IN THE

SUPREME COURT OF VIRGINIA

Record NO: _______

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DR. PAUL E. MARIK

***Petitioner*,**

v.

SENTARA HEALTHCARE

***Respondent*.**

____

PETITION FOR REVIEW OF INJUNCTION PURSUANT TO CODE OF VIRGINIA § 8.01-626

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COMES NOW the Petitioner, Dr. Paul E. Marik, pursuant to Code of Virginia§ 8.01-626, and files this Petition for review of the Circuit Court's denial of a temporary injunction, and in support thereof states as follows:

NATURE OF THE CASE AND MATERIAL PROCEEDINGS

Genuine life-or-death legal cases are rare. This is one. COVID patients at Defendant Sentara Healthcare's hospitals are dying unnecessarily. From October 25-31, 2021, seven critically ill COVID patients came under the care of Petitioner Dr. Marik, Director of the Intensive Care Unit ("ICU") at Sentara Norfolk General Hospital (the "Hospital"). R16, 18[1]. For the previous year and a half, Dr. Marik had achieved a remarkable 80% survival rate for his hundreds of ICU COVID patients, using five safe, FDA-approved medicines, each proven effective against COVID in gold-standard published studies. R24. But on October 6, 2021, *without any scientific basis*, Sentara prohibited these five medicines. R117. Dr. Marik had to watch helplessly as his patients worsened. Six died, including one only 32 years old. R631. Dr. Marik had never lost a COVID patient so young before.

To prevent this horrific tragedy from taking more lives, Dr. Marik filed the underlying Complaint that is the subject of this Motion for Temporary Injunction on November 9, 2021. R12. A hearing on the Motion was held on November 18.

[1] Attached hereto and incorporated herein are pertinent portions of the record of the Norfolk Circuit Court as required by Rule 5:17A(c)(ii). Citations to this record are included herein as "R page number."

R777. On November 23, the Circuit Court denied the injunction. R.776. Dr. Marik then timely filed this Petition. Dr. Marik begs this Court to temporarily restore the status quo ante pending a full trial. The legal rule governing this case is basic: "absent the [doctor's] instructions being obviously negligent or dangerous," it is "axiomatic that the hospital has the duty not to institute policies or practices which interfere with the doctor's medical judgment." *Muse v. Charter Hosp.*, 117 N.C. App. 468, 474 (1995); see additional cases *infra*. Dr. Marik is not asking this Court to practice medicine, to decide whether any drug is a good treatment for COVID, or to compel any other physician to use his COVID protocol. Rather he is asking this Court to uphold the foundational legal rule just quoted—and allow him try to save his own patients' lives, as he is ethically and legally bound to do.

STATEMENT OF FACTS

The following facts stand *undisputed* on the record evidence.

On October 6, 2021, Defendant Sentara Healthcare notified Sentara's physicians by email of a new prohibition (the "Prohibition"), banning certain medicines for the treatment of COVID-19. R117. Among the Prohibited medicines, five are at issue here: Fluvoxamine, Vitamin C, Bicalutamide, Dutasteride, and Finasteride (the "Five Medicines"). *Id*. All five are FDA-approved, R636-37, meaning they have been proven safe at established dosages.

More fundamentally, as shown in the Court below, randomized controlled trials ("RCTs")—the "gold standard" of medical evidence—prove that each of the Five Medicines is effective against COVID, with several significantly *reducing mortality*. R483-89. These studies, incorporated in the record below, *are unrebutted*.

Sentara's only explanation of its Prohibition was the following assertion in the October 6, 2021 notice: "safety/efficacy is not supported in peer reviewed published RCT." R117. But this assertion is simply false, as was proven below with undisputed evidence. For example, a large, peer-reviewed RCT published in the *Lancet Global Health* proves that Fluvoxamine significantly reduces COVID mortality (*i.e.*, saves lives).[1] Sentara, which had nine days to prepare for the hearing below, did not submit a scintilla of evidence supporting its Prohibition of Fluvoxamine. It did not (because it could not) dispute the conclusive Lancet study. And the same is true of the other Prohibited Medicines. Each has separately been proven safe and effective against COVID in RCTs put before the Court below.[2]

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[1] *See* R483 (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). Fluvoxamine proved so safe and effective the study had to be halted in order to give the drug to the placebo patients as well. *Id*.

[2] *See* R489 (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 (Vitamin C "reduce[s] mortality" in critical COVID patients)); R489 (F. Mauvais-Jarvis, *Do Anti-androgens Have*

Sentara submitted no evidence at all rebutting them.

