VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF NORFOLK

DR. PAUL E. MARIK,

Plaintiff,

v. **Case No.: CL21_____**

SENTARA HEALTHCARE,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR TEMPORARY INJUNCTION

Critically ill patients at Sentara Norfolk General Hospital (the "Hospital"), operated by the Defendant Sentara Healthcare ("Sentara"), are dying unnecessarily and unjustifiably.

In the fall of this year, Sentara flatly banned the use against COVID-19 of certain safe, life-saving, FDA-approved medicines, thereby violating the rights of COVID patients to be informed of, and to receive, treatment determined to be appropriate for them by their attending physician, Plaintiff Dr. Paul E. Marik, the Director of the Hospital's Intensive Care Unit ("ICU") and a world-renowned critical care expert.

From October 25-31, 2021, Dr. Marik was the ICU's attending physician and had to watch helplessly as seven COVID patients grew increasingly and desperately ill, never given the opportunity to learn of or be treated with potentially life-saving medicines—medicines used against COVID by doctors around the world and that have been shown in numerous studies to reduce mortality.[1] Of the seven COVID patients who came under his care in this

[1] The evidence submitted herewith shows that the COVID protocol Dr. Marik recommends have saved the lives of many other hospitalized COVID patients under Plaintiff's and two other ICU physician-declarants' critical care (Marik Dec. ¶¶ 13-15, 20-22; Varon Dec. ¶¶ 4-12; Kory Dec. ¶ 5), and their use is well-supported by the relevant literature. *See infra* Point III(C).

period, four died. The remaining three will likely die as well. (Marik Dec. ¶¶ 6-7.) In stark contrast, doctors in other hospitals using the protocol of COVID medicines that Dr. Marik favors have achieved mortality rates of 4-7%. (Varon Dec. ¶¶ 8-9.)

On November 15, 2021, Dr. Marik will resume his monthly one-week-in-four duties as attending physician at the ICU, where he will again be responsible for the care of critically ill COVID patients. (*Id.* ¶8.) Without this Court's immediate intervention, these patients too will be denied their right to choose life-saving medicines their attending physician considers appropriate for them. Because Sentara's prohibition of these medicines is causing needless deaths, because it violates patients' right to informed consent, because it contravenes Virginia's Health Care Decisions Act, and because it flies in the face of Virginia public policy as expressed in its Right to Try statute, Plaintiff begs this Court to restrain Sentara from enforcing it.

Dr. Marik is not asking this Court to practice medicine. He is not asking the Court to tell any doctor what he or she should or should not do. He is not asking the Court to make a medical determination of any kind—for example, of what the standard of care for COVID patients ought to be. Instead, Dr. Marik is asking only that Sentara respect—as the law requires Sentara to respect—his and his critically ill patients' rights to discuss and decide to use FDA-approved, potentially life-saving medicines that their attending physician deems medically appropriate.

STATEMENT OF FACTS

Plaintiff Dr. Paul Marik is the Director of the Intensive Care Unit at Sentara Norfolk General Hospital and one of the world's leading critical care specialists. He is the author of over 500 published peer-reviewed articles, eighty book chapters, and four books on critical

care topics. (Marik Dec. ¶¶ 2-3.) His findings and recommendations on sepsis and pulmonary thrombosis have influenced standard-of-care treatment guidelines around the world. His work has been cited over 44,000 times in peer-reviewed publications. He won the American College of Physicians' National Teacher of the Year award in 2017. (*Id.* at ¶3; Kory Dec. at ¶¶ 6-7.) He has never previously been a plaintiff (or defendant) in a legal proceeding; no patient in decades of practice has ever filed a complaint against him. (Marik Dec. ¶ 5.)

Over the past eighteen months, Dr. Marik has also become a world-leading authority on the pathophysiology and treatment of COVID—indeed perhaps the foremost COVID critical care specialist alive. (Kory Dec. ¶¶ 8-12.) He has published 15 articles in peer-reviewed medical journals, and delivered 11 invited national and international lectures, on various COVID topics, with a focus on clinical treatment. (*Id.*) A review paper on COVID treatment for which Dr. Marik served as senior author has an altimetric popularity rank of #38 out of the last 19,278,000 scientific papers published on any topic. (*Id.*)

In 2020, Dr. Marik, together with other critical care specialists, co-founded a nonprofit charitable organization known as Front Line COVID-19 Critical Care Alliance ("FLCCC"). Their purpose was to "gather, research and share information among health care professionals and the public." They "had no pre-set agendas or therapies in mind, and still don't;" their "singular purpose is to meet this disease head-on and to save lives." (Varon Dec. ¶5.)

Together with these colleagues, Dr. Marik began analyzing, devising, and publicizing best-practice treatment regimens for the novel, deadly coronavirus. Many of the treatments they pioneered have now become standard of care. For example, Dr. Marik and his

colleagues were the first in the world to use high dose steroids against COVID; today, it is standard of care. Dr. Marik and his colleagues were also early users of blood thinners (Heparin); it is now standard of care as well. (Marik Dec. ¶ 20.) Today, the FLCCC's multi-drug regimen for COVID, known as the MATH+ Protocol, consists of (in alphabetical order): Ascorbic Acid (Vitamin C); Atorvastatin; Bicalutamide; Cyproheptadine ; Dutasteride; Famotidine; Finasteride; Fluvoxamine; Ivermectin; Melatonin; Methylprednisolone; Nitazoxanide; Statin; Therapeutic Plasma Exchange; Thiamine; Vitamin D; and Zinc. (*Id.*)

The MATH+ Protocol is used by physicians all over the world in the fight against COVID, and data indicate that it is saving lives. (Kory Dec. ¶ 5; 10-11; Varon Dec. ¶¶ 4, 6-10.) Submitted with this Motion is the Declaration of Dr. Joseph Varon, one of the FLCCC's co-founders, a board-certified critical care and pulmonary specialist, a professor of medicine at universities around the world, the author of numerous books and hundreds of peer-reviewed articles, and the Chief of Staff and Chief of Critical Care Services at two Houston hospitals. Dr. Varon states (under penalty of perjury) that the MATH+ Protocol has cut the mortality rate at his hospitals to 4-7%, as compared to a national average hospital mortality rate of roughly 20%:

> Over the past 18 months of our hospitals' use during the COVID pandemic, I can confidently testify that the MATH+ protocol saves lives, and saves them in substantial numbers. I know this first, and foremost, from my own experience in our hospital, where we were able to lower our mortality for COVID-19 patients (both critically ill and those on regular wards) beginning in March 2020 (when we began utilizing the MATH+ protocol) to **4.4**% as of August 2020—a dramatic improvement over the national average of 22% over the same time period. Reported mortality averages across the globe have varied widely, but our hospitals' results have successfully maintained far lower patient mortality rate—between 4.4% and 7%—to the present day. Multiple studies report much higher national mortality averages, including one such study that I participated in and published in June 2021 in the *Journal of Community Medicine and Public Health Reports* . . . . That study,

> reviewing some 85 hospital studies worldwide, establishes an average 28-day hospital mortality rate among COVID-19 patients of 20% nationwide, and 21% globally. . . . To this day—even with the advent of the "Delta variant" of COVID-19, our mortality rate has not risen above 7%. Bottom line: our hospitals' use of the MATH+ protocol has reduced mortality of hospitalized COVID-19 patients by ***at least 50%*** below the national average.
>
> Our experience of substantially lowering the mortality rate using MATH+ protocols is made all the more remarkable by the fact that our hospital now routinely admits severely ill patients referred by other hospitals and ICUs that for whatever reason are not administering the MATH+ protocol. These patients, in many cases, are those that the referring hospital/physician has determined will not likely survive. As our success has become increasingly known among treating physicians in the Houston area, and beyond, those referrals have risen to account for approximately 10-15% of our admitted COVID-19 patients. While we have been able to cure the vast majority of those patients using MATH+, in my opinion, the advanced stage of the disease we see in the referred patients likely accounts for some of the increase in our mortality rate for COVID patients. Nevertheless, we are currently experiencing a mortality rate in our hospitals of just 5%.

(Varon Dec. ¶¶ 8-9.)

Dr. Marik's personal experience in the Sentara Norfolk ICU, where he treats only the most severely critically ill COVID patients, facing potentially imminent death, is substantially similar. (Marik Dec. ¶ 22.) Dr. Marik rotates into the ICU as the on-call attending physician on a monthly one-week-in-four schedule, and his treatment of COVID patients differs from that used by the other, far less experienced attending physicians at the Norfolk ICU, who do not employ the distinctive medicines in the MATH+ Protocol. (*Id.* at ¶¶ 10-15, 22.) Comparing the mortality rate of the COVID patients under his direct care to that of COVID patients treated by other physicians at the ICU, Dr. Marik estimates that his treatment has reduced ICU COVID patients' mortality "without question . . . *by half*." *Id.* at ¶ 22. Dr. Varon's and Dr. Marik's extraordinary life-saving results are confirmed by published clinical studies, which (as will be shown below) find that medicines in the MATH+ Protocol are associated with significant reductions of up to 50% in COVID mortality. (*Id.*; Varon Dec. ¶¶ 8-9.)

Patients who have received Dr. Marik's extraordinary care and the MATH+ Protocol frequently ask if they can make testimonials bearing witness to their belief that Dr. Marik and his colleagues have saved their lives. Several such testimonials are before the Court. (Kamen Dec. ¶¶ 2-8; Lawson Dec. ¶¶ 2-13. On a daily basis, without fanfare, Dr. Marik devotes unparalleled skill and care to his patients. (Marik Dec. ¶¶ 11-17 [offering brief glimpse of a "day in the life of Sentara ICU during COVID"].)

But through a prohibition (the "Prohibition") codified in Sentara's Comprehensive COVID-19 Treatment Guidelines Version 26, dated Sept. 27, 2021, and announced to hospital physicians by email on October 6, 2021, Defendant Sentara has, without justification, flatly banned the use of several of the MATH+ treatments. (Marik Dec. ¶ 6 & Ex. B.) As a result, Dr. Marik is now barred from using these treatments even when he deems them appropriate and necessary to save a patient's life. Indeed, as a result of the Prohibition, Dr. Marik is not permitted even to inform his COVID patients of his belief that the hospital's proposed course of treatment may result unnecessarily in their death, or of his professional judgment that the banned medicines (which he cannot offer) are superior and would give these patients a better chance at survival—acts that would be in violation of Hospital protocol and would subject Dr. Marik to immediate loss of his privileges. (Marik Dec. ¶ 8.)

From October 25-31, 2021, Dr. Marik was the attending physician at the Hospital ICU and subject for the first time to the Prohibition. Seven COVID patients came under his care in that week. He had to watch, with his hands tied, as these seven people grew increasingly ill, never given the opportunity to learn of or be treated with potentially life-saving medicines. Of the seven, four died, and the remaining three will likely die as well. (*Id.* ¶ 7.)

From November 15-21, 2021, Dr. Marik will resume his one-week-per-month duties as attending physician at the Hospital's ICU, where he will again be responsible for the care of critically ill COVID patients. (*Id.* at ¶ 8.) The window in which to give ICU COVID patients effective, life-saving treatment is vanishingly small; usually Dr. Marik has only one or at most two days after patients are admitted to the ICU to begin administering the MATH+ Protocol if that treatment is to give those patients their best (in many cases, their only) chance of surviving. (*Id.* at ¶¶ 13-14.) As a result, without this Court's *immediate* intervention, more patients at Norfolk General Hospital will be denied their right to choose life-saving medicines their attending physician considers appropriate for them.

Because Sentara's Prohibition is causing needless death, because it violates patients' right to informed consent, because it contravenes Virginia's Health Care Decisions Act, and because it flies in the face of Virginia public policy as expressed in its Right to Try statute, Plaintiff begs this Court to restrain Sentara from enforcing it.

ARGUMENT

Under Virginia law, plaintiffs are entitled to a temporary injunction if they establish that: "(1) [they are] likely to succeed on the merits, (2) [they are] likely to suffer irreparable harm in the absence of preliminary relief, (3) a balance of the equities tips in [their] favor, and (4) an injunction is in the public interest." *McEachin v. Boiling*, 84 Va. Cir. 76, at *1 (2011). Because "there are no Virginia Supreme Court cases directly setting forth the standard for an injunction," Virginia circuit courts have consistently applied federal preliminary injunction law when analyzing Virginia temporary injunctions. *Id.* (citing *Winter v. Nat. Res. Def Council*, 555 U.S. 7 (2008)); *see also Freemason Street Area Assoc., Inc. v. City of Norfolk*, 100 Va. Cir. 172, at *8 (2018). All four factors are satisfied here.

Point I

Plaintiff is Likely to Succeed in Showing that the Prohibition Violates Patients' Right to Informed Consent

A. Plaintiff Has Standing to Assert this Claim

Under Virginia law, an "attending physician" at a hospital is personally "responsible for the exercise of professional skill and judgment" in determining what treatment a patient under his care receives. *Keophumihae v. Brewer*, 6 Va. Cir. 80, 84 (Va. Cir. Ct. 1983) (citing *Stuart Circle Hospital v. Curry*, 173 Va. 136, 149 (1939)). In other words, the attending is legally responsible for the patient's care, *id.*, and thus the Prohibition directly impacts Dr. Marik's own legal rights and duties to the COVID patients he treats. Because the Prohibition prevents him from giving patients potentially life-saving treatment that in "the exercise of his [his] professional skill and judgment" is medically appropriate for them (Marik Dec. ¶¶ 6-9)—violating his Hippocratic oath, derogating from his professional duty, and potentially subjecting him to legal liability—Dr. Marik plainly has standing to challenge it. If Dr. Marik were to violate the Hospital's Prohibition, he would be subject to revocation of his Hospital privileges, giving him a further personal, direct stake in the success of this lawsuit. (*Id.* at ¶ 8.)

In addition to asserting his own rights and protecting himself from legal injury, it is well established that a "physician has standing to assert his or her patient's rights where they may not otherwise be established." *Lewis v. Superior Court*, 3 Cal. 5th 561, 571 (2017). This is particularly so where, as here: (1) patients cannot meaningfully litigate these rights because any lawsuit they brought themselves would be moot by the time it was adjudicated; *or* (2) the physician is challenging a prohibition that regulates his actions in such a way as to cause him to violate the rights of his patients. *See Singleton v. Wulff*, 428 U.S. 106 (1976);

Quill v. Vacco, 80 F.3d 716, 722-23 (2nd Cir. 1996); *Compassion in Dying v. State of Washington*, 79 F.3d 790, 794-97 (9th Cir. 1996) (en banc); *Planned Parenthood Ass'n v. City of Cincinnati*, 822 F.2d 1390, 1394 (6th Cir. 1987) (standing "uniformly" recognized where plaintiffs challenge prohibitions that "regulate their activity and, as a result, violate the rights of third parties"); *see generally Kevorkian v. Thompson*, 947 F. Supp. 1152, 1159-61 (E.D. Mich. 1997) (discussing the general rule of "physician-patient standing"). Hence Dr. Marik has standing not only because his own personal rights are at stake, but also because, in these circumstances, he is permitted to seek vindication of the rights of his patients.

B. ***The Prohibition Violates Patients' Right of Informed Consent.***

It is hornbook law that medical treatment given to individuals without their consent is unlawful and actionable, constituting either battery or negligence depending on the particular facts alleged. *Allison v. Brown*, 293 Va. 617, 628 (2017). Fundamentally, a patient's right of informed consent includes the right to be informed of "the existence of alternatives if there are any." *Id.* at 628. As the Virginia Supreme Court has held, a patient has an "informed consent claim" against a health care provider if the provider "fail[ed] to disclose the . . . existence of alternatives if there are any, thereby precluding the plaintiff from making an informed decision about whether to undertake a particular procedure or course of treatment." *Id.* at 628-29; *Tashman v. Gibbs*, 263 Va. 65, 73-74 (2002).

