protocol into a national treatment guideline. We know of no similar effort by any US health care agency at this time. (This point can be omitted if necessary)

This is unacceptable as we have documented evidence that leading members of Operation Warp Speed, including Janet Woodcock had planned to watch our press conference as have multiple members of the CDC and military as well as journalists from major national news outlets who watched. Again, 48 hours later and no contact from any health official or major news outlet. We are still hopeful to hear soon from the government and media.

I now will briefly review and summarize the emerging scientific data demonstrating the efficacy of ivermectin in the treatment of COVID-19

<u>Data Supporting Ivermectin as a Potential Global Solution to the COVID-19 Pandemic</u>

Ivermectin is already eradicating coronavirus infections in multiple regions of the world. Dozens of studies demonstrate its efficacy from studies done from " bench to the bedside" as follows:

1) Since 2012, multiple in-vitro studies have demonstrated that Ivermectin inhibits the replication of many viruses, including influenza, Zika, Dengue and others (*19-27*).
2) Ivermectin inhibits SARS-CoV-2 replication, leading to the absence of nearly all viral material by 48h in infected cell cultures (*28)*.
3) Ivermectin has potent anti-inflammatory properties with in-vitro data demonstrating profound inhibition of both cytokine production and transcription of nuclear factor-κB (NF-κB), the most potent mediator of inflammation (*29-31*).
4) Ivermectin significantly diminishes viral load and protects against organ damage in multiple animal models when infected with SARS-CoV-2 or similar coronaviruses (*32, 33)*.
5) Ivermectin prevents transmission and development of COVID-19 disease in those exposed to infected patients (*34-36,54,88*).
6) Ivermectin hastens recovery and prevents deterioration in patients with mild to moderate disease treated early after symptoms (*37-42,54*).
7) Ivermectin hastens recovery and avoidance of ICU admission and death in hospitalized patients (*40,43,45,54,63,67*).
8) Ivermectin reduces mortality in critically ill patients with COVID-19 (*43,45,54*).
9) Ivermectin leads to striking reductions in case-fatality rates in regions with widespread use (*46-48*).
10) The safety of ivermectin is nearly unparalleled given its near nil drug interactions along with only mild and rare side effects observed in almost 40 years of use and billions of doses administered (*49*).
11) The World Health Organization has long included ivermectin on its "List of Essential Medicines" (*50*).

A more detailed summary of ivermectin's existing clinical studies in the prevention, early, and late treatment phases of COVID-19 follows below. All studies are positive, with considerable magnitude benefits, with the vast majority reaching strong statistical significance. Note that in the below summary, RCT's refers to "prospective randomized controlled trials" where patients were assigned randomly to a planned treatment with ivermectin or placebo and OCT's refer to "observational controlled trials" where ivermectin treated patients were compared to concurrently or previously treated patients that did not receive ivermectin.

1) **Prevention Studies**: Six studies, 4 RCTs, 2 OCT's with total patients included now over 2,400 patients – all showing near-perfect prevention of transmission of this virus in people with unprotected exposure to COVID-19 patients compared to high measured rates of transmission in those that did not receive ivermectin treatment.

2) **Early treatment:** Three RCT's and multiple large case series –patients in these studies total over 3,000. All studies show either a considerable, statistically significant reduction in the number of patients who deteriorated into hospital or ICU or they reported faster recovery from all symptoms when treated with ivermectin.

3) **Hospital Treatment**: Four large RCT's, 4 well designed OCT's, total amount of patients studied approach 3,000, and almost all show large and statistically significant reductions in mortality when treated with ivermectin.

