



DAVID W. LANNETTI
JUDGE

FOURTH JUDICIAL CIRCUIT OF VIRGINIA
CIRCUIT COURT OF THE CITY OF NORFOLK

150 ST. PAUL'S BOULEVARD
NORFOLK, VIRGINIA 23510

November 23, 2021

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Re: Dr. Paul E. Marik v. Sentara Healthcare
Docket No.: CL21-13852

Dear Counsel:

Today the Court rules on a “Motion to Dismiss for Lack of Standing” filed by Defendant Sentara Healthcare (“Sentara”), which seeks to dismiss the “Verified Complaint” filed by Plaintiff Dr. Paul E. Marik (“Marik”) asking for declaratory and injunctive relief, and on a “Motion for Temporary Injunction” filed by Marik. More specifically, Marik requests a temporary injunction that will “enjoin Sentara Healthcare from prohibiting the prescription and use of certain medications that may prevent and/or treat Covid.”

The Court finds that Marik has third-party standing to bring an informed consent claim on behalf of his patients but that he lacks standing to bring a claim under Virginia’s Health Care Decisions Act. The Court further finds that, for purposes of a temporary injunction, Marik has failed to prove that he is likely to succeed on the merits of his informed consent claim. The Court therefore **GRANTS IN PART AND DENIES IN PART** Sentara’s motion to dismiss and **DENIES** Marik’s motion for a temporary injunction.

Background

On October 6, 2021, Dr. Joel Bundy, Sentara's Chief Quality and Safety Officer, notified Sentara hospital physicians via email that Sentara had revised its "COVID-19 Comprehensive Treatment Guidelines" (the "Guidelines").¹ (Compl. Ex. A.) The revision indicated that Sentara no longer supported or endorsed certain treatment therapies to treat COVID-19, including use of the medications ivermectin, bicalutamide, etoposide, fluvoxamine, dutasteride, finasteride, and ascorbic acid (the "Medications"). (*Id.*) The email states that the Medications, other than ascorbic acid,² "may cause harm[,] and efficacy/safety is not supported in peer reviewed, published RCT" and that they "should only be prescribed if the patient is enrolled in a clinical trial." (*Id.*)

Marik, the director of the general intensive care unit ("ICU") at Sentara Norfolk General Hospital, filed a complaint against Sentara. (Compl. 2.) In his complaint, Marik alleges two causes of action: (1) breach of the duty of informed consent and (2) violation of Virginia's Health Care Decisions Act. (*Id.* at 8–9.) Marik states that he supports the "MATH+ Protocol" to treat COVID-19 patients, which consists in part of prescribing ivermectin, bicalutamide, fluvoxamine, dutasteride, finasteride, and/or ascorbic acid. (Mem. Supp. Mot. Temporary Inj. 4.) Marik claims that the Guidelines prevent him from treating COVID-19 patients using the MATH+ Protocol or informing patients of this alternative treatment. (*Id.* at 6.) Marik ultimately seeks a declaration that the Guidelines are "unlawful and unenforceable" and an injunction enjoining Sentara, its agent, or its affiliate "from applying or enforcing the [Guidelines], thereby permitting patients to be informed of and to receive the currently banned COVID treatments provided their attending physician deems them medically appropriate." (Compl. 10–11.)

On November 9, 2021, Marik filed a "Motion for Temporary Injunction," seeking to enjoin Sentara "from prohibiting the prescription and use of certain medications that may prevent and/or treat Covid." (Mot. Temporary Inj. 1.) On November 12, 2021, Sentara filed a "Motion to Dismiss for Lack of Standing." A hearing was held on November 18, 2021 (the "Hearing"). At the Hearing, Marik testified that he had used the MATH+ Protocol since March 2020 and that, because of the Guidelines, he no longer can do so. More specifically, Marik stated that the Guidelines effectively preclude use of any of the Medications to treat COVID-19 because the Sentara pharmacy, which he is required to use, will not fill the prescriptions. Marik testified that he also cannot inform his COVID-19 patients in the hospital ICU of this alternate treatment because they are often acute patients who are unresponsive; he admitted that he could call patients' families and inform them of this alternative treatment but claimed that to do so under the circumstances would constitute cruel and unusual punishment.

At the Hearing, Bundy referred to the September 1, 2021, joint statement released by the American Medical Association, American Pharmacists Association, and American Society of

¹ Sentara updated the Guidelines on September 27, 2021, and it is apparently the 26th version of Sentara's "Comprehensive COVID-19 Treatment Guidelines."

² Per the Guidelines, ascorbic acid, also known as Vitamin C, "is not endorsed for prevention or treatment of COVID-19," although—based on the cover email—Sentara presumably is not including it on its list of therapies that it will not support. The Guidelines are not clear on this issue, however.

Health-System Pharmacists, which states that these organizations “strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial”; states that “[u]se of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients”; and references a CDC Health Alert Network Advisory that “recommends that health care professionals should counsel patients against use of ivermectin as a treatment for COVID-19, including emphasizing the potentially toxic effects of this drug.” *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19*, AMA (Sept. 1, 2021), <https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19>. Bundy testified that, based on this joint statement, Sentara’s Pharmacy and Therapeutics (“P&T”) Committee voted to preclude use of the Medications, including ivermectin, outside clinical trials due to safety and efficacy concerns.³

At the conclusion of the Hearing, the Court took both motions under advisement.