In the hospital setting, it is settled law that patients are to exercise their informed consent rights with and through the advice of their attending physician, and as a result "unduly restrictive" hospital oversight regulations violate both the patients' "right to receive medical care in accordance with [their] licensed physician's best judgment and the physician's right to administer it." *Doe v. Bolton*, 410 U.S. 179, 197 (1973). A hospital does

not itself have a "doctor-patient relationship" with its patients. *See Keophumihae*, 6 Va. Cir. at 85 (a "hospital cannot engage in a doctor-patient relationship"). Thus it is the treating physician, "*and he alone*," *id.* (emphasis added), who is "responsible for the exercise of professional skill and judgment" and hence for informing patients of the existence of alternative treatments so that the patient can give informed consent to a proposed course of treatment.

Given these authorities and principles, the Prohibition manifestly effects a violation of Virginia informed consent law, preventing Dr. Marik, as attending physician, from informing his COVID patients about, and giving them an opportunity to choose, alternative, potentially life-saving medicines that he, their attending physician, in the exercise of his skill and professional judgment, believes to be medically appropriate for them, "thereby precluding the [patients] from making an informed decision about whether to undertake a particular procedure or course of treatment." *Allison*, 293 Va. at 629.

Based on Dr. Marik's own personal experience in the Hospital prior to Sentara's adopting the Prohibition—a period in which he oversaw the recovery of numerous critically ill COVID patients by treating them with medicines now banned (Marik Dec. ¶¶ 6, 9, 20-22)—there can be no doubt that many if not all ICU COVID patients under Dr. Marik's care would choose to receive these FDA-approved, science-backed, potentially life-saving medicines if he were permitted to inform his patients (or their families) about them and about his judgment that they are appropriate and represent the best (in many cases, the only) chance of saving the patient's life. Thus the Prohibition violates the duty of informed consent, at the cost of its patients' lives.

Sentara is not legally permitted to give its COVID patients a course of treatment without informing them of existing, feasible alternatives. This duty is fundamental to informed consent and is recognized and enforced by courts all over the country. As summarized in the American Law Reports, "There is a duty imposed on the physician to disclose to the patient the existence of any methods of diagnosis or treatment that would serve as feasible alternatives to the method initially selected by the physician to diagnose or treat the patient's illness or injury." *Medical malpractice: liability for failure of physician to inform patient of alternative modes of diagnosis or treatment*, 38 A.L.R.4th 900 at *2 (2021) (collecting case law from all over the country); *see, e.g.*, *Bubb v. Brusky*, 321 Wis. 2d 1, 4 (2009) (the "duty of informed consent" requires "any physician who treats a patient to inform the patient about the availability of all alternate, viable medical modes of treatment . . . as well as the benefits and risks of such treatments"). Sentara's Prohibition violates this fundamental duty of informed consent should therefore be enjoined.

Point II

Plaintiff is Likely to Succeed in Showing That the Prohibition Violates Patients' Rights Recognized in Virginia's Advance Directive Statute

A. Plaintiff Has Standing to Assert this Claim

Under Virginia's Health Care Decisions Act, individuals have a right to execute an Advance Medical Directive specifying what treatment they are to receive under certain circumstances. Va. Code § 54.1-2983. Such directives are legally binding on hospitals, and all terms of such a directive, unless in contravention of law, "shall otherwise be given full effect." Va. Code § 54.1-2981 et seq.

With regard to standing, the Act creates a private cause of action and expressly grants to "*any person*" the right to bring suit in Circuit Court to enforce by injunction the Advance Directive of "*any patient*" who is currently or "*will be*" subject to health care actions, including the "withhold[ing]" of the patient's specifically authorized health care, in violation of the patient's directive. Va. Code § 54.1-2985 (emphasis added) ("On petition of any person to the circuit court of the county or city in which any patient resides or is located for whom health care will be . . . provided [or] withheld pursuant to this article, the court may enjoin such action upon finding by a preponderance of the evidence that the action is not lawfully authorized by this article.").

Before this Court are over 20 Advance Medical Directives executed by Norfolk residents, where Sentara is the only tertiary-level 1 trauma medical care facility, specifying the care they are to receive in the event they should be hospitalized with COVID, specifically referencing the medicines included in the MATH+ Protocol, provided their attending physician deems those medicines appropriate for them. These Directives are legally binding, and under Va. Code § 54.1-2985, "any person," including Dr. Marik, has a right to bring suit to enforce them.

B. The Prohibition Violates Patients' Rights Established by Virginia's Advance Directive Statute

Virginia's Health Care Decisions Act, like many statutes of its kind, permits an individual to provide in advance for situations in which the individual is hospitalized and incapacitated—*i.e.*, no longer capable of making informed decisions for himself. Virginia's Act is unusual in that it expressly grants individuals not only the right to direct what treatments they do *not* wish to receive (for example, mechanical life-prolonging measures), but in addition the right to direct what specific treatments they *do* wish to receive, so long as

such treatment is "determined by [their] attending physician" to be "medically appropriate." Va. Code § 54.1-2984.

The officially authorized Advance Directive form set forth in the statute itself contains the following language:

> OPTION III: HEALTH CARE INSTRUCTIONS
>
> (CROSS THROUGH PARAGRAPHS A AND/OR B IF YOU DO NOT WANT TO GIVE ADDITIONAL SPECIFIC INSTRUCTIONS ABOUT YOUR HEALTH CARE.)
>
> A. *I specifically direct that* ***I receive the following health care if it is medically appropriate under the circumstances as determined by my attending physician***:
>
> _____
> _____
> _____
> _____.
>
> B. I specifically direct that the following health care ***not*** be provided to me under the following circumstances (you may specify that certain health care not be provided under any circumstances):
>
> _____
> _____
> _____
> _____.

Id. (emphasis added). "Health care" is statutorily defined to mean "the furnishing of services to any individual for the purpose of preventing, alleviating, curing, or healing human illness, . . . , including but not limited to, medications." Va. Code § 54.1-2982. Thus the above-quoted language from the statutorily prescribed Advance Directive makes clear beyond question that Virginians have the right not only to instruct health care providers about what treatments they do *not* want under certain circumstances, *regardless* of whether their attending physician would otherwise deem it appropriate, but also to instruct health care

providers about what specific medicines they *do* want under specified circumstances, *provided* their attending physicians deem it appropriate.

Indeed, the statute recognizes two distinct rights to affirmatively decide what specific medicines one wishes to receive, upon the recommendation of one's attending physician, both of which are violated by Sentara's Prohibition.

First, on its face, the statute allows patients to name specific medications they are to receive for certain illnesses in case they become incapacitated, provided those medicines are determined to be appropriate for them under the circumstances by their "attending physician"—their attending, not their hospital. Accordingly, any individual in Virginia has the right to specifically direct that in the event they are hospitalized with COVID, and become incapacitated, they are to receive the medicines in Dr. Marik's MATH+ Protocol, provided that their attending physician deems them medically appropriate.

Before the Court are over twenty Advance Directives from Norfolk residents doing just that. Each is signed, duly witnessed, and fully valid, written with the precise language set forth in the statute. All of them specifically list the medicines in the MATH+ Protocol and direct that the individual declarants are to receive these medicines in case they are hospitalized with COVID and become incapacitated, provided their attending physician deems these medicines appropriate under the circumstances. Several of these medicines are categorically blocked by Sentara's Prohibition. Thus the Prohibition will prevent these Advance Directives from being honored, in violation of the Health Care Decisions Act.[2] For this reason alone, the Prohibition must be enjoined.

---

[2] Moreover, the Health Care Decisions Act gives patients with a terminal condition the right to make an *oral* Advance Directive. Va. Code § 54.1-2983. For terminally ill COVID patients under Dr. Marik's care who wish to receive the banned medicines if Dr. Marik deems them appropriate, the Prohibition prevents such patients from exercising this right.

Second, even more fundamentally, the Health Care Decisions Act assumes and recognizes that *all patients* in the Commonwealth of Virginia, including those *who are not incapacitated*, must also have an equal right to instruct their health care provider to give them medicines deemed appropriate for them by their attending physician. For it would be nonsensical to interpret the Act as giving patients greater rights over their health care decisions *when incapacitated* than they possess when *they are of sound mind.*

If a patient has a legal right under the Act to instruct doctors not to put him on a mechanical ventilator in the event he should become incapacitated—and the Act precisely gives patients such a right—it would be palpably absurd to conclude that the patient lacks the right to refuse ventilation *before* he becomes incapacitated. The idea that a hospital could intubate a patient against his express will *so long as he is conscious and of sound mind*, but may not do so once he is incapacitated, would be manifestly absurd and intolerable.

"[A] statute should never be construed in a way that leads to absurd results." *Meeks v. Commonwealth*, 274 Va. 798, 802 (2007) (citation omitted); *see Saddlebrook Estates Cmty. Ass'n v. City of Suffolk*, 292 Va. 35, 40 (2016) ("We presume that the legislature completely expressed its intention in the statutory language it enacted unless that language is ambiguous or leads to an absurd result."). Given that COVID patients have a legal right under the Health Care Decisions Act to specify and receive FDA-approved medicines deemed appropriate for them by their attending physician in the event of incapacitation, the Act must therefore be read to recognize the equal right of COVID patients to specify and receive those medicines *before* they become incapacitated.

In *Doe v. Bolton*, *supra*, the United States Supreme Court enforced, as a matter of constitutional law, a hospitalized "patient's right to receive medical care in accordance with

[his] licensed physician's best judgment and the physician's right to administer it," rejecting the claim that these rights could be conditioned on a hospital committee's approval of the attending physician's proposed treatment. 410 U.S. at 197. Virginia's Health Care Decisions Act does no more and no less than to recognize, as a matter of state statutory law, the very same right upheld by the Supreme Court in *Bolton*—the right of hospitalized patients to choose and to receive the specific treatment deemed medically appropriate for them by their attending physician. Sentara's Prohibition manifestly violates that right and is therefore unlawful.

Point III

Sentara's Prohibition Is Scientifically Baseless And Violates Virginia Public Policy As Expressed in the Commonwealth's Right to Try Statute

Sentara's Prohibition violates the duty of informed consent and the rights established by Virginia's Health Care Decisions Act; these violations are a more than sufficient basis for this Court to issue an injunction. But it is important to emphasize that the Prohibition is also scientifically baseless and in direct opposition to Virginia public policy as expressed in the Commonwealth's Right to Try statute.

A. Insisting Exclusively on RCT Evidence Is Scientifically Baseless

Sentara's primary justification for the Prohibition is that the "safety/efficacy" of the medicines it has banned "is not supported in peer reviewed, published RCT" ("RCT" is an acronym referring to randomized, controlled trials). As will be shown below, this statement is simply false; the banned medicines that form part of the MATH+ protocol *are* supported by peer-reviewed, published RCT data. But even if they were not, Sentara's justification would still be baseless. As every competent expert in evidence-based medicine knows,

exclusive reliance on RCT evidence—and refusing to use or approve a medicine in the absence of conclusive RCT data—is "scientifically unwarranted" and, in pandemic conditions, can lead to "unjustifiable, needless death."

As stated by epidemiological expert Prof. Harvey Risch of Yale Medical School, "Definitive studies have demonstrated that overall, RCTs do not provide a superior evidentiary basis for clinical decision-making as compared to modern, adjusted non-RTC studies. . . . For this reason, the sole reliance on RCT evidence is *scientifically unwarranted.*" (Risch Dec. ¶ 17.) This is especially true, as Prof. Risch points out, during a pandemic:

> When considering the efficacy or safety of medical treatments, all relevant evidence needs to be evaluated. Particularly in a pandemic, where the world confronts a novel, deadly, fast-spreading infection, a policy of insisting exclusively on RCT evidence—and refusing to use or approve medicines without conclusive RCT evidence—not only is scientifically unwarranted, but can lead to unjustifiable, needless death.
>
> In pandemic conditions, clinicians all over the world dealing with a novel virus will attempt to save patients' lives by using the medicines that previous experience and scientific study suggest may be potentially therapeutic agents. Some of these medicines will prove effective, and some will not. Clinicians will begin reporting preliminary results, and more and more clinicians will try the medicines reportedly showing therapeutic effect. They will conduct observational (non-RTC) studies and report the results. As more and more data from these observational studies come in, evidence can emerge in favor of a therapeutic agent that rises to the level of reliability such that evidence-based medicine and reasonable clinical judgment will support use of that medicine well before conclusive RCT data can be had.
>
> This is exactly what has happened during the COVID-19 pandemic. Substantial amounts of non-RCT (as well as RCT) data has by now emerged on the basis of which clinicians can reasonably administer certain medicines to COVID patients even though conclusive RCT data may not be available for a number of years.

Id. Thus Sentara's primary purported justification for the Prohibition—that the banned medicines have not yet been validated by RCTs—is scientifically unsound and a recipe for needless death.

B. *Sentara's Prohibition of the Banned Medicines Except for Patients Enrolled in Clinical Trials Violates Virginia Public Policy*

The banned medicines that Dr. Marik seeks to be able to prescribe to his COVID patients are all FDA-approved drugs, known to be safe at specified dosages. Sentara, however, states that it will permit the banned medicines to be used against COVID only for "patients enrolled in a clinical trial." This restriction flies in the face of Virginia public policy as expressed in the Commonwealth's Right to Try law. *See* Va. Code § 54.1-3442.1 et seq.

Under that statute, individuals with a "terminal condition" "shall be eligible" to try medicines still undergoing clinical trials that have not yet been approved by the FDA if their "treating physician"—not their hospital, but their treating physician—so "recommends." Va. Code § 54.1-3442.2. The statute does not create a cause of action, but clearly expresses the public policy of the Commonwealth: terminally ill patients, on the recommendation of their treating physician, ought to have a chance to try potentially life-saving medicines still undergoing clinical trials, even if those medicines are not yet fully FDA-approved.

Here, Sentara is denying terminally ill COVID patients access to potentially life-saving medicines that *have* been approved by the FDA. Sentara is taking the position that these medicines remain investigational, and that access to investigational medicines must be limited exclusively to patients enrolled in clinical trials even if a patient is terminally ill and his treating physician recommends that he try those medicines. Thus the Prohibition flies directly in the face of Virginia public policy as expressed in the Right to Try statute, adding a further ground for this Court to enjoin it.

C. ***The Use Against COVID Of Every One Of The MATH+ Protocol Medicines Banned By The Prohibition Is Amply Supported By Clinical Data.***

But the most fundamental reason why Sentara's purported justifications for the Prohibition are baseless is the simplest. The safety and efficacy of the banned medicines against COVID are amply supported by clinical data, including RCT data.

1. *Fluvoxamine*

One of the medicines in the MATH+ protocol now banned by Sentara is fluvoxamine, a selective serotonin reuptake inhibitor approved by the FDA for the treatment of a psychiatric disorder and commonly used (off-label) against depression.[3] The NIH does *not* advise either for or against the use of fluvoxamine for COVID,[4] but Sentara bans it, claiming that its "safety/efficacy" is "not supported by published, peer-reviewed RCT."

