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Date: 08/30/2021

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Gangemi, Michael T.

Unity Hospital, an Affiliate of Rochester Regional Health

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MONROE COUNTY CLERK

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF MONROE

MICHAEL T. GANGEMI,
Plaintiff/Petitioner,

v.

UNITY HOSPITAL, AN AFFILIATE OF ROCHESTER REGIONAL HEALTH,
Defendant/Respondent.

INDEX No.: E2021007156

AFFIRMATION OF PIERRE KORY, M.D.

I, Pierre Kory, M.D., do hereby affirm, pursuant to Rule 2106 of the New York Civil Practice Law and Rules, under the penalties of perjury, as follows:

1. I am a pulmonary and critical care doctor of medicine and am board certified by the American Board of Internal Medicine in Internal Medicine, Pulmonary Diseases, and Critical Care Medicine. I am licensed to practice medicine in Wisconsin. From 2008 to 2015, I was an attending physician providing critical care medicine, inpatient pulmonary consultation, and outpatient pulmonary consultation services at Mount Sinai Beth Israel Medical Center in New York City. From 2015 to 2020, I was an Associate Professor at the University of Wisconsin where I served as the Medical Director of the main medical-surgical Intensive Care Unit (ICU) called the Trauma and Life Support Center and was also the Critical Care Service Chief. I am considered a world expert and pioneer in the field of critical care ultrasonography as I am the senior author of a best-selling textbook on the topic which has been translated into six languages.

2. Since the onset of COVID-19, I have worked in numerous "hot spots" around the United States, including Mount Sinai Beth Israel in New York City, Greenville Memorial in South Carolina, Aurora St. Luke's Medical Center in Milwaukee, Wisconsin, and the University of Wisconsin. I am considered an expert in the pathophysiology and management of COVID-19, having published ten increasingly cited papers on the disease and its clinical management. Further, I am a member of an expert panel of highly-published thought leaders in critical care medicine that formed in March 2020, the Front Line COVID-19 Critical Care Alliance (FLCCC Alliance), with the sole intent of developing the most effective treatment protocols for COVID-19. Our review paper on ivermectin, of which I am the first author, concludes that ivermectin should be immediately and systematically deployed in the prevention and treatment of COVID-19.
3. The paper is published, having passed peer review at the American Journal of Therapeutics. The peer reviewers included two career U.S. Food and Drug Administration (FDA) scientists, a senior scientist at the Defense Threat Reduction Agency, and an expert ICU clinician – all the reviewers' identities, and their reviews, are publicly available.
4. I serve as president and chief medical officer of the FLCCC Alliance, a non-profit organization, which regularly updates its specific protocols regarding COVID-19. The FLCCC Alliance developed the MATH+ Protocol (most recently updated on August 27, 2021) to provide specific guidance for the treatment of the pulmonary phase of COVID-19 with the goal of reducing hospital mortality.

5. The FLCCC Alliance's protocols address preventive and propholaxis therapies for COVID-19; post-exposure for symptomatic patients at home; treatment of mildly-symptomatic patients who are hospitalized on a floor/ward in a hospital; patients admitted to the ICU (the MATH+ Protocol); an approach to treating patients with severe life-threatening COVID-19 Organizing Pneumonia; and, a protocol to address so-called "long-haulers' syndrome," a condition in which persons who have had COVID-19 continue to suffer debilitating long-term effects of the virus.
6. On May 6, 2020 and December 8, 2020, I testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs at hearings regarding prevention and early out-patient treatment of COVID-19.
7. A true and correct copy of my curriculum vitae, which contains a more detailed and accurate summary of my education, training and experience is attached hereto.
8. Although I have not reviewed the medical records of Plaintiff/Petitioner Michael T. Gangemi and make no recommendation as to his treatment, I submit this Affirmation in support of the efficacy of ivermectin to treat even critically-ill, hospitalized COVID-19 patients in the ICU, and those hospitalized patients who no longer test positive for the virus, but still require mechanical ventilation and supportive therapies.
9. As my colleagues in the FLCCC Alliance and I state in our COVID-19 Protocols, there is currently no "Magic-bullet" or cure for COVID-19, however, "a number of therapeutic agents have shown great promise for both the prevention and treatment of this disease, including ivermectin,Vitamin D, quercetin, melatonin, Vitamin C, fluvoxamine and corticosteroids. It is likely that no single drug will be

effective in treating this complex disease and that multiple drugs with different mechanisms of action used in specific phases of the disease will be required. Furthermore, a growing body of evidence suggests that many of these agents may act synergistically in various phases of the disease."

10. Ivermectin has significant anti-viral and anti-inflammatory properties. Studies show that one of its several anti-viral properties strongly binds to COVID-19's spike protein, keeping the virus from entering the cell. These effects, along with its multiple abilities to control inflammation, inform the markedly positive trial results already reported.
11. In a patient who has suffered COVID-19 and has developed the severe condition called viral induced, fulminant organizing pneumonia (for reference, see my paper, Kory, Kanne, SARS-CoV2 Organizing Pneumonia) leading to respiratory failure with mechanical ventilation, generally, on or about day 10, viral replication can no longer be identified and it is a condition mostly characterized by what is called the host inflammatory response. Ivermectin has multiple anti-inflammatory and immune-modulatory properties and that is why its efficacy is consistently being observed in later phases of the disease beyond the viral replicative stage.
12. As I stated in my paper: The in-vitro properties of ivermectin as an inhibitor of inflammation are far more clinically potent than previously recognized. The growing list of studies demonstrating the anti-inflammatory properties of ivermectin include its ability to inhibit cytokine production after lipopolysaccharide exposure, downregulate transcription of NF-kB, and limit the production of both nitric oxide and prostaglandin.