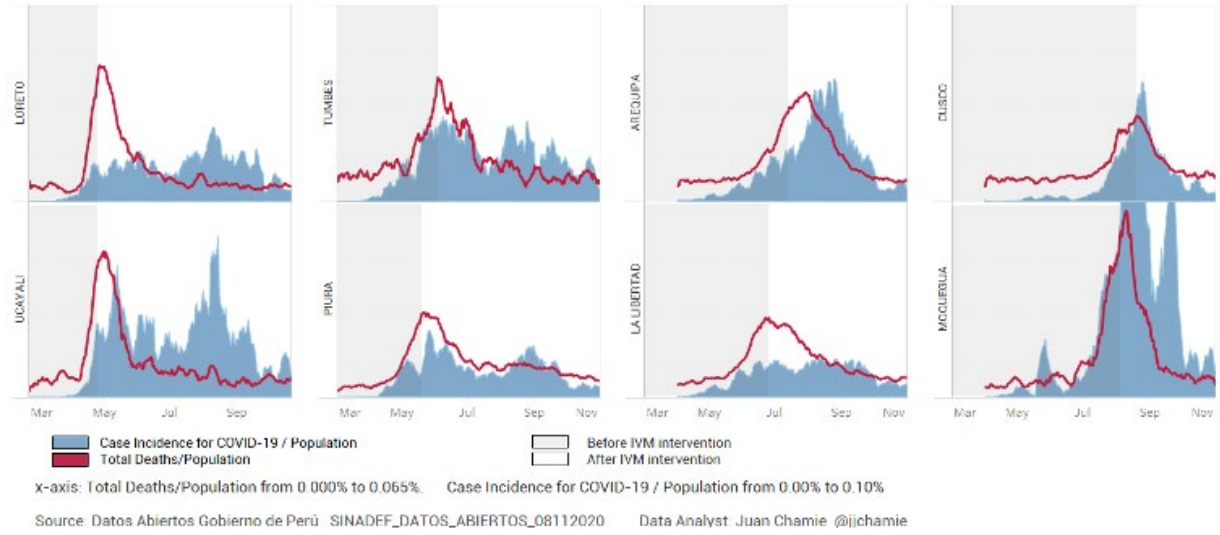
Table 1 below summarizes the existing clinical trials data as of November 24, 2020; however, the number of positive studies has since increased

Treatment time	Number of studies reporting positive results	Total number of studies	Percentage of studies reporting positive results
Early treatment	3	3	**100%**
Late treatment	12	12	**100%**
Pre-Exposure Prophylaxis	4	4	**100%**
Post-Exposure Prophylaxis	2	2	**100%**
All studies	21	21	**100%**

And now, most importantly, I will present the increasing amounts of epidemiologic analyses finding that COVID-19 is being eradicated in many regions of the world that have adopted the widespread use of ivermectin. The two analysts that are part of our Alliance organization are Juan Chamie and Alan Cannell. Their data sources and analyses can be made available to any health authority on request. We have even more population-wide impacts of ivermectin examples included on our website. In my brief allotted time, I can only present a minority, but I ask that all visit our website to review their work showing that ivermectin can control the spread and mortality of this pandemic. Some of these examples are as follows:

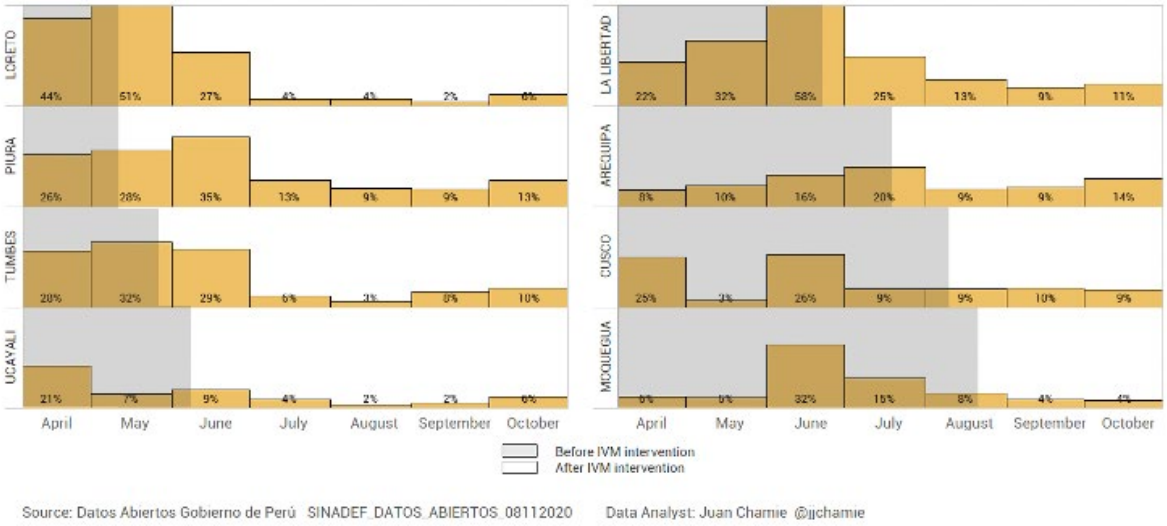
Figure 1. Death Rates in Patients over 60 after Peruvian states began mass distribution of Ivermectin (shaded areas on each graph reflect the time period before ivermectin distribution began.)