In fact, a large, peer-reviewed, randomized, placebo-controlled study just published in the prestigious *Lancet Global Health* refutes this claim, reporting that fluvoxamine administered to emergency-admitted COVID patients significantly reduced hospitalization and death. G. Reis et al., *Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19*, LANCET GLOBAL HEALTH, Oct. 27, 2021, https://doi.org/10.1016/S2214-109X(21)00448-4. Notably, the study also found no safety issues among the patients treated with fluvoxamine. *Id.* Indeed the efficacy and safety results of fluvoxamine were so strong that the study had to be halted in order that the patients in the placebo group could be treated with fluvoxamine as well. *Id.*

In other words, as with several other components in Dr. Marik's pioneering MATH+ protocol, RCT data has now caught up with and validated the use of fluvoxamine, confirming the reasonableness of Dr. Marik's professional judgment and undermining Sentara's

[3] NIH, https://www.covid19treatmentguidelines.nih.gov/therapies/immunomodulators/fluvoxamine/.
[4] *Id.*

Prohibition. For the record, a 2020 published, randomized controlled trial had also shown positive benefits of fluvoxamine on COVID patients,[5] meaning that Sentara's claim (that there was no published RCT support for fluvoxamine's efficacy against COVID) was false even before the *Lancet Global Health* study was published.

2. *Ivermectin*

Rare among medicines, ivermectin has in recent months become a household word, as a result of a widespread, startling, highly successful—but false and misleading—campaign to discredit and impugn the drug. The FDA, for example, has taken to social media to denounce ivermectin (falsely) as a veterinary-only medicine (in a viral tweet calling for a halt on the use of Ivermectin against COVID, the FDA said, "You're not a horse. You're not a cow. Seriously, y'all. Stop it.", U.S. FDA, Twitter, https://twitter.com/us_fda/status/1429050070243192839)—even as, in fine print on another web page, the FDA conceded that it had not actually "reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19."[6] Merck, the original manufacturer of ivermectin, recommended against its use as well—failing to mention that the company was developing its own billion-dollar alternative COVID treatment or that Ivermectin is now off-patent and generically available, thus of no financial value to Merck.[7] Even Dr. Anthony Fauci, the White House Chief Medical Advisor, went on CNN and stated that "there is no evidence whatsoever that [Ivermectin] works" against COVID.[8]

---

[5] E.J. Lenze et al., *Fluvoxamine vs placebo and clinical deterioration in outpatients with symptomatic COVID-19: a randomized clinical trial*, JAMA 2020, 324: 2292–300.

[6] U.S. FDA, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (archived Mar. 5, 2021), https:llweb.archive.orq/web/20210305163946/https://www.fda.qov/ consumers/consumer-updates/whv-you-should-not-use-ivermectin-treat-or-prevent-covid-lg.

[7] Merck Statement on Ivermectin use During the COVID-19 Pandemic, Feb. 4, 2021, https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/.

[8] CNN Health, *'Don't do it': Dr. Fauci warns against taking Ivermectin to fight Covid-19,* Aug. 29, 2021, https://edition.cnn.com/videos/health/2021/08/29/dr-anthony-fauci-ivermectin-covid-19-sotuvpx.cnn.

But as the Attorney General of Nebraska recently put it in an official Attorney General's Opinion, Fauci's claim "directly contradicts the NIH's recognition that 'several randomized trials . . published in peer-reviewed journals' have reported data indicating that ivermectin is effective as a COVID-19 treatment."[9] In fact, as the Attorney General Opinion further states, "researchers have conducted over 20 randomized controlled trials (RCTs) and more observational trials to evaluate ivermectin's effectiveness in the prevention and treatment of COVID-19," almost all of which demonstrate significant, positive therapeutic effects.[10] A published, peer-reviewed meta-analysis reviewing twenty-four ivermectin RCTs—involving a total of over three thousand patients—found "with moderate certainty that ivermectin treatment in COVID-19 provides a significant survival benefit."[11] Indeed, the authors of that meta-analysis (who are unaffiliated with Dr. Marik or the FLCCC) recently concluded that taking all ivermectin RCTs together, even after excluding those the results of which have been questioned, ivermectin has been found to reduce mortality in COVID patients overall *by almost 50%.*[12] At the same time, ivermectin has an extraordinary safety record, with billions of doses administered over the last several decades.[13]

---

[9] Nebraska Attorney General, Prescription of Ivermectin or Hydroxychloroquine as Off-Label Medicines for the Prevention or Treatment of Covid-19, Op. No. 21-017, Oct. 15, 2021, at 21, https://ago.nebraska.gov/sites/ago.nebraska.gov/files/docs/opinions/21-017_0.pdf (quoting NIH, COVID-19 Treatment Guidelines: Ivermectin, https://www.covid19 treatmentguidelines.nih.qov/therapies/antiviral-therapy/ivermectin/) (hereafter Nebraska AG Opinion).

[10] *Id.* at 12.

[11] A. Bryant et al., Ivermectin for Prevention and Treatment of COVID- 19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines, 28 American Journal of Therapeutics 434, 451 (Jul./Aug. 2021), https:i/journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin for prevention and treatment of.7.aspx.

[12] A. Bryant et al., Letter to the Editor: Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines, 28 American Journal of Therapeutics 573, 573 (Sept./Oct. 2021), https://covid19critical care.com/wp-content/uploads/2021/09/Response-to-Elgazzar.pdf.

[13] Nebraska AG Opinion, *supra*, at 11 ("incredibly low" adverse effects); Risch Dec. ¶ 21 ("exceedingly safe").

This year, two separate, comprehensive reviews of the available clinical evidence—one co-authored by Satoshi Omura,[14] who won the Nobel Prize for his discovery of ivermectin, and the other co-authored by Yale Professor Alessandro Santin[15]—"concluded that the preponderance of the evidence demonstrated major reductions in mortality and morbidity" achieved by ivermectin in the fight against COVID.[16]

Why the FDA would unjustifiably attack a safe, inexpensive, promising COVID treatment is a question that many have raised but that has not yet been answered. *See, e.g.*, The Wall Street Journal, July 28, 2021, *Why Is the FDA Attacking a Safe, Effective Drug? Ivermectin is a promising Covid treatment and prophylaxis, but the agency is denigrating it*, https://www.wsj.com/articles/fda-ivermectin-covid-19-coronavirus-masks-anti-science-11627482393. But there is no question that the FDA, in addition to falsely suggesting that ivermectin is a veterinary-only medicine, has made other outright misrepresentations when condemning ivermectin—misrepresentations contradicted not only by the true facts, but by other FDA webpages. As summarized by the Nebraska Attorney General:

> the FDA also declared that "[i]vermectin is not an anti-viral (a drug for treating viruses)." It did so while another one of its webpages simultaneously cited a study in Antiviral Research that identified ivermectin as a medicine "previously shown to have broad-spectrum anti-viral activity." . . .
>
> The FDA has additionally assailed ivermectin's safety by suggesting, though not outright stating, that even a proper dose of human ivermectin might be dangerous when used to treat COVID-19. For example, the FDA announced that "[t]aking a drug for an unapproved use can be very dangerous" and "[t]his is true of ivermectin." Yet this ignores the fact that . . . doctors routinely prescribe medicines for off-label use and that ivermectin is a particularly well-tolerated medicine with an established safety record.

---

[14] M. Yagisawa, P.J. Foster, H. Hanaki, S. Omura, Global trends in clinical studies of ivermectin in COVID-19 Japanese J. Antib, 74 (1) (2021), https://www.psychoactif.org/forum/uploads/documents/161/74-1_44-95.pdf.
[15] A. Santin et al., Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19, 43 New Microbes and New Infections, Sept. 2021, https://www.sciencedirect.com/science/article/pii/S2052297521000883#!.
[16] *Id.*

Nebraska AG Opinion, *supra*, at 21.

With specific reference to late-stage, hospitalized COVID patients—the cohort Dr. Marik treats—a published "randomized, double-blind, placebo-controlled, multicenter clinical trial" on 180 hospitalized COVID patients found that ivermectin "reduces the rate of mortality and duration of hospitalization in adult COVID-19 patients."[17] And an Internet-available meta-analysis of all existing ivermectin studies, including both RCTs and observational trials, reports that even when used on late-stage, hospitalized COVID patients, ivermectin still reduces mortality by roughly 50%.[18]

Thus Sentara's claim that "[t]here is no available data on [ivermectin] outcomes or efficacy in humans from a RCT" is stunningly, utterly false. In addition, real-world epidemiologic data from countries such as Peru, where ivermectin has been widely used to combat the pandemic, provides significant further evidence of effectiveness:

> Peru deployed mass ivermectin-based COVID-19 treatments from April 2020 through November 2020 throughout its 25 states. In ten of those states, a maximal amount of "mass [ivermectin] treatments of COVID-19 were conducted through a broadside, army-led effort, Mega-Operación Tayta (MOT)." Fourteen other states had a medium distribution of ivermectin administered at the local level. And one state, Lima, distributed a minimal amount of ivermectin due to restrictive government policies. "The mean reduction in excess deaths 30 days after peak deaths was 74% for the maximal [ivermectin] distribution group, 53% for the medium group[,] and 25% for Lima."
> Furthermore, throughout the country of Peru, "excess deaths decreased 14-fold over four months" leading up to December 1, 2020, "after which deaths then increased 13-fold when ivermectin use was restricted under a new president."

Nebraska AG Opinion, *supra*, at 17-18 (citations omitted).[19]

---

[17] M.S. Niaee et al., Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: A randomized multi-center clinical trial, 14 Asian Pac. J. of Trop. Med. 266 (2021), https://www.apjtm.org/article.asp?issn=1995-7645;year=2021;volume=14;issue=6;spage=266;epage=273;aulast=Shakhsi.

[18] Ivermectin for COVID-19: real-time meta analysis of 65 studies, Nov. 5, 2021, https://ivmmeta.com/.

[19] Sentara also claims that dosages of ivermectin sufficient "to inhibit SARS-COV-2 would be difficult to achieve in humans and are extremely toxic." (Varik Dec. Exh. B.) But Sentara offers no basis or citation to data for this claim, which is either ignorant or knowingly false given the dozens of studies cited above confirming ivermectin's life-saving effect against COVID without safety concerns. Sentara further states that

In short, while other physicians are free to disagree, and to wait for even more evidence, it is indisputable that, on the basis of the existing data, a prudent, knowledgeable physician with COVID clinical expertise, such as Dr. Marik, can in the exercise of reasonable, professionally sound judgment determine that ivermectin is a medically appropriate treatment for COVID. As Yale Professor, epidemiologist and COVID expert Dr. Risch states, "There have by now been many dozens of reported studies of Ivermectin conducted on COVID patients, and overall there is very clearly significant evidence of reduced risks of hospitalization and mortality. There is also dramatically strong evidence both from these studies as well as from decades of use of this medication by hundreds of millions of people in billions of doses worldwide that Ivermectin is exceedingly safe. In my expert opinion, this evidence rises to the level of reliability such that reasonable physicians could elect to use Ivermectin to combat COVID." (Risch Dec. ¶ 21.)

3. *Vitamin C*

Vitamin C is a safe, essential nutrient, yet it is banned by Sentara as a treatment for "COVID or sepsis/septic shock" even if the patient's attending physician considers it appropriate. Vitamin C infusion (intravenous administration) is part of the MATH+ Protocol, and contrary to Sentara's claims, RCT data amply support its use against COVID, including on the most severely ill patients. As stated in the abstract of a recently published review of the evidence, "To date there have been 12 vitamin C and COVID-19 trials published, including five randomised controlled trials (RCTs) and seven retrospective cohort studies. The current level of evidence from the RCTs suggests that intravenous vitamin C

---

several organizations such as the FDA, CDC, Merck, and the AMA have recommended against ivermectin, but as pointed out by Nebraska's Attorney General, these organizations also cite no data and make numerous demonstrably false or misleading statements about ivermectin. *See* Nebraska AG Opinion, *supra*, at 21-22, 26-27.

intervention may improve oxygenation parameters, reduce inflammatory markers, decrease days in hospital and reduce mortality, particularly in the more severely ill patients."[20] As to safety, the review further states, "no adverse events have been reported in the published vitamin C and COVID-19 clinical trials."[21] Thus with respect to Vitamin D too, while doctors are free to come to their own conclusions, a reasonable ICU physician could clearly, on the basis of published scientific data, including RCT data, elect to use Vitamin C against COVID.

4. *Bicalutamide, Dutasteride, Finasteride*

The remaining three medications used in the MATH+ protocol but banned by the Prohibition are bicalutamide, dutasteride, and finasteride. All three are well-tolerated, FDA-approved anti-androgens, which began to be considered for use against COVID when researchers discovered spike-protein receptor mechanisms associated with androgens and showed that anti-androgens had in-vitro positive effects combating the COVID virus. A recent review of the available evidence in the respected Oxford journal *Endocrinology* discusses "several randomized clinical trials" that have found "a reduced rate of hospitalization" and "accelerate[d] viral clearance" in COVID patients treated with anti-androgens.[22] Thus with respect to these medicines too, Dr. Marik's professional judgment is well supported, and Sentara's claim that no RCTs support use of these medicines is once again false.

---

[20] P. Holford et al., *Vitamin C Intervention for Critical COVID-19: A Pragmatic Review of the Current Level of Evidence*, Nov. 1, 2021, https://www.mdpi.com/2075-1729/11/11/1166.
[21] *Id.*
[22] F. Mauvais-Jarvis, *Do Anti-androgens Have Potential as Therapeutics for COVID-19?*, ENDOCRINOLOGY, Aug. 2021, https://academic.oup.com/endo/article/162/8/bqab114/6293822.

D. The Clinical Data on Remdesivir Further Supports Dr. Marik's Clinical Judgment and Undermines Sentara's Supposed Commitment to Scientific Evidence

Finally, Sentara's policy on a different drug, remdesivir, further undermines its purported commitment to scientific evidence when telling expert clinical physicians what medicines they may and may use against COVID. Studies published after the FDA issued remdesivir an Emergency Use Authorization for use against COVID have demonstrated that remdesivir is not effective after all. A massive WHO study in Europe came to this conclusion,[23] and a large recent study conducted by the Veterans' Administration showed that remdesivir not only failed to reduce mortality, but *increased* patients' length of hospitalization.[24] Moreover, the drug is known to be dangerously toxic.[25]

As a result of this damning, accumulating evidence, Dr. Marik—because he bases his treatment decisions on actual data and his patients' best interests—never uses remdesivir to his COVID patients. (Marik Dec. ¶ 15.) But Sentara recommends and "endorses" the drug, ignoring the evidence. (*Id.* Exh. B.) Dr. Marik's refusal to use remdesivir adds further support and credibility to his evidence-based clinical judgment; Sentara's endorsement undermines its supposed commitment to scientific evidence and data.

Point IV

Plaintiff Has Shown Likely, Imminent Irreparable Harm

If an injunction is not issued in this case, there is an extremely high likelihood that the events of October 21-25, 2021 will be replayed in the immediate future, and critically ill

---

[23] Repurposed Antiviral Drugs for Covid-19 — Interim WHO Solidarity Trial Results, N Engl J Med 2021, 384:497-51, Feb. 11, 2021, https://www.nejm.org/doi/full/10.1056/nejmoa2023184.
[24] M.E. Ohl et al., Association of Remdesivir Treatment With Survival and Length of Hospital Stay Among US Veterans Hospitalized With COVID-19, JAMA Open Network, Jul. 1, 2021, https://pubmed.ncbi.nlm.nih.gov/34264329/.
[25] Nebraska AG Opinion, *supra*, at 11.

COVID patients at the Hospital will needlessly die, when Dr. Marik resumes his on-call duties at the ICU on November 15 and Sentara prevents him from offering his critically ill COVID patients an opportunity to receive the potentially life-saving treatments to which they are legally entitled.