From October 25-31, 2021, Petitioner Dr. Marik assumed his regular one-week-in-four duty as attending physician at the Hospital ICU. R18. Dr. Marik is not only the ICU's Director, but a world-renowned, board-certified critical care specialist, a highly published scientist, a distinguished Professor of medicine at Eastern Virginia Medical School ("EVMS"), and Chair of EVMS's Division of Pulmonary and Critical Care Medicine. R16, 786. Using the Five Medicines, Dr. Marik had achieved an extraordinarily low 20% mortality rate for his ICU patients—roughly half the 40-60% national average for ICU COVID patients. R24. These facts too stand *unrebutted and undisputed* on the record.

Another drug covered by the Prohibition is the controversial Ivermectin. Although Ivermectin has been shown in RCTs to save up to 50% of COVID patients' lives,[3] its use has been intensely politicized, and it is much decried in certain quarters. With respect to Ivermectin—and Ivermectin alone—Sentara did put on evidence supposedly supporting its ban: not data, not evidence, not studies,

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Potential as Therapeutics for COVID-19?, Endocrinology, Aug. 2021, https://academic.oup.com/endo/article/162/8/bqab114/6293822 (RCTs show "a reduced rate of hospitalization" and "accelerate[d] viral clearance" in COVID patients treated with anti-androgens such as Bicalutamide, Dutasteride, and Finasteride)).

[3] R485 (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.

but only that certain federal agencies have recommended against its use. R681, 684. *But the protocol that Dr. Marik had been using on his Sentara COVID patients did* ***not*** *include Ivermectin*. R645. He achieved his extraordinary low mortality rate using the Five Medicines, **not** Ivermectin.[4]

Tragically, however, after October 6, because of the Prohibition, Dr. Marik was no longer able to use any of these medicines. His hands were tied. Of the seven COVID patients admitted to the ICU from October 15-21, six died, and the seventh was on death's door as of the hearing below. R631.

If Dr. Marik had been able to achieve his 20-30% mortality rate with these patients, then only two of these seven people might have died. Instead, at least six died—a *tripling* of mortality.

STANDARD OF REVIEW

As this Court has stated, "No single test is to be mechanically applied" in temporary injunction cases, "and no single factor can be considered alone as dispositive. Instead, a court must consider the totality of the circumstances and decide whether equity counsels for the temporary preservation of the status quo."

[4] Prior to October, 2021, Ivermectin was not "supported or endorsed" for COVID at Sentara, which Dr. Marik understood as a prohibition (with which he complied). R640. At the hearing below, Sentara claimed that this non-endorsement was merely recommendatory. *Id*. Regardless, there is no dispute as to the following facts: (1) Dr. Marik has never in fact used Ivermectin for COVID at the Hospital (R591, 640); and (2) Ivermectin and the other Five Medicines are now, because of the Prohibition, flatly prohibited (R117, 656-57).

Commonwealth ex rel. Bowyer v. Sweet Briar Inst., No. 150619, 2015 Va. Unpub. LEXIS 22 at *5 (Va. June 9, 2015).

This Court "reviews a circuit court's decision to grant or deny a temporary injunction for an abuse of discretion," but issues of law are de novo, and a "circuit court abuses it discretion, by definition, when it commits an error of law." *Stoney v. Anonymous*, No. 200901, 2020 Va. Unpub. LEXIS 19 at *5 (Va. Aug. 26, 2020).

ASSIGNMENTS OF ERROR

All of the following assignments of error, being errors of law, are de novo in this Court. The Circuit Court erred:

1. When it found that Dr. Marik had not established a likelihood of success, R787, given that on the undisputed evidence the Prohibition plainly violates the hospital's legal duty to obey the instructions of a patient's physician unless "obviously negligent or dangerous." R. 792-793.
2. When, contrary to this Court's statements in *Sweet Briar*, *supra*, it treated the single factor of likelihood of success as dispositive, rather than considering the totality of the circumstances. R790, 792-793.
3. When it wholly failed to address Dr. Marik's claims concerning the Five Medicines, instead addressing only Ivermectin. R787n.7, 790, 792-793.
4. When it found that Sentara had not violated informed consent, R788, even though Sentara does not let patients know about the banned medicines. R792-793.
5. When it found that Dr. Marik lacked standing to assert a violation of the Health Care Decisions Act, which allows "any person" to sue. R784, 792-793.
6. When it failed to address Dr. Marik's claim, R482, that the Prohibition violates public policy as expressed in Virginia's Right to Try statute. R792-793.