13. One of the most compelling studies showing the dramatic impacts of ivermectin in late phase, intubated patients was that of Broward County, Florida by Jean-Jacques Rajter, M.D., *et al*.

14. In a system of four hospitals there, a large propensity matched trial of hospitalized patients with COVID-19 was conducted between March 15, 2020 and May 11, 2020. The results, published in the major American medical journal, *Chest*, in October 2020, showed a decrease in mortality in the most severely ill hospitalized patients who received ivermectin. Dr. Rajter, *et al*., studied 280 hospitalized patients using a sophisticated, and highly accurate propensity-matched design. One hundred seventy-three (173) patients were treated with ivermectin and in both unmatched and propensity-matched cohort comparisons, similar, large, and statistically significant lower mortality was found among ivermectin-treated patients (15.0% vs. 25.2%, P =0.03). Furthermore, in the subgroup of patients with severe pulmonary involvement, mortality was profoundly reduced when patients were treated with ivermectin (38.8% vs. 80.7%, P =0.001).

15. In my over 10 months' experience using ivermectin, along with my large network of COVID-19 expert clinicians, I am unaware of a single negative sequelae of late treatment with ivermectin, nor is there any pathophysiologic or pharmacologic reason to expect such a response.

16. Based on my knowledge, education, training and experience with COVID-19, as well as on my extensive research in the compiling of the existing, up-to-date evidence base supporting the use of ivermectin, in the form produced for human consumption, I am generally considered the foremost expert on ivermectin in the treatment of COVID-19 in the world. The current evidence base now includes 63

controlled studies with 31 randomized controlled trials, with only 3 suggesting a lack of benefit, thus, the near entirety of the trials' evidence report benefits in at least one important clinical outcome, with many finding statistically significant benefits. Moreover, the mortality benefits are beyond striking, even in the late phase of the disease, such as that found in the propensity matched study from Broward County, Florida by Dr. Rajter, *et al*.

17. The conclusions of the FLCCC Alliance's review paper on ivermectin that the existing data indicates a significant mortality benefit is also supported by multiple other, very recent, expert research groups, including a group from Kitsato University in Tokyo, Japan, senior authored by Professor Satoshi Amura, Nobel Prize Winner in Medicine in 2015. Other posted and published review papers calling for adoption of ivermectin come from the United Kingdom, Spain, and Italy. One large randomized controlled trial has since been retracted and removed from these reviews, however, this did not affect the statistically significant conclusions of the meta-analyses as well as our own review.
18. Further, the reports most relevant to public health officials are from the national and regional health ministries that employed "test and treat" programs with ivermectin:

- Mexico City – The Mexican Institute of Social Security (Instituto Mexicano del Seguro Social (IMSS)) Health Agency compared over 50,000 patients treated early with ivermectin to over 70,000 not treated and found <u>up to a 75% reduction in need for hospitalization;</u>

- La Pampas, Argentina – Health Ministry compared over 2,000 patients treated early with ivermectin to over 12,000 without treatment and found a 40% reduction in hospitalization and 35% less ICU hospitalization or death in older patients;
- La Misiones, Argentina – Health Ministry just analyzed the first 800 of 4,000 ivermectin treated patients and compared to the rest of the population over the same time period, they found a 75% reduction in the need for hospitalization and an 88% reduction in death.

19. In the United States, the National Institute of Health (NIH) revised its position on the use of ivermectin in the treatment of COVID-19 from "against" to "neutral" in January 2021. NIH guidelines find that "there is insufficient data to recommend for or against use" of ivermectin. This is important to note because (1) such a recommendation is identical to that in support of the use of convalescent plasma and monoclonal antibodies, both widely used medicines throughout the entire U.S. health system throughout the pandemic, thus instead, would similarly suggest a physician's decision to use the medicine depending on clinical context and a risk/benefit analysis; and (2) in the NIH recommendation, they identify and review multiple trials supporting use, as do the recommendations by the World Health Organization (WHO) and the Infectious Diseases Society of American (IDSA)**.** In fact, the IDSA review includes the following statement, "the available evidence consisted mostly of positive trials of smaller size." Further, increasing numbers of national health ministries around the world have incorporated ivermectin into their country's treatment guidelines, including India, Mexico, Czech Republic, Slovakia, Bulgaria, South Africa, and Zimbabwe.

20. Public health agencies and medical societies have historically issued recommendations only after they have devoted the resources and time to allow for sufficient evidence to be compiled reviewed, and assessed, with these efforts largely relying on the peer-reviewed literature to do so. As an expert in the most current body of peer-reviewed literature, it must be noted that as of the date this Affirmation was signed, that the most current expert reviews from UK, Japan, Italy, Spain and the U.S. all find evidence for and recommend widespread use of ivermectin in treating COVID-19.
21. As for the safety of ivermectin, an expert review by one of the most prominent toxicologists in the world, after reviewing 350 studies over several decades and almost 4 billion doses administered worldwide, found that "the incidence of severe adverse events are unequivocally and exceedingly rare.
22. Further, based on our group's analysis of the reported adverse event profiles in pharmaceutical databases, including the United States' Vaccine Adverse Event Reporting System (VAERS) and the WHO's Vigiaccess, we instead find that ivermectin is actually one of the safest medicines in history, and has been distributed widely by the WHO across many continents to children, pregnant women and adults, and is thus on the WHO's List of Essential Medicines. Its safety is unparalleled, and in the setting of a patient in severe critical illness, any risk/benefit analysis would strongly indicate that the provision of this medicine should be undertaken immediately.

I declare under the penalty of perjury of the laws of the State of Wisconsin that the foregoing is true and correct.

Executed on August 27, 2021 at Madison, Wisconsin.

Pierre Kory

Pierre Kory, M.D., M.P.A.