No harm is more irreparable than death. *See Lopez v. Holder*, 578 Fed. Appx. 681, 685 (9th Cir. 2014) (referring to "the most irreparable harm of all: death"); *Grandison v. Stanford*, No. 7:16cv00189, 2016 U.S. Dist. LEXIS 124447 at *28 (W.D. Va. Sept. 14, 2016) ("[P]ain, suffering and the risk of death constitute 'irreparable harm' sufficient to support a preliminary injunction . . . .") (citations omitted). Thus Dr. Marik has plainly met his burden of showing irreparable harm.

Point V

The Balance of Equities Tips Sharply in Plaintiff's Favor And the Injunction Will Serve the Public Interest

By contrast, Sentara can show no competing harm at all. Sentara has no conceivable legitimate interest in preventing its COVID patients from being informed of and having the opportunity to receive inexpensive, safe, potentially life-saving medicines. Any notion that Sentara might run the risk of legal liability—simply by allowing Dr. Marik to practice medicine according to his professional duty and Hippocratic Oath, and allowing COVID patients to exercise their rights of informed consent—is dispelled by a federal statute (known as the PREP Act) that immunizes health care providers from "suit and liability" for all claims based on the use of any drug "to diagnose, mitigate, prevent, treat, or cure [the] pandemic." 42 U.S.C. § 247d–6d(a)(1), (i)(1)(A), (i)(7)(A)(I-II).

At the same time, and for the same reasons, an injunction will serve the public interest. The public is not served by allowing Sentara to deny patients their right to informed

consent, to deny individuals their rights under the Health Care Decisions Act, or to flout the public policy of Virginia that terminally ill patients should be eligible to try investigational if their treating physician recommends them. On the contrary, honoring those rights will advance the public interest, respect Virginians' autonomy, and save lives.

Thus Dr. Marik has shown not only irreparable harm, but a balance of hardships that tips sharply in his favor and the advancement of the public interest.

Point VI
There Is No Adequate Remedy at Law

Money can never adequately compensate for death. *See, e.g.*, *People v. Harris*, 98 N.Y.2d 452, 504 (1982) ("The right to monetary compensation, however, can never adequately compensate the person wrongly put to death."); *Gulf Refining Co. v. Miller*, 153 Miss. 741, 745 (1929) ("the loss sustained by a wife and children in the death of the husband and father frequently cannot be compensated by any amount of money"); *Gates v. Syrian Arab Republic*, 580 F. Supp. 2d 53, 75 (D.D.C. 2008) ("Money judgments cannot compensate [individuals] for their . . . deaths or compensate their family members for their losses."). Thus there is no adequate remedy at law in this case, and injunctive relief is both warranted and necessary.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that this Court enjoin Sentara from enforcing the Prohibition, so that its COVID patients can exercise their right to be advised of and to receive the treatment deemed appropriate for them by their attending physician.

Respectfully submitted,

DR. PAUL E. MARIK

BY: 

Counsel

Fred D. Taylor, Esquire
VSB# 77987
Bush & Taylor, P.C.
200 N. Main Street
Suffolk, Virginia 23434
Telephone: 757-935-5544
Facsimile: 757-935-5533
E-Mail: fred@bushtaylor.com
Http://www.bushtaylor.com
Counsel for Plaintiff

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF NORFOLK

DR. PAUL E. MARIK,

Plaintiff,

v. **Case No.: CL21_____**

SENTARA HEALTHCARE,

Defendant.

Serve: CT Corporation System
4701 Cox Rd Ste 285
Glen Allen, VA, 23060-6808

VERIFIED COMPLAINT

COMES NOW the Plaintiff Dr. Paul Marik, by his undersigned counsel, Fred D. Taylor, Esq., and hereby submits his Verified Complaint against the named Defendant Sentara Healthcare. Plaintiff alleges and avers as follows:

NATURE OF THE CASE

1. This is a proceeding pursuant to Code of Virginia § 8.01-184 for a judgment against Sentara Healthcare ("Sentara" or "Defendant") declaring that Sentara's treatment guidelines and procedures in regard to the treatment of Covid-19 are unlawful and unenforceable under Virginia law and policy; additionally, this case comes on related requests for injunctive relief.

PARTIES

2. The Plaintiff is Dr. Paul E. Marik ("Dr. Marik"). Dr. Marik is a licensed physician in the State of Virginia (License #: 0109-542065). He has specialized over the past thirty-five years as a bedside clinician, lecturer and author in the field of critical care medicine. He is a tenured Professor of Medicine at the Eastern Virginia Medical School

("EVMS"), and the Chief of EVMS's Division of Pulmonary and Critical Care Medicine within its Department of Internal Medicine. Dr. Marik is also the Director of the General Intensive Care Unit ("GICU") at Sentara Norfolk General Hospital. Crucially, over the past twelve years Dr. Marik has served as the attending physician of record to all patients (up to 20 at a time) in the Sentara Hospital GICU during his regular one week per month, 24/7, call rotation.

3. The Defendant Sentara Healthcare is a health care system with principal place of business in the Commonwealth of Virginia, and operating a number of hospitals and facilities, to include Sentara Norfolk General Hospital.

JURISDICTION

4. This Court has jurisdiction over this action, which seeks a declaratory judgment and ancillary relief, pursuant to Code of Virginia §§ 8.01-184 and 17.1-513.

5. That all matters at issue herein occurred in Norfolk, Virginia.

FACTUAL ALLEGATIONS

6. Patients at Sentara Norfolk General Hospital are dying who should not be.

7. They are dying because, unjustifiably and unlawfully, they are being denied potentially life-saving treatment determined to be medically appropriate for them by their attending physician.

8. Through a prohibition (the "Prohibition") codified in Sentara's Comprehensive COVID-19 Treatment Guidelines Version 26, dated Sept. 27, 2021 and announced to hospital physicians by email on October 6, 2021, Defendant Sentara Healthcare has, without justification, flatly banned the use of certain safe, potentially life-saving medicines for COVID-19, thereby violating the rights of COVID patients at Sentara

Norfolk General Hospital (the "Hospital") to be informed of and to receive treatment determined to be appropriate for them by their attending physician, Plaintiff Dr. Paul Marik, the Director of the Hospital's Intensive Care Unit ("ICU") and a world-renowned critical care expert.

9. When Dr. Marik was permitted to administer to ICU COVID patients the medicines he believed medically appropriate, he reduced COVID mortality in the Hospital's ICU by roughly fifty percent.

10. Other doctors using Dr. Marik's protocol for COVID patients—which is used by physicians all over the world—report mortality rates for hospitalized COVID patients of approximately 4-7%. By comparison, average nationwide mortality for COVID patients in U.S. hospitals is approximately 20%.

11. The Prohibition is not only costing lives. It violates the most fundamental principle of American medical law—informed consent—as well as express Virginia statutory law regarding Advance Medical Directives and Virginia's declared public policy as expressed in its Right to Try statute.

12. In Virginia (as elsewhere), informed consent requires that patients be told of, and permitted to choose among, existing alternatives to a proposed course of treatment. Health care providers violate patients' informed consent rights if they "fail[] to disclose . . . *the existence of alternatives if there are any*, thereby precluding the plaintiff from making an informed decision about whether to undertake a particular procedure or course of treatment." *Allison v. Brown*, 293 Va. 617, 628-29 (2017) (emphasis added); *Tashman v. Gibbs*, 263 Va. 65, 73-74 (2002).

13. As recognized by the United States Supreme Court, hospitalized patients are to exercise their right of informed consent primarily with and through the advice of their treating physician, and "unduly restrictive" hospital oversight regulations violate both the patients' "right to receive medical care in accordance with [their] licensed physician's best judgment and the physician's right to administer it." *Doe v. Bolton*, 410 U.S. 179, 197 (1973).

14. Moreover, under Virginia's Advance Directive statute, hospitalized individuals have the right not only to specify in advance what treatment they choose *not* to receive in case of incapacity, but "to specifically direct" the treatment they *are* to receive so long as that treatment "is medically appropriate under the circumstances *as determined by [their] attending physician.*" Va. Code § 54.1-2984 (emphasis added).

15. The statute does not say, "as determined by the *hospital.*" It specifically and expressly says, "as determined by [their] *attending physician.*" *Id.* (emphasis added).

16. The Advance Directive statute assumes and recognizes that patients who are not incapacitated (*i.e.*, patients who are capable of make informed decisions for themselves) must also have the right "to specifically direct" the treatment they are to receive, so long as that treatment "is medically appropriate under the circumstances as determined by [their] attending physician," for it would be nonsensical to believe that the Virginia legislature gave patients greater rights over their treatment decisions when they are incapacitated than they possess when they are not incapacitated.

17. Unless the treatment specifications in an individual's Advance Directive are in violation of law, or are deemed inappropriate by the individual's attending physician, "a patient's advance directive *shall . . . be given full effect,*" and "*any person*" may bring suit in

this Court for injunctive relief to ensure that treatment will not be "withheld" from a patient in violation of his or her directive. Va. Code §§ 54.1-2983.3 (emphasis added), 54.1-2985 (emphasis added).

18. In addition, under Virginia's Right to Try statute, patients with a "terminal condition" "shall be eligible" to receive medicines still undergoing clinical trials if "recommend[ed]" by their "treating physician." Va. Code § 54.1-3442.2. The statute establishes a clear public policy in favor of the right of terminally ill patients to try not-fully-approved, still-investigational, but potentially life-saving drugs if such drugs are recommended to them by their "treating physician."

19. The statute does not say that such medicines must be recommended or endorsed by a patient's *hospital*. It says that patients "*shall* be eligible" to receive such medicines if the medicines have been recommended by their "*treating physician*." *Id.* (emphasis added).

20. Because the Prohibition prevents COVID patients from being informed of and choosing existing alternative courses of treatment recommended by, and determined to be medically appropriate for them by, their attending physician, it violates patients' core rights of informed consent, their rights under Virginia's Advance Directive statute, and Virginia's public policy as expressed in its Right to Try law. The Prohibition also puts Plaintiff Dr. Marik, as attending physician to Sentara COVID patients, in the legally untenable and morally and professionally unacceptable position of having to remain silent about, and forfeit the use of, treatments that in his expert medical opinion are appropriate and necessary to save these patients' lives.

21. As detailed more fully below, Sentara's asserted justifications for the Prohibition are baseless. For example, Sentara states that the "efficacy/safety" of the prohibited medicines "is not supported in peer reviewed, published RCT" ("RCT" refers to randomized, controlled trials), when in fact: (1) the efficacy as well as the safety of the prohibited medicines *is* supported in peer-reviewed, published RCTs; (2) numerous studies confirm the life-saving effects of the medicines Dr. Marik considers appropriate, demonstrating that these medicines reduce mortality in hospitalized COVID patients by as much as 50%; (3) the medicines in question are FDA-approved and therefore known to be safe at specified dosages; and (4) Sentara (like other hospitals all over the country) in all other instances respects and abides by its attending physicians' professional right to prescribe many other drugs for uses that have *not* been validated through RCTs.

22. From October 25 to October 31, Dr. Marik assumed his regular one-week-in-four monthly duty as attending physician at the Hospital's ICU, for the first time categorically barred by the Prohibition from offering his COVID patients life-saving medicines he has previously been permitted to use.

23. Seven ICU COVID patients came under Dr. Marik's care in that period of time, and Dr. Marik was prevented from offering any of them the treatment protocol he believed medically appropriate and necessary to give them their best chance at surviving. Four died. The remaining three are now probably beyond help.

24. In short, as a result of Sentara's unlawful Prohibition, patients are dying unnecessarily at Sentara Norfolk General Hospital. Several have died in just the last few weeks, and without this Court's intervention more will needlessly die in the immediate future.

25. The Prohibition prevents Dr. Marik from: (a) attempting to save the lives of his acute COVID patients in accordance with his own best medical judgment by administering to them a COVID treatment protocol followed by many physicians all over the world and well-supported by real-world, epidemiologic, and clinical study data; and (b) from even informing patients of the existence of medically appropriate, potentially life-saving alternatives to the treatment Sentara is giving them.

26. Dr. Marik will once again resume his duties as attending physician at the ICU from November 15 to November 21, 2021, where he will certainly once again be treating acutely ill COVID patients and where he will once be barred from offering them life-saving treatment he deems medically appropriate, in violation of his Hippocratic Oath and his and his patients' legal rights.

27. Because Dr. Marik believes that there exist other, medically superior alternatives to the treatment Sentara is forcing him to give to acute COVID patients without allowing him to offer these alternatives to his patients, or even to inform his patients of their availability, Sentara is in effect asking Dr. Marik to be complicit in a violation of his patients' right to informed consent.

28. The plight of acutely ill COVID patients at Sentara Norfolk General Hospital, deprived by the Prohibition of the right to make an informed choice to receive potentially life-saving treatments deemed medically appropriate by their attending physician, Dr. Marik, is a paradigmatic example of a legal violation "capable of repetition yet evading review." *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1976 (2016); *Virginia Broad. Corp. v. Commonwealth*, 286 Va. 239, 248 (2013). COVID patients admitted to the ICU are terminally ill and face imminent death. There is only a one- to two-day window after a

COVID patient is admitted to the ICU during which life-saving treatment can be maximally effective. If legal proceedings only became available after an acute COVID patient at the Hospital is admitted to the ICU, the suit would end up moot before the Court could adjudicate it.

29. In other words, this lawsuit is genuinely a life-or-death matter, and if this Court does not intervene now, critically ill people will in the immediate future—for no good reason—be denied the opportunity to receive life-saving treatment.

30. Accordingly, Dr. Marik begs this Court to vindicate his and his patients' legal rights, to declare Sentara's Prohibition unlawful and unenforceable, and to give Sentara's acutely ill COVID patients the chance to save their lives to which they are entitled to under Virginia law.

COUNT ONE
BREACH OF THE DUTY OF INFORMED CONSENT

31. Each and every allegation set forth in the above paragraphs of this Complaint is hereby repeated, reiterated, and realleged.

32. Virginia law (like the law of every state in the country) recognizes a patient's right of informed consent.

33. The right to informed consent includes the right to be informed of, and to have an opportunity to choose, feasible existing alternative treatments, if any, known to or reasonably knowable by a patient's treating physician.

34. In the hospital setting, this right is exercised with and through the advice of the patient's attending physician, and a hospital's attempt to silence the attending physician, and to bar him from discussing with and offering to patients alternative treatments that he in the reasonable exercise of his professional judgment believes appropriate, violates both the

"patient[s'] right to receive medical care in accordance with [their] licensed physician's best judgment and the physician's right to administer it." *Doe v. Bolton*, 410 U.S. 179, 197 (1973).

35. Accordingly, by preventing Dr. Marik from discussing, advising and offering his COVID patients the medicines banned by Sentara, the Prohibition violates the right of informed consent.

COUNT TWO
VIOLATION OF THE HEALTH CARE DECISIONS ACT

36. Each and every allegation set forth in the above paragraphs of this Complaint is hereby repeated, reiterated, and realleged.

37. Under Virginia's Health Care Decisions Act, individuals have the right to execute an Advance Directive not only to declare in advance what treatment they choose *not* to receive in case of incapacity, but "to specifically direct" the treatment they *are* to receive, so long as that treatment "is medically appropriate under the circumstances *as determined by [their] attending physician*." Va. Code § 54.1-2984 (emphasis added).

38. The statute does not say, "as determined by the *hospital*." It specifically and expressly says, "as determined by [their] *attending physician*." *Id.* (emphasis added).