AUTHORITIES AND ARGUMENT

I. Dr. Marik Established a Likelihood of Success on the Merits

The foundational, time-honored legal rule governing this case is widely established. "[A]bsent the instructions being obviously negligent or dangerous," it is "axiomatic that the hospital has the duty not to institute policies or practices which interfere with the doctor's medical judgment." *Muse v. Charter Hosp.*, 117 N.C. App. 468, 474 (1995); *Mesedahl v. St. Luke's Hosp. Ass'n of Duluth*, 194 Minn. 198, 206 (1935) (hospital "must obey . . . the orders of the physician . . . in charge of the patient, unless, of course, such order was . . . obviously negligent"); *Franken v. Davis*, No. 5:93CV79-V, 1997 U.S. Dist. LEXIS 16081 at *36 (W.D.N.C. July 25, 1997) ("[A] hospital has a duty to obey the instructions of a patient's physician, so long as the instructions are not obviously negligent or dangerous.").[5] Where, as here, the attending physician is an independent

[5] *See also, e.g.*, *Abrams v Bute*, 138 A.D.3d 179 (NY App. Div. 2d Dept. 2016) ("hospital staff" "may not invade the area of the physician's competence and . . . overrule his orders"); *Kellner v. Schultz*, 937 F. Supp. 2d 1319, 1326 (D. Colo. 2013) (hospital "may not interfere with the physician's independent medical judgment"); *Alden v. Providence Hospital*, 382 F.2d 163 (D.C. Cir. 1967) (Burger, J., concurring and dissenting) ("The hospital assumes the duty to carry out the instructions of the doctor"); Einer Elhauge, *Symposium on Regulating Medical Innovation*, 82 VA. L. REV. 1525, 1559 (1996) ("The hospital's legal duty is to provide the services the physician orders."). This is a duty owed both to the patient and the doctor. *See, e.g.*, *Doe v. Bolton*, 410 U.S. 179, 197 (1973) (recognizing, as against "unduly restrictive" hospital interference, the patients' "right to receive medical care in accordance with [their] licensed physician's best judgment and the physician's right to administer it").

contractor (Record cite?),, he "alone is responsible for the exercise of professional skill and judgment, subject to no control by the hospital in the execution thereof." *Stuart Circle Hospital v. Curry*, 173 Va. 136, 149 (1939). Because Sentara has submitted *no* evidence suggesting, that any of the Prohibited medicines are "obviously negligent or dangerous"—on the contrary, the unrebutted evidence shows that the Five Medicines have proven safe *and* effective against COVID in gold-standard RCTs, and in Dr. Marik's clinical experience—Dr. Marik plainly established a likelihood of success on the merits.[6]

II. The Court Below "Mechanically Applied" a "Single Factor"

Choosing to follow federal preliminary injunction law, the Circuit Court denied the temporary injunction based solely upon its (erroneous) finding of insufficient likelihood of success on the merits, without considering the magnitude of the threatened irreparable harm, balance of hardships, or public interest. R790. Thus the Circuit Court violated this Court's admonition that "[n]o single test is to be mechanically applied, and no single factor can be considered alone as dispositive. Instead, a court must consider the totality of the circumstances and decide whether equity counsels for the temporary preservation of the status quo."

[6] The Circuit Court refused to recognize *any* legal rule governing this case, though it conceded that "the issue of whether Marik's professional judgment can . . . trump the guidelines ultimately may be an issue of law that can be resolved short of trial." R788.

Sweet Briar, 2015 Va. Unpub. LEXIS 22 at *5.[7]

III. The Court Below Failed to Address the Five Medicines Dr. Marik Has Actually Been Using, Instead Addressing Only Ivermectin

The Court below *never addressed* Dr. Marik's unrebutted evidence about the Five Medicines he has actually been using. Instead, the Circuit Court repeatedly but exclusively addressed Ivermectin, which Dr. Marik has *not* been using, which Sentara deemed inadvisable because certain federal agencies have recommended against it. R787n.7, 790. Not only did this ruling fail to apply the correct legal standard;[8] more fundamentally, it wholly failed to address the other Five Medicines. As stated above, Sentara submitted *no* scientific evidence to support its Prohibition of the five medicines; Defendant never disputed (because it could not dispute) the RCT proof of their safety and life-saving effects. Accordingly, on the unrebutted, evidence that those medicines are neither dangerous nor obviously negligent in Dr. Marik's capable hands, and in fact have already saved many of his COVID ICU patients' lives, the Prohibition must be enjoined, pending full adjudication.

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[7] If federal precedents matter, Appellant respectfully directs attention to the Ninth Circuit's "serious questions" test, which grants a preliminary injunction where plaintiff establishes "serious questions going to the merits" and a "balance of hardships tip[ping] sharply in the plaintiff's favor." *Ramos v. Wolf*, 975 F.3d 872, 887-88 (2020).