In all eight states, the peak in deaths occurred at the time of distribution, followed by rapid and sustained reduction in both case counts and death rates in patients over 60 years old.



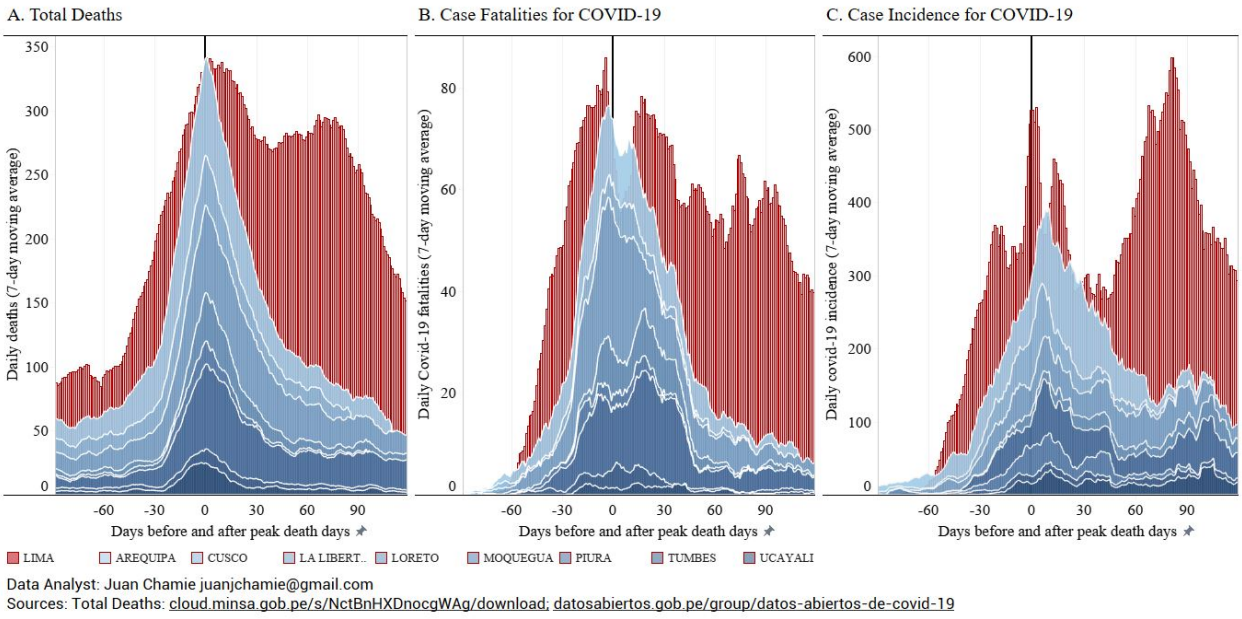
Similarly, the case fatality rates among these 8 states can be seen below in Figure 2.