39. The health care decisions that the Act gives individuals the right to make for themselves, provided the treatment is recommended by their attending physician, include decisions to specify particular "medications" for particular illnesses. Va. Code § 54.1-2982.

40. Unless the treatment specifications in an individual's Advance Directive are in violation of law, or are deemed inappropriate by the individual's attending physician, "a patient's advance directive *shall . . . be given full effect*," and "*any person*" may bring suit in this Court for injunctive relief to ensure that treatment will not be "withheld" from a patient

in violation of his or her directive. Va. Code §§ 54.1-2983.3 (emphasis added), 54.1-2985 (emphasis added).

41. The Health Care Decisions Act establishes two distinct rights of patients to decide specifically what medicines they shall receive if recommended by their attending physician.

42. First, it gives each individual Virginian a right to make that decision *for situations in which he becomes incapaciated.* And second, it assumes and equally recognizes an individual's equivalent right to make that decision *if he is conscious and of sound mind.* For it would be absurd to read the statute as creating a greater right to decide what one's medical treatment will be when incapacitated than to decide what one's medical treatment will be when one is conscious and of sound mind.

43. The Prohibition violates both these rights. It prohibits the enforcement of Advance Directives (such as those submitted in this case) in which individuals specifically direct that they are to receive the banned medicines in the event of incapacity if their attending physician deems them medically appropriate. And it also prohibits individuals who are not incapacitated from exercising the right to specifically direct that they are to receive the banned medicines if their attending physician deems them medically appropriate.

44. Thus the Prohibition violates the Health Care Decisions Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dr. Paul E. Marik respectfully request that the Court enter judgment in his favor as follows:

A. An order declaring Defendant's Prohibition unlawful and unenforceable;

B. An order enjoining Defendant or anyone serving as Defendant's agent or affiliate from applying or enforcing the Prohibition, thereby permitting patients to be informed of and to receive the currently banned COVID treatments provided their attending physician deems them medically appropriate; from continuing to engage in conduct found to be unconstitutional and requiring Defendant to issue a public retraction of its letter;

C. Any and all such other relief, including attorneys' fees, this honorable Court determines to be just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

DR. PAUL E. MARIK

BY: _____
Counsel

Fred D. Taylor, Esquire
VSB# 77987
Bush & Taylor, P.C.
200 N. Main Street
Suffolk, Virginia 23434
Telephone: 757-935-5544
Facsimile: 757-935-5533
E-Mail: fred@bushtaylor.com
Http://www.bushtaylor.com
Counsel for Plaintiff

Verification

I, Dr. Paul E. Marik, hereby verify under penalty of perjury that the factual allegations in the foregoing are true and correct to the best of my knowledge and belief.

Dr. Paul E. Marik

Commonwealth of Virginia
City / County of Norfolk, to-wit:

This Verification was acknowledged before me on the 8 day of November 2021, by Dr. Paul E. Marik.

Deborah Marie Lucas
Notary Public
7181351

My commission expires: 3-31-2024

FRED D. TAYLOR
Bush & Taylor, P.C.
4445 Corporate Lane
Virginia Beach, VA 23462
Telephone: (757) 926-0078
E-Mail Address: fred@bushtaylor.com

Attorney for Plaintiff
DR. PAUL MARIK, M.D.

NORFOLK CIRCUIT COURT

FOURTH JUDICIAL CIRCUIT OF VIRGINIA

DR. PAUL MARIK, M.D. Plaintiff, v. SENTARA HEALTHCARE SYSTEM, Defendant.	Case No. **DR. PAUL MARIK, M.D., DECLARATION**

DECLARATION OF PAUL MARIK, M.D.

I, Paul Marik, M.D., declare as follows:

1. I am the Plaintiff in the above-entitled action. This declaration is made in support of my verified complaint and request for emergency relief. I have personal knowledge of all of the facts set forth herein, except as to those matters stated on information and belief

2. I am a licensed physician in the State of Virginia (License #: 0109-542065). I have specialized over the past 35-years as a bedside clinician, lecturer and author in the field of critical care medicine. I am a tenured Professor of Medicine at the Eastern Virginia Medical School ("EVMS"), and the Chief of EVMS's Division of Pulmonary and Critical Care Medicine within its Department of Internal Medicine. I am also the Director of the General Intensive Care Unit ("GICU") at Sentara Norfolk General Hospital ("Sentara Hospital"), the corporate defendant named in this action. Crucially, over the past 12 years I have served as the attending physician of record to all patients (up to 20 at a time) in the Sentara Hospital GICU during my regular one week per month 24/7 call rotation.

Background and Experience

3. I am board-certified by the American Board of Internal Medicine in Internal Medicine and Critical Care Medicine. I am a Fellow of the American College of Physicians, the American College of Chest Physicians, and the Society of Critical Care Medicine. I hold the EVMS Foundation Distinguished Professorship in Internal Medicine. I have authored or co-authored over 520 peer-reviewed journal articles on diverse topics in the critical care setting, including Sepsis and Myocardial Infarction; most recently, co-authored 10 papers on treatment of COVID-19. I have authored four critical care books, as well as 80 book chapters, and have delivered over 350 lectures on that subject at international conferences and visiting professorships, and received numerous teaching awards, including the National Teacher of the Year award by the American College of Physicians in 2017.

4. I am the developer of the EVMS COVID-19 Protocol, and one of the developers of the similar MATH+ Protocol[1] which I discuss in detail below, and a founding member of the Frontline Critical Care COVID Alliance. I have consulted or appeared as a critical care expert in roughly 50 cases for both plaintiffs and defendants.

5. I have never previously been a plaintiff or defendant. There has never been a formal patient complaint directed against me. A true and correct copy of my Curriculum Vitae is attached as **Exhibit "A"**.

The Urgency of the Moment

6. Since the COVID Pandemic began in March 2020, I have treated my Sentara GICU patients with an evolving MATH+ Protocol of anti-inflammatory agents which has saved lives, and in my real-world experience, has substantially reduced COVID mortality . On October 6, 2021, I received an email message sent to my EVMS work email address entitled "A Message from Dr. Joel Bundy, MD, Chief Quality and Safety Officer," ("Sentara Hospital Prohibition"), which stated in pertinent part:

> Colleagues,
>
> Please see the newest COVID-19 Comprehensive Treatment Guidelines (Version 26). Updates are emphasized below.
>
> - Added a "do not endorse" section which includes medications that may cause harm and efficacy/safety is not supported in peer reviewed, published RCT. These medications will not be verified or dispensed for prevention or treatment of COVID: ivermectin, bicalutamide, etoposide, fluvoxamine, dutasteride, and finasteride. These medications should only be prescribed if the patient is enrolled in a clinical trial.

---

[1] "MATH+" Protocol stands for **M**ethylpredinose - **A**scorbic Acid (Vitamin C) – **T**hiamine (Vitamin B1) – **H**eparin + Ivermectin – Statin – Zinc – Vitamin D – Famotidine – Melatonin.

- Ascorbic acid (Vitamin C) IV is not endorsed for prevention or treatment of COVID-19 or sepsis/septic shock.

A true and correct copy of Dr. Bundy's email and Sentara Hospital Prohibition is attached as **Exhibit "B".**

7. From October 25 to 31, 2021, I worked my GICU 24/7 weekly call rotation, my first since Dr. Bundy's message conveying the Sentara Hospital Prohibition. This turned out to be the most harrowing week of my life. I was barred from telling my GICU patients about alternative available COVID treatments (the MATH+ Protocol) not being offered to them. I would have had my hospital privileges revoked should I do otherwise, and the hospital pharmacy is under the same Prohibition from dispensing these medicines. I had to sit idly by and watch *four* of my patients die, including a 32-year-old woman, while being prohibited from providing the treatment that they so desperately needed, and which had proven so effective with other patients in the past. When I ended this 7-day rotation on October 31, another *three* patients were on a similar downward path: one was chemically paralyzed and on a ventilator; one was tracheostomized being ventilator dependent, being fed with a PEG feeding tube and was severely encephalopathic; while the third remained in the ICU dependent on a high concentration of oxygen and likely to die. All of these patients were "full code" on GICU admission, *i.e.*, had no restrictions on their care. For each of those patients, I would have given the MATH+ protocol in the crucial 1-2 day window after they were first admitted to my GICU. I could not honor their "full code" directive because of the Sentara Hospital imposed prohibition, which I believe is violative of the very essence of the doctor/patient relationship. As the clinician, I also am bound by the Hippocratic duty to provide the best care I deem possible for these patients.

8. My next GICU 24/7 weekly call will be November 15 to 21, 2021. When I report for duty as the attending physician of record for those 20 GICU patients, it is virtually certain that I will treat acutely ill COVID patients, and several or more of these patients may die if the

operation of the Sentara Hospital Prohibition is not stayed or reversed. All of those patients – those 2 to 4 who have Advance Directives for all measures to save their lives, and those without Advance Directives from whom "full code" is the basic standard of care – should be advised of the alternative medicines that can save their lives, and with their informed consent, provided with that life-saving care. The Sentara Hospital Prohibition bars me from discussing or advising my GICU patients of my professional opinion that the MATH+ Protocol is *the* optimal medical treatment alternative for severe COVID-19 infection. I believe I will have my Sentara Hospital privileges revoked, and face other severe discipline or termination, should I violate that ban.

9. My MATH+ Protocol saves lives. I know this from administering it myself on the Sentara GICU whenever possible over the past 20-months of COVID. I co-chartered an organization called "Front Line COVID-19 Critical Care Alliance" ("FLCCC"), a 501(c)(3) non-profit organization dedicated to developing highly effective treatment protocols to prevent the transmission of COVID-19 and to improve the outcomes for patients ill with the disease. The FLCCC includes a network of many worldwide physicians, nurses, and others health professionals, and is an invaluable resource to many people worldwide. My clinical results with the MATH+ Protocol are collaborated by the reported clinical experiences of fellow FLCCC and other clinicians, documented worldwide practices and results, and published studies supporting the safety and efficacy of many of these drugs in treating the novel Coronavirus. I am an expert on COVID, but because of the Sentara Hospital Prohibition, I am prevented from using my expertise to treat these people. My hands are tied completely. I seek this Court's urgent intercession to prevent this avoidable tragedy and violation of my Hippocratic Oath, and my patients' legal rights. The Hospital, as an entity, should not interpose itself between the patient and their doctor, or predetermine the standard of care in a Pandemic and at the most critical time in that patient's life.

A "Day in the Life" of Sentara Hospital GICU During COVID-19

10. Sentara Hospital has around 560 beds total. It is the only tertiary-care level facility for the community of 1.8 million people who live in Hampton Roads, Norfolk, Virginia Beach, and Suffolk, Virginia. The Sentara Hospital GICU has a total capacity for 20 patients at a time, 16 on the tenth floor with four overflow beds on the ninth floor.

11. With 35-years under my belt, I am the most experienced of the four physicians who rotate through the Sentara Hospital GIC; three of these physicians are one to three years out of fellowship training. As the attending GICU physician of record one week out of four, I am responsible for all aspects of my GICU patients' care, their complete management, including examination, diagnosis, treatment, and whether the patient requires additional or other consulting services. In providing such care, I direct one fellow (a resident studying pulmonary critical care); six-to-eight residents in either internal medicine or emergency medicine on two-to-four week GICU rotations; a chief nurse (the manager); other nurses, each of whom is assigned to two patients; and two respiratory therapists. Typically, in the morning, the residents will examine the patients; the fellow will help the residents. At 8:30 to 11:30 a.m. each morning, I lead teaching rounds from patient to patient. The residents present each patient to me and the fellow, the patients' nurse, and the other residents. We see and examine the patient, we make a treatment plan, and I give the fellow, residents and nurse some teaching on the patient's condition, for all 16 to 20 GICU patients. I then enter my notes into the desktop computer, sign medication orders, and do the billing. The fellow meets with all the residents to"run the list," *i.e.*, set forth the daily to-do list for each patient.

12. I then look at patient X-rays and CT-scans, and reflect on their labs or other results, and research issues on my computer. If a new patient comes in, the ER calls me about whether it's appropriate to transfer the patient to the GICU. To come to the GICU, a patient has to be unstable. The broad criteria include low blood pressure or respiratory distress (insufficient oxygen), which is the reason most of the COVID patients are admitted to the Unit

for respiratory support. The GICU is the predominant ICU at Sentara Norfolk General Hospital where COVID patients can be on the following advanced therapies: (a) High-flow oxygen devices; (b) CPAP, which is a mask that goes on the face; (c) ventilator; or (d) vasopressor support (drugs to increase blood pressure). The respiratory therapist is in charge of the ventilator and the oxygen, and, under my direction, they will increase the oxygenation, or change the ventilator settings or advise whether the patient needs to be ventilated.

13. If COVID patients come to the Emergency Department and have respiratory issues or their blood pressure is low, they are admitted directly to the GICU where we can provide a higher level of respiratory support or ventilation. If patients are stable with low level oxygen, they can go to a hospital floor, but if they need a higher level of respiratory support they come to the GICU. It is crucial to understand that *there is only a narrow window of therapeutic opportunity here. The earlier I treat COVID patients, the better they do. As the window closes, it's more difficult to treat them.*

14. "Early" is a relative term. The goal is to prevent the disease from advancing to the point where the patient's lungs are failing and, as a result, the patient has to be put on a ventilator. When patients arrive in the GICU, they need to be treated aggressively so their disease doesn't progress. *The therapeutic window varies from patient to patient, but usually I have a day or two to make a big difference, because the disease can progress quickly, especially with Delta variant. That's where MATH+ protocol comes in. I adjust the treatment protocol according to how sick the patient is. By definition, and in reality, they are critically ill and have a high risk of dying. In terms of COVID, every patient who comes to the GICU is in a terminal state, if not treated. Without the MATH+ protocol,many if not most of these patients will not, to a reasonable degree of medical probability, recover from their illness and face imminent death.*

15. We look at the patients' bio-markers and CT-scans, and decide how severe they are, and how aggressive we should be. Once they come to the GICU, we need to escalate the

standard of care and give them the "Full Monty" to prevent their disease from progressing further. You have to escalate the care from what they do on the floor (medical ward) in the hospital, because obviously what they were doing was *not* working. It is critical to understand that the breathing machines do not treat the underlying COVID disease, *i.e.*, the inflammation. Everything on the MATH+ protocol is there to escalate the care by treating the underlying disease process; *everything else we can offer on the GICU is only supportive. The MATH+ protocol treats the otherwise uncontrolled inflammation of the lung*s. Clearly, patients arrive at the GICU because what they were getting on the hospital floor was not working. In my judgment, it is vital within that first 1-to-2 day "window" to increase the intensity of anti-inflammatory treatment. We put out the fire with the best anti-flame retardants we have. I need that opportunity to escalate the care as I see fit to control COVID, and my patients desperately need me to do this. My basic responsibility as a physician is to figure out how we escalate the treatment. In that regard, I believe that about 50% of my patients have received or are getting Remdesivir when they are admitted to me at the GICU. I do *not* prescribe Remdesivir to them, and discontinue its use if they are on it beforehand. I consider it inappropriate to prescribe a medication that is ineffective, does not benefit patients, and is potentially toxic (damages kidney) by the great weight of the scientific evidence.

16. Typically, after lunch, I go back to the GICU, see patients, and answer questions. Pre-COVID, I would spend a reasonable amount of time talking with family. In COVID, there's no family, which is one of the terrible things about COVID. They are isolated from somebody who is really sick. We only allow families (one or two members) in when the patient is dying. The worst part about COVID is that family is really important support for the patient, and helps physician decisionmaking. In their absence, I believe that my responsibility as the attending physician of record to make competent decisions which maximize the patients' chances of recovery is all the more important, austere, and sacrosanct.