[8] The Circuit Court did not find—and could not have found, given the RCTs showing its safety and efficacy against COVID—that Ivermectin was "obviously negligent or dangerous."

IV. Defendant Is Violating Informed Consent

A health care provider has the duty to "disclose the . . . existence of alternatives [to a proposed treatment] if there are any" so that patients can "mak[e] an informed decision." *Allison v. Brown*, 293 Va. 617, 628-29 (2017) *Tashman v. Gibbs*, 263 Va. 65, 73-74 (2002). The Circuit Court found that Sentara was not in violation of this duty on the ground that Dr. Marik is free to tell his COVID patients (or their families) about the banned medicines. R788. This was error for two reasons. First, if Sentara claims the right to dictate treatment (overruling the physician), it is *Sentara's* duty to inform patients of the banned alternatives, and Sentara is not doing so. Second, while Dr. Marik acknowledged that he was physically able to speak to patients (or their families) about the banned medicines, he also stated that he was prohibited from doing so in that he would be penalized—stripped of his privileges—if he did. R17, 19. At the hearing, Sentara denied this, assuring the Court that Dr. Marik would suffer no discipline for speaking about the Prohibition, R672, but two days later this assurance was proven to be a flagrant (and possibly knowing) misrepresentation when Dr. Marik learned that on the very date of the hearing, Sentara had suspended him for allegedly telling COVID patients his "*hands were tied*" and that "there was *nothing more [he] could do for them*." R771. The Circuit Court plainly erred in finding that the Hospital has met its duty to patients -- and not interfered with Dr. Marik's – under these facts.

V. Dr. Marik Has Standing Under the Health Care Decisions Act, And The Prohibition Violates That Act

Under Virginia's Health Care Decisions Act (the "Act"), individuals have the right to execute Advance Directives specifying the particular treatments they wish to receive in hospital if they become incapacitated, provided their attending physician so recommends. Va. Code § 54.1-2984. Hospitals are legally required to give these Directives "full effect." *Id*. § 54.1-2983.3(C). Submitted below were over 20 Advance Directives signed by Norfolk individuals specifying Dr. Marik's COVID protocol in case of incapacity. R270-464. Because of the Prohibition, Sentara will not honor these Advance Directives, violating the Act.

The Court below found that Dr. Marik lacked standing to bring this claim. R783. But the Act expressly allows "*any person*" to sue to ensure enforcement of an Advance Directive, Va. Code § 54.1-2985, so Dr. Marik plainly has standing. The Circuit Court observed that none of the signees was yet incapacitated, R783, but the Act nowhere says that individuals must be incapacitated before they (or others on their behalf) can sue to ensure enforcement of their Directives. On the contrary, the Act expressly allows suit to be brought not only if an individual's specified treatment is "*currently* being withheld," but if the specified treatment "*will be* . . . withheld." Va. Code § 54.1-2985 (emphasis added). That is precisely the case here.

VI. The Prohibition Violates Virginia Public Policy as Expressed in the Commonwealth's Right to Try Statute

By statute, individuals in Virginia with a "terminal condition" "shall be eligible" to try medicines still undergoing clinical trials 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, should be eligible for potentially life-saving investigational medicines.

The Prohibition states that the banned medicines can only be given to patients "enrolled in clinical trials." R120. Thus the Prohibition violates express Virginia public policy, denying terminally ill COVID patients access to potentially life-saving medicines, recommended by their treating physician, on the ground that these medicines are investigational, for clinical trials only. Dr. Marik made this claim below, R482, but the Circuit Court wholly failed to address it.

That the Prohibition violates public policy is an additional reason to temporarily enjoin it, both on the merits and because it proves that such an injunction would advance the public interest. Given, in addition, the obvious irreparable harm in this case (no harm is more irreparable than death), the inadequacy of any remedy at law (money damages can never adequately compensate for death), and a balance of equities tipping sharply in Petitioner's

favor (Sentara has identified no hardship at all), there can be no doubt that equity counsels in favor of restoring the status quo ante pending final adjudication.

CONCLUSION

For the foregoing reasons, the Court should grant this Petition for a temporary injunction.

Respectfully submitted,

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I certify that on December 6, 2021, I e-mailed a true copy of the foregoing Petition to Jason R. Davis at jrdavis@kaufcan.com, Kristan B. Burch at kbburch@kaufcan.com, and Lauren S. Kadish at lskadish@kaufcan.com.

I certify that the record being filed is an accurate copy of the pertinent parts of the record of the Norfolk Circuit Court.

The filing fee will be delivered by Lantagne Legal Printing on December 6 or December 7, 2021.

By */s/ Fred D. Taylor*
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