Figure 2. Case fatality rate decreases among patients over 60 in eight Peruvian states after deploying mass ivermectin treatment

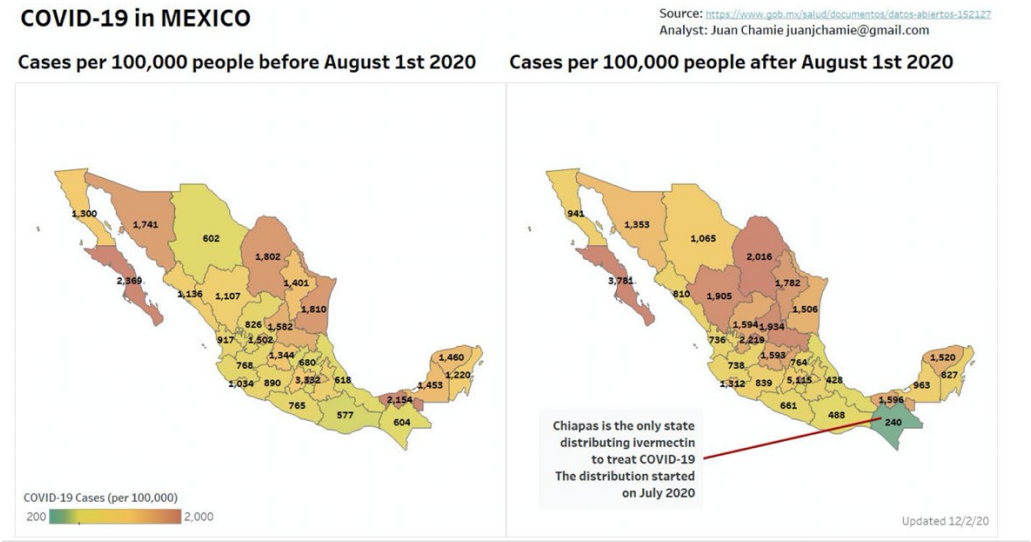


The figure below presents the most dramatic example of ivermectin's population effects by comparing the case counts and deaths with the largest city in Peru where they did not adopt or distribute ivermectin.

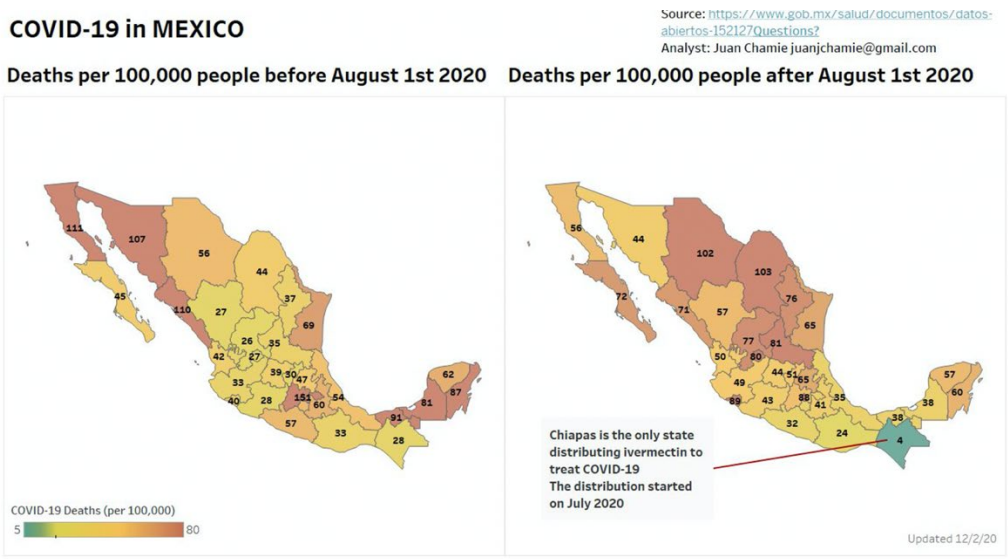
Total deaths, case incidence and case fatality for COVID-19 in populations older than 60 years old for eight states deploying early mass ivermectin treatments vs Lima in Peru.