17. I monitor the patients and usually go home around 5:00 pm. I'm on call at night, so when the residents have questions at night, they call me. Typically, I do a 24/7 rotation from Monday morning 8:00 am to the next Monday morning 8:00 a.m. I am currently assigned to perform 24/7 weekly rotations on the Sentara Hospital GICU from November 15 to 21, and from December 20 to 26, 2021.

Advance Directives, Physician Advice, and Informed Consent

18. Whenever a patient is admitted to the GICU, they are always asked whether they have an Advance Directive, and their code status has to be recorded in their chart. If they are being admitted for COVID-19, this is when I would like to advise them of the availability of alternative medicines that can save their lives. The default position is "full code" written in red on top of their chart – this means we do everything medically appropriate, including CPR for cardiac arrest; DNR means do not resuscitate if the patient has cardiac arrest. The least aggressive is comfort care, but those patients do not come to the GICU by definition. In my experience, 20 to 30% of patients have an Advance Directive on admission. There is a box to check that says the equivalent of "Full Code" – full, aggressive care. To the doctor, this means "Do everything possible to save my life."

19. "Informed consent" is *the* bedrock principle by which physicians render care to their partients. It is my professional duty and prerogative to discuss with patients upon GICU admission my own judgments about the optimal treatment for their COVID-19, including available alternative treatments, in order to obtain their informed consent.

MATH+ Protocol for Treating ICU COVID Patients

20. It is my professional judgment that *the* reason the MATH+ Protocol has been of such benefit, and has saved so many lives of ICU COVID patients, lies in the entire combination of medicines making up the protocol. All the elements work together like a perfect baking recipe. "We," by which I mean FLCCC alliance physicians, who practice

medicine in varied locations throughout the United States, used high dose steroids before anyone in the world was using steroids. It's now standard of care; however, most doctors use the wrong dose. We were using blood thinners (Heparin) very early; it is now standard of care. We are using (in alphabetic order): IV Ascorbic Acid (Vitamin C - infusion); Atorvastatin; Bicalutamide; Cyproheptadine ; Dutasteride; Famotidone (an anti-acid)-pepsid; Finasteride; Fluvoxamine; Ivermectin; Melatonin; Methylprednisolone; Nitazoxanide; Statin; Therapeutic Plasma Exchange; Thiamine; Vitamin D; and Zinc.

21. Of these medicines, the Sentara Hospital Prohibition prevents me from prescribing or using Acorbic Acid (Vitamin C); Bicalutamide; Dutasteride; Finasteride; Etoposide; Fluvoxamine; and Ivermectin which, as noted above, vitiates the MATH+ Protocol.

22. My real world experience over the 20-month course of the COVID Pandemic, and prior to the Sentara Hospital Prohibition, is that my use of the MATH+ Protocol has reduced ICU COVID patients' mortality rates from approximately between 40 to 60% to less than 20%. This is my assessment based on the outcomes of roughly 200 ICU COVID patients whom I have treated at Sentara Hospital, in comparison to those other patients whom I have not treated, since March 2019. I believe these reduced mortality rates (without question reduced *by half*) are consistent with those of my FLCCC physician colleagues as described in other supporting declarations of Drs. Pierre Kory and Joseph Varon. Additionally, there is a wealth of scientific literature supporting the use of these therapeutic medicines and supplements to treat ICU COVID patients, so their lives can be saved. (https://covid19criticalcare.com/covid-19-protocols/medical-evidence-and-optional-medicines/); *see also* https://covid19criticalcare.com/wp-content/uploads/2021/01/FLCCC-Alliance-MATHplus-Protocol-ENGLISH.pdf; Pierre Kory, et al., "Clinical and Scientific Rationale for the "MATH+" Hospital Treatment Protocol for COVID-19," *Journal of Intensive Care Medicine*1-22, https://covid19criticalcare.com/wp-content/uploads/2020/12/MATH-plus-Rationale-Journal-of-Intensive-Care-Medicine-Dec2020.pdf

23. Outside the Norfolk, Virginia geographic scope of Sentara Hospital's Prohibition, I am informed that the MATH+ Protocol is having a profound impact in the worldwide fight against COVID. It is certainly able to be accessed and discussed; in the past three months, I am told that website views of the MATH+ Protocol Page averaged 1.69 million views per month; and as of September, 2021, the FLCCC membership includes 1,340 health care professionals (doctors, pharmacists, RN's, PA's).

I declare under penalty of perjury under the laws of the Commonwealth of Virginia that the foregoing is true and correct to the best of my knowledge and that this declaration was executed in Norfolk, Virginia, on November 9, 2021.

_____
PAUL MARIK, M.D.

Director, General Intensive Care Unit
Sentara Norfolk Hospital

FRED D. TAYLOR
Bush & Taylor, P.C.
4445 Corporate Lane
Virginia Beach, VA 23462
Telephone: (757) 926-0078
E-Mail Address: fred@bushtaylor.com

Attorney for Plaintiff
DR. PAUL MARIK, M.D.

NORFOLK CIRCUIT COURT

FOURTH JUDICIAL CIRCUIT OF VIRGINIA

DR. PAUL MARIK, M.D. Plaintiff, v. SENTARA HEALTHCARE SYSTEM, Defendant.	Case No. **DR. PIERRE KORY, M.D., M.P.A. DECLARATION**

DECLARATION OF PIERRE KORY, M.D., M.P.A.

I, Pierre Kory, M.D., M.P.A., declare as follows:

1. I submit this declaration in support of the Plaintiff, Dr. Paul Marik's, verified complaint and request for emergency relief in the above entitled action. If called as a witness, I could and would testify competently to the facts herein, except as to those matters stated on information and belief.

2. My purpose in submitting this declaration is to express my view that Dr. Marik is an extraordinary clinician, possessed of stellar medical and academic credentials, and an exceptional breadth and depth of experience as a physician. More specifically, I believe that the COVID treatment protocol that he has developed and prescribed works and has saved patients' lives. This is confirmed by the results I have seen in using these protocols to treat my own patients. In summary, it is my view that Dr. Marik, an attending physician of vast experience and widely recognized excellence and expertise, should not be prevented by hospital administration at Sentara Healthcare System from using those protocols and advising his patients of their safety and efficacy in accordance with his seasoned medical judgment in order to alleviate the suffering of his patients and avoid unnecessary deaths from COVID.

3. Before I discuss Dr. Marik, I believe it is relevant to discuss briefly my own credentials and medical background. A true and correct copy of my *Curriculum Vitae* is attached to this declaration as **Exhibit** "**A**." I am an American critical care physician and have practiced medicine for almost twenty years. In 2002, I graduated with an MD degree from St. George's University and completed my residency and fellowship training in critical care and pulmonary medicine. In addition, I did clinical rotations at the Weill Cornell School of Medicine. I am board certified in Internal Medicine, Pulmonary Diseases, and Critical Care Medicine. I first practiced for seven years at Beth Israel Medical Center in New York City as an ICU and pulmonary outpatient physician, and bronchoscopist. I was then recruited to the University of Wisconsin in Madison, Wisconsin at UW Health University Hospital, the academic medical center that is part of the University of Wisconsin School of Medicine and Public Health. While at UW Health I served as Medical Director of the Trauma and Life Support Center, as the

critical care service chief, and as an attending physician in the outpatient pulmonary medical clinic, where I performed bronchioscopic and pleural procedures. I am a recognized expert in critical care ultrasonography. In 2015, along with my two co-editors, I was awarded the British Medical Association's President's Choice award for our work in producing the medical textbook *Point of Care Ultrasound.* I served as the critical care service chief at UW Health until May, 2020. At that time, I resigned from UW Health largely due to the frustration I felt at UW Health's reluctance to implement treatment measures for COVID-19 patients that I believed to be effective. These treatment measures involved the use of anti-coagulation and corticosteroids, both of which later became the standard of care worldwide. After my resignation from UW Health, I became an emergency volunteer in my old ICU at Beth Israel Medical Center during the months of April-May 2020 in New York City where I was the Attending in the main COVID-ICU. I then worked as a *locum tenens* physician from August to October 2020 at Greenville Memorial Hospital in Greenville, SC, where I cared for COVID patients during the summer surge. I then joined Aurora St. Luke's Medical Center in Milwaukee, Wisconsin in October 2020. I left that institution two months later, in December 2020, after testifying before the U.S. Senate on effective early treatment of COVID with ivermectin. This action led to Aurora offering me a new contract containing multiple infringements on my ability to speak publicly. Consequently, I declined the contract offer. I have again become a *locum tenens* physician, attending in ICUs and on pulmonary wards as an independent contractor at a hospital in central Wisconsin.

4. I am the President and co-founder, along with Dr. Paul Marik, of the Front Line COVID-19 Critical Care Alliance ("FLCCC"), a US organization of physicians formed in March, 2020. The FLCCC's mission is to create and disseminate the most effective treatment protocols for COVID, and to advocate for such protocols, which include ivermectin, along with a combination of other medicines, therapies, and drugs. I have testified in support of these alternative therapies on several occasions, including on May 5, 2020 and December 8, 2020 at Senate hearings concerning COVID-19 called by U.S. Homeland Security Committee Chair Ron Johnson.

5. My own real-world experience over the past 20 months in dealing with the COVID pandemic has persuaded me that the use of the MATH+ Protocol devised by Dr. Paul Marik and the FLCCC is effective. Specifically, I have seen in treating my own patients that the Protocol not only reduces suffering, but saves lives. This is due to the fact that I have observed repeated changes in disease trajectories such that patients improve without need for invasive mechanical ventilation, and are thus discharged from the ICU earlier. I have also seen patients on mechanical ventilation begin to improve such that they are able to be weaned off mechanical ventilation. Based on my assessment of outcomes for the roughly 150 ICU COVID patients I have treated with the MATH+ Protocol since April, 2020 at Beth Israel Medical Center, Greenville Memorial Medical Center, Aurora St. Luke's Medical Center and then in ICUs as a *locum tenens* physician in comparison with those patients I have covered and followed that were managed by partners and colleagues who were not treated with the MATH+ Protocol, I believe that the use of this Protocol leads to lower rates of mechanical ventilation and death from COVID, with earlier and more frequent discharges from the ICU. These results are consistent with those experienced by my physician colleagues at FLCCC, and as described in particular in the declarations submitted by Dr. Joseph Varon and Dr. Paul Marik. In addition, as noted in Dr. Marik's declaration, a substantial scientific literature supports the use of these therapeutic medicines and supplements to treat ICU COVID patients and save lives. *Medical Evidence*, FRONT LINE COVID-19 CRITICAL CARE ALLIANCE, Prevention & Treatment Protocols for COVID-19, https://covid19criticalcare.com/covid-19-protocols/medical-evidence-and-optional-medicines/; *see also* Pierre Kory, et al., *Clinical and Scientific Rationale for the "MATH+" Hospital Treatment Protocol for COVID-19*, JOURNAL OF INTENSIVE CARE MEDICINE 1-22 (2020), https://covid19criticalcare.com/wp-content/uploads/2020/12/MATH-plus-Rationale-Journal-of-Intensive-Care-Medicine-Dec2020.pdf.

Dr. Paul Marik

6. Dr. Marik received his medical degree from the University of the Witwatersrand, Johannesburg, South Africa, followed by a Master of Medicine Degree, Bachelor of Science

Degree in Pharmacology, Diploma in Anesthesia, as well as a Diploma in Tropical Medicine and Hygiene. Dr. Marik did a Critical Care Fellowship in London, Ontario, Canada, during which time he was admitted as a Fellow to the Royal College of Physicians and Surgeon of Canada. Dr. Marik has worked in various teaching hospitals in the US since 1992. He is board certified in Internal Medicine, Critical Care Medicine, Neurocritical Care and Nutrition Science. Dr. Marik is currently a Professor of Medicine. He has authored over 500 peer reviewed journal articles, 80 book chapters, and four critical care books. He has been cited over 44,000 times in peer-reviewed publications and has an H-index of 98, a score that indicates exceptional productivity and scientific impact. Dr. Marik has delivered over 350 lectures at international conferences and visiting professorships. He has been an invited member of numerous society guideline development committees.

7. Some of Dr. Marik's notable contributions include:

- In 2011, an international committee assembled by the main thoracic and respiratory national societies published guidelines for the diagnosis and management of idiopathic pulmonary fibrosis. The guidelines' section on the treatment of complications relied in part on the results of Dr. Marik's 2001 research on the association of gastric reflux and aspiration.
- In 2012, an international committee updated guidelines for the management of severe sepsis and septic shock. In its section of supportive therapy recommendations, the committee based its concept on blood product administrations partly on research performed by Paul Marik and W. Sibbald in 1993. Dr. Marik has also received numerous teaching awards, including the National Teacher of the Year award by the American College of Physicians in 2017.

Dr. Marik's Expertise in the Area of COVID-19

8. Since the onset of the COVID Pandemic, Dr. Marik has become a world-renowned expert in the pathophysiology and treatment of COVID, having published 15 articles in peer-

reviewed medical journals and delivered 11 invited national and international lectures on various COVID-19 topics. In several of the lectures, many thousands of physicians attended remotely (India – approximately 20,000 attendees; Ukraine – approximately 3,000 attendees). He is one of the foremost experts on the use of Ivermectin in the treatment of COVID-19. The review paper concerning Ivermectin as a COVID treatment on which he served as senior author has an altmetric popularity rank of #38 out of the last 19,278,000 scientific papers published.

9. Further, Dr. Marik is the co-founder of the non-profit organization FLCCC, formed in March 2020 and consisting of a group of clinical experts whose sole mission was to develop the most effective COVID-19 treatment protocols. To date, FLCCC has developed treatment protocols for: a) prevention, b) early treatment, c) hospital treatment, and d) long haul COVID syndrome. Currently, the FLCCC has over 1,500 physicians, pharmacists, advanced practice providers and nurses who have signed up as Alliance members, with over 400 from outside the U.S.A.; a further 96,000 individuals globally have signed up for regular protocol and other news updates. The FLCCC website averages 1.7 million visitors a month, with 5.9 million page views and protocol page views of 1.7 million a month.

10. The FLCCC protocols have been adopted by many clinicians, hospitals, and regions worldwide. Dr. Marik and his co-members of the FLCCC have been asked to present these treatment protocols around the world. Some notable impacts are that a leading Physician in the country of Ukraine informed the FLCCC that her national medical society adopted MATH+ as the protocol for COVID-19 treatment of hospital patients. As an FLCCC member, I was invited to present the science of Ivermectin and the I-MASK+ protocol to the President of Sri Lanka, and to make presentations on this subject to the press in several well-attended lectures in Malaysia and Indonesia.

11. Dr. Marik's Peer-Reviewed Publications on COVID-19 and Presentations include the following:

Publications

- Marik PE, Kory P, Varon J, Iglesias J. Meduri GU. MATH+ Protocol for the treatment of SARS-CoV-2 infection: The Scientific Rationale. Expert Review of

anti-infective therapy 2020; ePub. 450.

- Arvinte C, Singh M, Marik PE. Serum levels of vitamin C and vitamin D in a cohort of critically ill COVID-19 patients of a North American Community Hospital Intensive Care Unit in May 2020. A Pilot study. Medicine in Drug Discovery 2020; (in press).
- Kory P, Meduri GU, Varon J, Marik PE. The Clinical and Scientific Rationale for the MATH+ Hospital Treatment Protocol in COVID-19. J Intensive Care Med 2020; (ePub).
- Marik PE, Varon J. Kory P. The treatment of COVID-19 is critically phase specific. Crit Care Shock 2020; 23:10-12.
- Ahmad Q, DePerrior SE, Dodani S, Edwards JF, Marik PE. Role of inflammatory biomarkers in the prediction of ICU admission and mortality in patients with COVID-19. Medical Research Archives 2020; 8:1-10.
- Reiter RJ, Sharma R, Castillo R, Marik PE, Rodriguez AD, Cardinalli DP. Coronavirus-19.
- monocyte/macrophage glycolysis and inhibition by melatonin. J SARS-CoV-2 COVID 2021; 2:29-31.
- Ngo BT, Marik P, Kory, P.; Shapiro L. et al. The Time to offer treatments for COVID-19. Expert Opinion on investigational drugs 2021; in press.
- Marik PE, DePerrior SE, Ahmad Q, Dodoan S. Gender-based disparities in COVID-19 patient outcomes. Journal of Investigative Medicine 2021; 69:814-818.
- Kory P, Meduri GU, Iglesias J, Varon J, Berkowitz K, Kornfeld H,Vinjevoll E, Mitchell S, Wagshul F, Marik PE. Review of the emerging evidence demonstrating the efficacy of ivermectin in the prophylaxis and treatment of COVID-19. American Journal of Therapeutics 2021; 28:e299-e318.
- Griffin DO, Brennan-Reider D, Ngo B, Kory P, Confalonieri M, Shapiro L, Iglesias J, Dube M, Nanda N, Marik P. The importance of understanding the stages of COVID-19 in treatment and trials. AIDS Reviews 2021; 23:1-8.

- Colunga Biancatelli R. Solopov P, Sharlow E, Lazo J, Marik PE, Catravas J. The SARS-CoV-2 spike protein subunit 1 induces COVID-19-like acute lung injury in K18-hACE2 transgenic mice and barrier dysfunction in human endothelial cell. Am J Physio-Lung Cellular and Molecular Physiology 2021; in press.
- Araiza A, Duran M, Patino C, Marik P, Varon J. The Ichikado CT score as a prognostic tool for coronavirus disease 2019 pneumonia: a retrospective cohort study. J Intensive Care 2021; 9:51.
- Marik PE, Iglesias J., Varon, J., Kory P. COVID-19 in-hospital mortality: A concise Worldwide Review. J Community Medicine and Public Health Reports, 2021; 2.
- Marik P., Iglesias J., Varon J., Kory P. A scoping Review of the pathophysiology of COVID-19.
- International Journal of Immunopathology and Pharmacology 2021; in press.

National and International Invited Lectures and Presentations on COVID-19

- COVID-19: A clinician's perspective. Plenary Lecture. EVMS Research Day, October 16th, 2020.
- I-MASK Protocol: The Prevention and Early Treatment of COVID-19 and the role of Vitamin C. Webinar. Indian Critical Care Society, December 23, 2020.
- COVID-19: A Clinicians Perspective-A Review of the MATH + and i-MASK Protocols. Pulmonary and Critical Care Grand Rounds (Webinar). Renaissance School of Medicine at Stony Brook University. January 20th, 2021.
- COVID-19: A Clinicians Perspective-A Review of the MATH + and i-MASK Protocols. Pulmonary and Critical Care Grand Rounds (Webinar). Massachusetts General Hospital and Harvard Medical School, Anesthesia Grand Rounds, January 21, 2021.
- The Lactate Myths. University of Liverpool (UK) Anesthesia Grand Rounds. 10th March 2021 via teleconference.

- Ivermectin for the treatment of COVID-19: A brief review. Northwest Anesthesia Conference. March 20, 2021, via teleconference.
- Ivermectin for the treatment of COVID-19. Spring 2021 Oncology Investor Conference. March 30, 2021, via teleconference.
- Corticosteroids and Ivermectin for the Treatment of COVID-19. MAAFIM 2021 International Virtual COVID -19 Symposium, April 10, 2021, Malaysia, via teleconference.
- Ivermectin for the treatment of COVID-19. Virginia Drug Discovery Consortium (VDDC) Conference, May 26, 2021, via Teleconference.
- An overview of the treatment of COVID-19. Trinity of COVID-19: Immunity, Inflammation & Intervention. May 29, 2021, for Critical Care Society of India, via teleconference.
- COVID-19: A focus on clinical management. Anesthesia Critical Care Grand Rounds, Tufts University Medical School, Boston, MA, November 2, 2021.

12. Finally, I respectfully note, based on my own experience as a treating physician directly responsible for the care and treatment of patients for nearly twenty years, that it is highly unusual for a hospital or hospital administrators to interfere in or countermand an attending physician's treatment decisions concerning his or her patients. This kind of intervention was virtually unheard of before COVID. It is my view that such intervention should be undertaken in only the rarest of circumstances, and even then only on the basis of specific and compelling medical reasons relevant to a particular case or situation. Respectfully, I do not believe that there is any justification for such interference with regard to Dr. Marik and his patients in the circumstances that have led to this legal action. On the contrary, it is my strongly held belief – based on my experience as a clinician for almost twenty years generally, and my real-world experience with the therapeutic protocols at issue here in particular – that the hospital's prohibition of Dr. Marik's use of his MATH+ Protocol in treating his patients will not help them, but will in many cases increase their suffering, advance their disease, and result in deaths which could have been avoided had Dr. Marik been permitted to use the Protocol.

13. I feel strongly that barring Dr. Marik from doing so is unconscionable, contrary to reason and science, and violative of the doctor/patient relationship – a relationship that has been recognized for centuries as one rooted in near sacred trust. It is the attending physician, the doctor at the bedside – the one who knows not only the fullest extent of patient details possible, but who watches and cares for the patient day-to-day such that needed adjustments to therapeutic approaches may be made based on improvements and/or deteriorations, and who possesses the knowledge, experience and hands-on involvement that are the keys to the most effective treatment possible – who is ultimately responsible for the patient and who customarily is, and must be, *the* decisionmaker for and with each patient, having fully informed and consulted with the patient regarding the treatment alternatives. The role of hospital administrators in such decisions, if they have any role at all, has historically been minimal. The blanket, one-size-fits-all Prohibition involved here is, in my medical opinion, without justification and contrary to good medical practice. Hospital administrators' judgments should not be substituted for the judgments of experienced attending physicians who have expertise in the relevant areas of medicine and specific knowledge of the particular patients under their care. All doctors are bound by a duty, as ancient as the Hippocratic Oath, to provide the best care that we possibly can to our patients. The action taken here by the Hospital, however well intentioned, is misguided, and effectively requires physicians to ignore that duty and to break that oath.

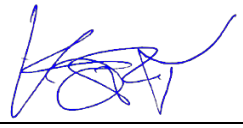
14. As noted herein, and as set forth in Dr. Marik's declaration, and the other declarations submitted in support of Dr. Marik's complaint and request for relief, the protocols at issue here work: they are demonstrably effective and have saved lives To deny these therapies to patients who are suffering from the dreadful disease of COVID – and who are in many instances facing the prospect of death as a result of the swift progress of that disease if left unchecked – is in my opinion just plain wrong, and is not in accordance with the duty and care owed our patients.

///

///

///

I declare under penalty of perjury under the laws of the Commonwealth of Virginia that the foregoing is true and correct to the best of my knowledge and that this declaration was executed in Madison, Wisconsin, on November 8, 2021.



PIERRE KORY, M.D., M.P.A.

DECLARATION OF DR. HARVEY A. RISCH

I, Dr. Harvey A. Risch, declare as follows:

1. I am an adult of sound mind and present this Declaration voluntarily, based upon my own personal and professional knowledge, education, and experience.

2. Accordingly, the following facts are within my own personal knowledge and, if called upon to do so, I could and would competently testify thereto under oath.

Background and Qualifications

3. I am a full professor of epidemiology at Yale School of Public Health and Yale School of Medicine, and a practicing academic epidemiologist with more than 40 years of experience in epidemiologic methods, both in research and teaching. Over this career, I have taught introductory, intermediate and advanced epidemiologic research methods to MPH and PhD students, postdoctoral fellows, hospital residents and junior faculty members. A true and correct copy of my curriculum vitae is attached hereto as Exhibit "1."

4. My 40 years of scientific research has primarily concerned the etiology of cancer according to various types of exposures including infectious, genetic, hormonal, pharmacologic, occupational, behavioral, dietary and other factors. I have been a member of the Society for Epidemiologic Research since 1982, the American Society of Preventive Oncology since 1984, and elected Fellow of the American College of Epidemiology since 1991. I received the Bachelor of Science degree in mathematics and biology from the California Institute of Technology in 1972 and completed medical training at UC San Diego School of Medicine in

1976. I then completed a PhD in biomathematics in 1980 at the University of Chicago, where my dissertation work involved mathematical solutions for the general stochastic epidemic model, on which I have published in the peer-reviewed scientific literature. During 1980-1983, I held a postdoctoral fellowship in the Department of Epidemiology at the University of Washington School of Public Health. In 1983, I moved to the University of Toronto, where I was Assistant and then Associate Professor, before moving in 1991 to Yale School of Public Health, becoming Professor of Epidemiology in 2001.

5. I have published more than 350 peer-reviewed original research papers in very well-regarded scientific journals and have an h-index of **96**, with more than 42,000 publication citations to my work to-date. I have served as grant reviewer or chair on some two dozen grant review panels including many at the National Institutes of Health (NIH), as well as peer reviewer for more than 50 scientific and medical journals. I have been Associate Editor of the *Journal of the National Cancer Institute* since 2000, Member of the Board of Editors of the *American Journal of Epidemiology* from 2014-2020, and Editor of the *International Journal of Cancer* since 2008.

6. In 2018, I received two prestigious awards for my research: the "Best of the AACR Journals" award for "Aspirin Use and Reduced Risk of Pancreatic Cancer," one of the most highly cited Cancer Epidemiology, Biomarkers & Prevention articles published in 2016 (April 2018) (http://aacrjournals.org/h-a-risch-bio), and the international Ruth Leff Siegel Award for Excellence in Pancreatic Cancer Research, (http://columbiasurgery.org/pancreas/ruth-leff-siegel-award), $50,000 cash stipend prize.

7. I am an elected member of the Connecticut Academy of Science and Engineering, and based on my strong epidemiologic methods experience and PhD work in infectious epidemic

models, was selected to be a member of the Academy committee that was organized in 2020 to formulate plans for the reopening of the state of Connecticut after its lockdown ended.

COVID-19 Research and Treatment Expertise

8. In May 2020, I published the seminal paper on early treatment of high-risk Covid-19 outpatients in the *American Journal of Epidemiology* (https://doi.org/10.1093/aje/kwaa093). This paper has been downloaded about 90,000 times and viewed by more than 150,000. I was senior author on the Covid-19 outpatient treatment clinical trial study in Brazil (https://doi.org/10.1016/j.tmaid.2020.101906), and have co-authored with Dr. Peter McCullough two papers that form the now-standard understanding of early outpatient Covid-19 management (https://doi.org/10.1016/j.amjmed.2020.07.003 and https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.264).

9. I began researching Covid-19 epidemiology, prevention, treatment and vaccination with my participation in the Connecticut Academy of Science and Engineering Covid-19 State Reopening Committee. In the subsequent 18 months, I have extensively studied medical and epidemiologic factors related to the virus and the disease in the US and internationally. I base my understandings of vaccine immunity and safety from studies and data of the three vaccines that have received emergency use authorization (EUA) from the US Food and Drug Administration (FDA): the two mRNA-technology vaccines (Pfizer-BioNTech and Moderna) and the adenovirus vector-based vaccine (Johnson & Johnson). None of these three vaccines available in the US to-date has received final FDA Biologics License Application

(BLA) licensure; the version of the Pfizer-BioNTech vaccine known as Comirnaty has had its FDA BLA approved but that vaccine version is not presently available for use in the US.

10. I have not had and have agreed not to receive any financial or other compensation for the preparation of this Declaration or for testifying in this case. I have received no financial or other compensation for providing expert consulting materials or affidavits or declarations in any other case related to the Covid-19 pandemic. My participation in the present and other cases has been motivated solely by what I believe professionally to be in the interests of public health and safety.

11. A long debate exists about types of studies upon which reliance can be placed for evidential reasoning and decisions about clinical utility. In particular, there has been a debate about whether or to what extent reliance can be placed on observational studies (nonrandomized trials, case-control studies, cohort studies, etc.) as opposed to double-blinded randomized controlled trials (RCTs).

12. There is no doubt that RCTs, if well conducted, large enough, and representative in the sample population tested, can provide quasi-experimental evidence on which reliance can be placed for evidential reasoning and decisions about clinical utility.

13. But in a *reductio ad absurdum*, some licensing, approval, and hospital bodies have adopted policies of basing drug-approval decisions *only* on evidence from RCTs. Such policies are not supported by science or data. Sole evidentiary reliance on RCTs was also rejected by the US Congress in the 21st Century Cures Act that it passed in 2016.

14. It is well known that RCTs (like non-RCT studies) are subject to many potential evidentiary flaws and are easily intentionally distorted or subverted in practice (Frieden, 2017; Deaton and Cartwright, 2018).

15. Additionally, a massive amount of work has been carried out empirically comparing the individual results of RCTs to their nonrandomized counterpart studies. The definitive Cochrane Library meta-analysis of what includes more than ten thousand individual studies demonstrates that standard adjusted modern nonrandomized trials show virtually identical results to their RCT counterparts (Anglemyer et al., 2014).

16. For clarity, let me repeat that conclusion. Definitive studies have demonstrated that overall, RCTs do not provide a superior evidentiary basis for clinical decision-making as compared to modern, adjusted non-randomized trial studies.

17. For this reason, the sole reliance on RCT evidence is *scientifically unwarranted* (Frieden, 2017), and while it may sometimes be challenging to summarize a more diverse body of scientific evidence, that is precisely how *scientific* conclusions are derived. This reasoning process most frequently follows the foundational schema of "aspects" of causal reasoning laid out by Sir Austin Bradford Hill more than 50 years ago (Hill, 1965) and is discussed at length in the "Reference Manual" (Committee on the Development of the Third Edition of the Reference Manual on Scientific Evidence, 2011).

18. When considering the efficacy or safety of medical treatments, all relevant evidence needs to be evaluated. Particularly in a pandemic, where the world confronts a novel, deadly, fast-spreading infection, a policy of insisting exclusively on RCT evidence—and refusing to use or approve medicines without conclusive RCT evidence—not only is scientifically unwarranted, but can lead to unjustifiable, needless death.

19. In pandemic conditions, clinicians all over the world dealing with a novel virus will attempt to save patients' lives by using the medicines that previous experience and scientific study suggest may be potentially therapeutic agents. Some of these medicines will prove

effective, and some will not. Clinicians will begin reporting preliminary results, and more and more clinicians will try the medicines reportedly showing therapeutic effect. They will conduct observational non-randomized trials and report the results. As more and more data from these observational studies come in, evidence can emerge in favor of a therapeutic agent that rises to the level of reliability such that evidence-based medicine and reasonable clinical judgment will support use of that medicine well before conclusive RCT data can be had.

20. This is exactly what has happened during the COVID-19 pandemic. Substantial amounts of non-RCT data have by now emerged on the basis of which clinicians can reasonably administer certain medicines to COVID patients even though conclusive RCT data may not be available for a number of years.