Another example can be seen in data from the southern Mexico state of Chiapas, the only state where Ivermectin was incorporated into treatment guidelines. This treatment was adopted on August 1st, 2020. In the maps shown below, you can see that the number of cases in Chiapas was 606 cases per 1000,000 people before August 1st and is now decreased by nearly two thirds to 240 cases per 1000,000. Note below that no other state has recorded decreases of this magnitude, with many states instead showing a large increase in case counts since August 1.

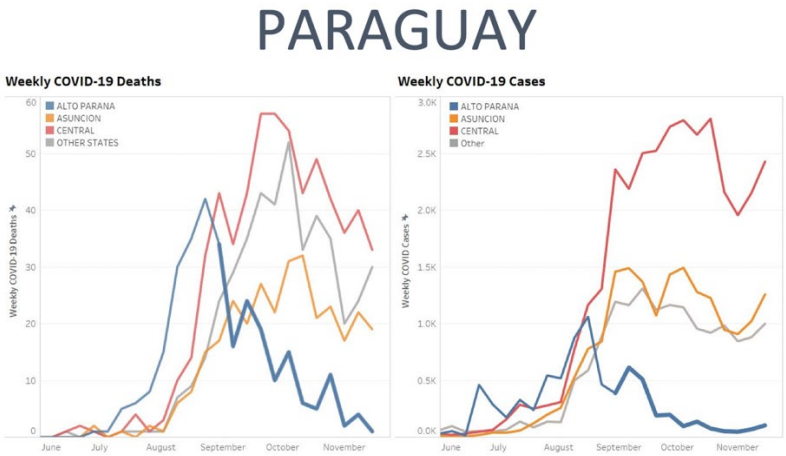


The below maps show the same findings as above in relation to death counts. Chiapas is now recording the fewest deaths per 100,000 people of any state in Mexico.



Another compelling example can be seen from the data compiled from Paraguay, again performed by analyst Juan Chamie who noted that the government of the state of Alto Parana had launched an ivermectin distribution campaign in early September. Although the campaign was officially described as a “de-worming” program, this was interpreted as a guise by the regions governor to avoid reprimand or conflict with the National Ministry of Health that recommended against use of ivermectin to treat COVID-19 in Paraguay (*74*). The program began with a distribution of 30,000 boxes of ivermectin, and by October 15, the governor declared that there were very few cases left in the state as can be seen in Figure 5 below (*48,75*).

Figure 5. Paraguay – COVID-19 case counts and deaths in Alto Parana (blue) after Ivermectin distribution began (bolded blue line) compared to other departments (*48,76*).



Numerous studies have consistently positive reported large magnitudes of benefits in all disease's phases but - with the most significant public health impact in the prevention of transmission. On this compelling evidence, we recommend ivermectin's administration for both prophylaxis in all high-risk patients as well as in the early and late phases of the disease. If this were to occur nationally and globally, we predict that, like in many of the regions shown above, the pandemic will end, the economy can re-open, social interactions and activity can resume, and life can normalize. The expected impact will allow our nation to grow and focus on the multitude of other pressing problems facing our society.