21. One such medication is Ivermectin. There have by now been many dozens of reported studies of Ivermectin conducted on COVID patients, and overall there is very clearly significant evidence of reduced risks of hospitalization and mortality. There is also dramatically strong evidence both from these studies as well as from decades of use of this medication by hundreds of millions of people in billions of doses worldwide that Ivermectin is exceedingly safe. In my expert opinion, this evidence rises to the level of reliability such that reasonable physicians could elect to use Ivermectin to combat COVID.

I declare under penalty of perjury under the laws of the Commonwealth of Virginia that the foregoing is true and correct, and that this Declaration was executed on November 8, 2021, in Fairfield, Connecticut.

SIGNATURE: 

DECLARATION OF DR. JOSEPH VARON

I, Joseph Varon, declare as follows:

Background and Qualifications

1. I am, and at all relevant times mentioned herein, have been, a licensed medical doctor, employed since the onset of the SARS-CoV-2 pandemic primarily as Chief of Staff and Chief of Critical Care Services at both United Memorial Medical Center and United General Hospital, in Houston, Texas. I am licensed to practice in California, Texas and all the states of Mexico. I am the Associate Dean of the Caribbean Medical University and I also hold active professorships in various fields of medicine and surgery in over 12 international medical schools and universities including multiple medical schools in Mexico (where I was born and raised), the Universite Claude Bernard, Lyon, , France, and The University of Houston School of Medicine and Baylor College of Medicine, in Houston, Texas.

2. I have been practicing medicine continually since 1987 and am Board certified in Internal Medicine, Critical Care Medicine and Pulmonary Disease. I have authored 12 textbooks, 15 dozen book chapters and more than 830 peer-reviewed articles on those and other medical subjects. A true and correct copy of my "mini bio" is attached as Exhibit "1" to this declaration. For brevity's sake a true and correct copy of my full *Curriculum Vitae* can be accessed at this Dropbox link: https://www.dropbox.com/sh/b7cr8kuoc50sx5e/AADLxatyq6ssK7HVadzfRAE0a?dl=0

3. I have personal knowledge of the facts set forth in this Declaration and, if called as a witness, could and would testify competently to such facts under oath.

Development of the MATH+ Protocol with Dr. Marik to Treat COVID-19

4. On or about March, 2020, I began collaborating with Dr. Paul Marik, a world-renowned intensivist, to try to arrive at a treatment protocol for patients with acute COVID-19 infections.

5. In December, 2020, Dr. Marik and I, along with other critical care specialists, formed the nonprofit charitable organization known as Frontline COVID-19 Critical Care Alliance ("FLCCC"), in order to gather, research and share information among health care professionals and the public. We had no pre-set agendas or therapies in mind, and still don't; our singular purpose is to meet this disease head-on and to save lives.

6. My position at the hospitals where I have privileges has fortunately enabled me to employ any, and all effective treatments to cure COVID-19 and its effects at every stage of the disease but, most particularly, at the critical care stage when patients are admitted to hospital and/or the Intensive Care Unit (ICU). As a result of the remarkable success our hospitals have enjoyed with such patients over the past 18 months since March 19, 2020, we have exclusively applied the MATH+ protocol, with small variations as appropriate to every COVID patient entering our hospitals and ICUs.

Mortality Rates *At Least* 50% Lower Than National/Global Averages

7. As Chief of Staff, I supervise and review periodically the mortality rates and other data we carefully maintain of our COVID-19 patients, including those admitted to the ICU.

8. Over the past 18 months of our hospitals' use during the COVID pandemic, I can confidently testify that the MATH+ protocol saves lives, and saves them in substantial numbers. I know this first, and foremost, from my own experience in our hospital, where we were able to lower our mortality for COVID-19 patients (both critically ill and those on regular wards) beginning in March 2020 (when we began utilizing the MATH+ protocol) to **4.4**% as of August 2020-- a dramatic improvement over the national average of 22% over the same time period. Reported mortality averages across the globe have varied

widely, but our hospitals' results have successfully maintained far lower patient mortality rate—between 4.4% and 7%—to the present day. Multiple studies report much higher national mortality averages, including one such study that I participated in and published in June 2021 in the *Journal of Community Medicine and Public Health Reports*, a true and correct copy of which is attached hereto as Exhibit "2." That study, reviewing some 85 hospital studies worldwide, establishes an average 28-day hospital mortality rate among COVID-19 patients of 20% nationwide, and 21% globally. Moreover, as the study points out, because a large percentage of patients remain hospitalized after Day 28, *the real average mortality rate is likely much higher*. To this day—even with the advent of the "Delta variant" of COVID-19, our mortality rate has not risen above 7%. Bottom line: our hospitals' use of the MATH+ protocol has reduced mortality of hospitalized COVID-19 patients by ***at least 50%*** below the national average.

9. Our experience of substantially lowering the mortality rate using MATH+ protocols is made all the more remarkable by the fact that our hospital now routinely admits severely ill patients referred by other hospitals and ICUs that for whatever reason are not administering the MATH+ protocol. These patients, in many cases, are those that the referring hospital/physician has determined will not likely survive. As our success has become increasingly known among treating physicians in the Houston area, and beyond, those referrals have risen to account for approximately 10-15% of our admitted COVID-19 patients. While we have been able to cure the vast majority of those patients using MATH+, in my opinion, the advanced stage of the disease we see in the referred patients likely accounts for some of the increase in our mortality rate for COVID patients. Nevertheless, we are currently experiencing a mortality rate in our hospitals of just 5%.

10. My experience with the success of the MATH+ protocol has been confirmed by (1) fellow FLCCC-physicians and other colleagues around the world, (2) over 30 randomized controlled trials reporting substantial improvements in a number of important outcomes associated with the various elements of the protocol, (3) several peer-reviewed articles both in journals and on the National Institute of Health website, and (4) well-

documented reports from India, Mexico and some 80 countries around the world showing dramatic improvement in the treatment and prevention of COVID using MATH+ protocols or variations thereof including early treatment and prevention protocol FLCCC physicians have created and known as I-MASK+.

Two Severely Ill Patient Success Stories: Dr. Espinoza and Mr. Boney

11. Two severely ill patients who were referred or transferred to me—Dr. Espinoza and Mr. Boney—are representative of the remarkable turn-arounds we have experienced with our critically-ill COVID patients. As a result of what they believed to be their life-saving treatment with our MATH+ protocol, they readily agreed to allow their stories to be recorded in the videos, linked below, that are submitted with this application for injunctive relief:

https://www.dropbox.com/s/9t5bd902c7gdz52/MARIK%20TRO%20MOTION%20KAMEN%20Dec%20EX%20A.m4v?dl=0

I participated in those videos and have personally viewed them. The videos accurately reflect the circumstances and successful treatment of both Dr. Espinoza and Mr. Boney.

12. In Dr. Espinoza's case, this well-respected clinician was suffering from acute respiratory failure due to COVID-19 and was not allowed to receive the MATH+ protocol at his hospital. Arrangements were being made to place him on an extracorporeal circulation machine (ECMO) when his wife contacted me. We emergently flew him to Houston via an air-ambulance and immediately on arrival he was started on the MATH+ protocol. Within a few days, this patient left the hospital walking by himself! His oxygen requirements and organ failure decreased within hours of starting the MATH+ treatment strategy. Dr. Espinoza now continues to practice medicine and has a full life. In Mr. Boney's case, this eminent Councilman from a city in the Houston area fell ill due to COVID-19. He presented to the hospital critically ill and with evidence of a clot in his lungs (pulmonary embolism). He was started on the MATH+ protocol, and just as in Dr. Espinoza's case, he was discharged to home within a few days. Mr. Boney fully recovered thanks to the MATH+ protocol.

Recognition and Awards By Community and National Leaders

13. None of us—Dr. Marik, myself or any of our colleagues in or outside FLCCC—do what we do for the accolades. Nonetheless, in my case, our successful efforts have not gone unnoticed or unappreciated by civic, national and international leadership, in part, perhaps, because our hospitals serve a largely minority and underprivileged community—in many cases folks who cannot afford to pay for the treatments they receive. But we never turn anyone away.

14. I'm pleased to say that, among other recognition I and our hospitals have received are the following:

a. In September 2020 I received a "Certificate of Congressional Recognition" Awarded by Congresswoman Sheila Jackson-Lee on the occasion of Distinguished Mexicans Award ceremony for the contributions to the Hispanic and Latino community in the City of Houston.

b. In September 2020 the Mayor of the City of Houston, Sylvester Turner issued a "Proclamation of Dr. Joseph Varon Day" in recognition of the outstanding work done in such city.

c. Most recently, in October 2021, the United Nations awarded me the Global Citizen Award for my work in COVID-19 citing that I was creating a blueprint for a better future..

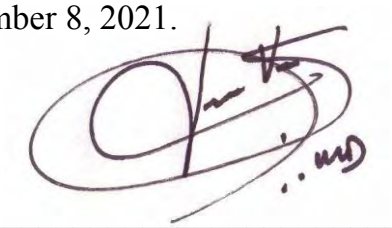
These awards were given specifically in recognition of my altruistic work, including our successful treatment of COVID-19 patients in the local community.

Conclusion.

15. Based on all the above, and most particularly my experience as the treating physician for thousands of severely ill COVID patients over the past 20+ months, I wholeheartedly believe that the MATH+ protocol, as administered on an individualized basis by competent physicians, saves lives, and saves them in significant numbers over and

above other treatments currently in widespread use, as evidenced by the data. Moreover, the protocol is extraordinarily safe. In short, there is no reason at all not, at minimum, to fully inform patients of its availability, risks and benefits, and to administer it upon their informed consent.

I declare under penalty of perjury under the laws of the Commonwealth of Virginia that the foregoing is true and correct to the best of my knowledge, and that this declaration was executed in Houston, Texas on November 8, 2021.



_____

Dr. Joseph Varon, M.D., FACP, FCCP, FCCM, FRSM

FRED D. TAYLOR
Bush & Taylor, P.C.
4445 Corporate Lane
Virginia Beach, VA 23462
Telephone: (757) 926-0078
E-Mail Address: fred@bushtaylor.com

JED RUBENFELD (*pro hac vice*)
1031 Forest Road
New Haven, CT 06515
Telephone: (203) 387-2505
E-Mail Address: rubenfeldjed@gmail.com

Attorneys for Plaintiff
DR. PAUL MARIK, M.D.

NORFOLK CIRCUIT COURT

FOURTH JUDICIAL CIRCUIT OF VIRGINIA

DR. PAUL MARIK, M.D.

Plaintiff,

v.

SENTARA HEALTHCARE SYSTEM,

Defendant.

Case No.

JOYCE KAMEN DECLARATION AND EXHIBIT "A" THERETO

DECLARATION OF JOYCE KAMEN

I, Joyce Kamen, declare as follows:

1. I am the Vice President for Public Information for the Front Line Critical Care COVID Alliance ("FLCCC"), of which Dr. Paul Marik, plaintiff in this action, is a founding physician member. This declaration is made in support of Dr. Marik's motion for temporary restraining order. If called as a witness, I could and would testify competently to the facts herein, except as to those matters stated on information and belief.

2. Attached hereto as **Exhibit "1"** is a true and correct DVD copy of the FLCCC Patient Testimonial Video (TRT: 10:06), which can also be accessed in its entirety at: https://www.dropbox.com/s/9t5bd902c7gdz52/MARIK TRO MOTION KAMEN Dec EX A.m4v?dl=0

3. The four individuals whose histories are related in this Video were each critically ill COVID-19 patients. Three of them received the MATH+ Protocol, and the fourth received Ivermectin only. Each of the patients survived COVID-19 as a result of these treatments when other treatments had not worked, and they were dying. The Video also includes some context from family (one of whom is herself a physician), Dr. Joseph Varon, attending physician for two of the patients, and in one case, an attorney who won a court order for Ivermectin based on the primary care physician's prescription of that drug.

4. The four individual patients featured in the Video have signed releases or given permissions for their images, likenesses, and voices to be used by the FLCCC. Briefly, their COVID-19 MATH+ Protocol treatment histories are as follows:

5. In March 2020, **Patient Jeffrey Boney** became alarmed when he began to cough up blood while awaiting the results of his COVID-19 test. He called Dr. Joseph Varon, Chief of Critical Care, United Memorial Medical Center (UMMC), Houston, Texas, who told him to come immediately to UMMC's ER. A CT scan revealed that Mr. Boney had COVID pneumonia in both lungs. He was admitted directly into the ICU, critically ill and struggling to

breathe. Dr. Varon said that Mr. Boney was nearly placed on a ventilator. Instead, Dr. Varon chose to administer the MATH+ Hospital Protocol. Within a few days, Mr. Boney's condition began to improve dramatically. He survived and recovered. Dr. Varon, a declarant, also appears in this segment.

6. In January 2021, **Patient Dr. Manuel Espinoza** contracted COVID-19. After being hospitalized locally in Brownsville, Texas, his condition continued to worsen. Dr. Espinoza's wife Erica, also a physician, describes in this segment how she had heard about the MATH+ Protocol and asked the medical team in Brownsville to start her husband on the protocol. They refused, so Dr. Erica Espinoza arranged to have her husband life-flighted to UMMC in Houston. There, Dr. Varon placed him on the MATH+ Protocol. Dr. Emanuel Espinoza was discharged 4 days later, and returned home.

7. In December 2020, **Patient Judith Smentkiewicz** contracted COVID-19 and was hospitalized at Millard Fillmore Suburban Hospital in Buffalo, New York. Her condition continued to worsen and she was placed on a ventilator. Ms. Smentkiewicz's son Michael was told that she might not survive. Michael learned about the MATH+ Protocol from his mother-in-law, who had been following the protocols of the FLCCC. Michael researched the protocol—and watched Dr. Pierre Kory's testimony about Ivermectin before the U.S. Senate Committee on Homeland Security and Governmental Affairs in early December, 2020. Michael asked the hospital [Millard Fillmore] to administer Ivermectin to his mother. They agreed to give her one dose. Less than 48 hours later, Judith was taken off the ventilator and removed from the ICU. Four days later, however, her condition again began to deteriorate. Michael requested that the hospital give his mother another dose of Ivermectin. This request was refused. Michael hired attorney Ralph Lorigo (who appears here) to seek a court order to compel the hospital to give his mother Ivermectin. The court order was approved, but the hospital refused to comply. Mr. Lorigo obtained a letter from the family's primary care physician, saying that he would prescribe the medicine and come to the hospital to administer

the drug to Ms. Smentkiewicz. The court then ordered that the hospital allow her to be given the drug by her primary care doctor. After three more doses were administered, Ms. Smentkiewicz's's health improved and she recovered.

8. On December 10, 2020, **Patient Marlin Anderson** was admitted to Converse County Memorial Hospital in Douglas, Wyoming with severe COVID-19 pneumonia. His condition worsened, and he was about to be placed on a ventilator. The doctors tried other options, including dexamethasone (steroid), Remdesivir (Covid antivirus), and an antibiotic. Mr. Anderson was also given a plasma therapy treatment on December 15. His daughter, Texie Baker, was researching other possible therapies for her father, and learned about Ivermectin. Texie consulted with her father's doctor, who agreed that there was nothing left to lose, given the severity of Mr. Anderson's condition— and that he would administer Ivermectin if it were his own parent who found himself in such circumstances. Mr. Anderson received his first dose of Ivermectin on December 16, and the second on December 17. He was released from the hospital four days later, on December 21.

I declare under penalty of perjury under the laws of the Commonwealth of Virginia that the foregoing is true and correct to the best of my knowledge and that this declaration was executed in Cincinnati, Ohio, on November 8, 2021.

JOYCE KAMEN