People are dying at unacceptable and untold rates. I am a lung and ICU specialist, and all I do right now is take care of COVID-19 patients dying of breathlessness in ICUs. By the time they get to the ICU, it is nearly impossible to save most patients. They simply cannot breathe – all are attached to high flow oxygen delivery devices or non-invasive ventilator masks strapped tight to their faces or they are placed in sedative comas and paralyzed so that mechanical ventilators can do the work of breathing for them. They are dying even with our armory of modern medicines and machines. And they are dying slowly. I have never witnessed a form of respiratory failure where patients can be consistently kept alive for weeks before finally succumbing. Besides the horrific amount of suffering by the patients, their families are also getting traumatized and destroyed. I have seen so many vibrant fathers and mothers of families die in my ICU. And most importantly, the majority are minorities, black and latino's, many of them poor and often without access to private doctors for early treatment. I have never seen such a disparity in any other illness I treat. Recognize that the amount of evidence that I have presented far exceed the level required for a compassionate use authorization as defined by the FDA. That happened for Remdesivir, a drug with far far less supportive evidence and much much higher cost. Why cant it happen for ivermectin given this level of evidence? How many more trials have to be done when our manuscript details results from over 20 with over ten of them randomized? We are in a pandemic, we are at war, stop pretending this is peacetime where we are conducting business as usual, the NIH must rapidly review the data and make a recommendation. That is not asking for much. The doctors and nurses are tired and getting burnt out. We must get it to stop. I don't know how much longer I can do this, especially knowing that it will all be needless death from

here on out, given there is a readily available solution. A solution that cannot be dismissed or ignored. There is a critical need to inform health care providers in this country and the world. The leadership of our governmental health care agencies has a great responsibility here. All we ask is for the NIH, the CDC, and the FDA to conduct a rapid review of the literature reviewed in this presentation and provide guidance to the country's health care providers. We have already taken steps to do so by developing the I-MASK prophylaxis and early outpatient treatment protocol, centered around the use of ivermectin. Beyond the evidence presented in support of ivermectin, each component of the protocol also has data showing efficacy either in COVID-19 or in similar respiratory viral illnesses. We include it below for reference.

In conclusion, the global impact of the COVID-19 pandemic on both lives and economic despair is in front of all. COVID-19, and the inflammatory response to this virus, ravages damage to the body in a way that we, healthcare providers in the front-line, have never seen before. The heavy burden placed on society, legislators, governmental and medical organizations is unprecedented. We are worried that if our call to action is not followed through, confidence in our health care leaders and agencies will be irreparably tarnished. Inaction in front of mounting evidence of safety and effectiveness during a catastrophic pandemic may also compromise widespread vaccination support. We will look back to the impact that actions versus inaction had on the US and the globe two months from now. If we do nothing, the present trend will continue. History will judge. The American people will cry for answers or will praise the courage of those elected to represent their interest.

Table 2. I-MASK+ Prophylaxis & Early Outpatient Treatment Protocol for COVID-19

PROPHYLAXIS PROTOCOL		
MEDICATION	RECOMMENDED DOSING	
Ivermectin	*Prophylaxis for high-risk individuals*:	0.2 mg/kg* dose on day 1 and day 3, then one dose/month
	*Post COVID-19 exposure prophylaxis***:	0.2 mg/kg dose on day 1 and day 3
Vitamin D3	1,000–3,000 IU/day	
Vitamin C	1,000 mg twice daily	
Quercetin	250 mg/day	

Melatonin	6 mg before bedtime (causes drowsiness)
Zinc	50 mg/day of elemental zinc

Table 2. I-MASK+ Prophylaxis & Early Outpatient Treatment Protocol for COVID-19

EARLY OUTPATIENT TREATMENT PROTOCOL* **	
MEDICATION	RECOMMENDED DOSING
Ivermectin	0.2 mg/kg x 1 dose on day 1 and day 3
Vitamin D3	4,000 IU/day
Vitamin C	2,000 mg 2–3 times daily and **Quercetin** 250 mg twice a day
Melatonin	10 mg before bedtime
Zinc	100 mg/day elemental zinc
Aspirin	325 mg/day (unless contraindicated)

* Example for a person of 50 kg body weight: 50 kg × 0.15 mg = 7.5 mg (1 kg = 2.2 lbs.)= 2.5 tablets (3mg/tablet). See table 6 for weight-based dose calculations

** To use if a household member is COVID-19 positive, or if you have had prolonged exposure to a COVID-19+ patient without wearing a mask

*** For late phase – hospitalized patients – see the FLCCC's "MATH+" protocol on www.flccc.net

ϕ Take on an empty stomach with water

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