Positions of the Parties

Sentara’s Position

Sentara argues that Marik lacks standing to bring his claims because any cause of action resides with patients affected by the Guidelines and not with an attending physician such as Marik. (Mot. Dismiss 1.) More specifically, Sentara asserts that Virginia’s informed consent doctrine only permits a patient to bring a cause of action against a physician. (*Id.* at 2.) “There is simply no authority that gives standing to a physician to bring a lack of informed consent claim on the patient’s behalf against another provider, in this case, a hospital.” (*Id.*) Sentara also argues that Marik lacks standing to bring a claim under the Virginia Health Care Decisions Act because he has not alleged that Sentara is withholding treatment for any particular patient who is currently incapacitated. (*Id.* at 3.)

As to Marik’s motion for a temporary injunction, Sentara initially argues that Marik is seeking a mandatory injunction—which he claims involves a higher burden of proof—because Marik seeks to alter the *status quo*.

Sentara also argues that Marik has failed to establish all four requisite elements of a temporary injunction under Virginia law: likelihood of success on the merits, irreparable injury without the preliminary relief, balance of equities tipping in his favor, and that the temporary injunction is in the public interest. (Mem. Opp’n Pl.’s Mot. Temporary Inj. 2.) Sentara argues that Marik is not likely to succeed on the merits of his informed consent claim because “there is absolutely nothing within Sentara’s policy that prevents [Marik] from providing his patients with informed consent and discussing alternative methods of treatment.” (*Id.*) As to Marik’s likelihood of success on the Virginia Health Care Decisions Act, Sentara contends that “nothing

³ The Guidelines state as follows: “Concentrations [of ivermectin] needed to inhibit SARS-COV-2 would be difficult to achieve in humans and are extremely toxic. There is no available data on outcomes or efficacy in humans from a [randomized controlled trial].” (Compl. Ex. A.)

in [the statute] gives a patient the right to control where his or her treatment must occur or compel a hospital to give treatment it does not believe should be given.” (*Id.*)

Regarding irreparable harm without preliminary relief, Sentara argues that Marik’s patients can be transported to other hospitals that offer the MATH+ Protocol if they desire. (*Id.*) It also claims that the weight of the evidence demonstrates that use of the Medications is not an effective treatment for COVID-19 and can actually harm patients. (*Id.* at 2–3.)

Sentara argues that the balance of the equities tips in its favor because “[r]equiring a hospital to disregard its obligations to comply with federal and state regulatory and accreditation requirements regarding provision of pharmaceuticals to hospital patients far outweighs [Marik’s] alleged harm in not being able to prescribe a treatment for COVID that is not supported by the medical community as within the standard of care or effective.” (*Id.* at 3.)

Finally, as to the public interest, Sentara argues that it is in the public interest to permit a healthcare provider to explore and decide appropriate treatments it offers to patients. (*Id.*)

Marik’s Position

Marik contends that he has standing to bring an informed consent claim because Sentara’s prohibition “directly injures [him]—legally, economically, and professionally—creating a real and substantial dispute between him and Sentara.” (Br. Opp’n Mot. Dismiss 3.) Marik argues that he faces potential injury because he could be sued for malpractice. (*Id.* at 4.) Additionally, Marik claims that he can legally assert the third-party rights of his patients under the circumstances. (*Id.*) He further argues that he has standing to bring a claim under the Virginia Health Care Decisions Act because the statute permits any person to sue when treatment *is being* withheld or *will be* withheld. (*Id.* at 6–7.)

Regarding his motion for a temporary injunction, Marik argues that he is likely to succeed on the merits of his underlying claims. (Mem. Supp. Mot. Temporary Inj. 9, 12.) He argues that the Guidelines violate Virginia’s informed consent law because they prevent him from informing his patients about alternative treatments and administering those treatments. (*Id.* at 10.) Marik also asserts that the Guidelines violate Virginia’s Health Care Decisions Act because they prevent patients with certain advance medical directives—requesting the MATH+ Protocol should they become incapacitated—from receiving their desired treatment. (*Id.* at 14.) Marik argues that the Health Care Decisions Act not only permits patients to specify the treatment they receive while incapacitated but that it also “must . . . be read to recognize the equal right of COVID patients to specify and receive those medicines *before* they become incapacitated.” (*Id.* at 15.)

Marik contends that he will suffer irreparable harm if the requested temporary injunction is not granted because COVID-19 patients will “needlessly die” if they do not receive the MATH+ Protocol. (*Id.* at 27.) He claims that the MATH+ Protocol reduces ICU COVID-19 patients’ mortality by half and that “[n]o harm is more irreparable than death.” (*Id.* at 5, 27.)

Marik asserts that there is no adequate remedy at law because money damages cannot adequately compensate for the loss of a life. (*Id.* at 28.)

Marik further argues that the balance of the equities tips in his favor because Sentara will not be harmed if the injunction is granted. (*Id.* at 27.)

Marik claims that a temporary injunction is in the public interest because patients should be informed of life-saving alternative treatment. (*Id.* at 28.)

Analysis

Legal Standard

Circuit courts have the power to issue declaratory judgments in cases of actual controversy and in instances of actual antagonistic assertion and denial of right. *Va. Code* § 8.01-184 (2015 Repl. Vol.). A plaintiff has standing to bring a declaratory judgment proceeding if he has a justiciable interest in the subject matter of the litigation, either in his own right or in a representative capacity. *Lynchburg Traffic Bureau v. Norfolk & W. Ry.*, 207 Va. 107, 108, 147 S.E.2d 744, 745 (1966). A plaintiff has a justiciable interest in a proceeding if the plaintiff demonstrates “an actual controversy between the plaintiff and the defendant, such that his rights will be affected by the outcome of the case.” *W.S. Carnes, Inc. v. Bd. of Supervisors*, 252 Va. 377, 383, 478 S.E.2d 295, 299 (1996). The actual controversy “must be one that is justiciable, that is, where specific adverse claims, based upon present rather than future or speculative facts, are ripe for judicial adjustment.” *Fairfax v. Shanklin*, 205 Va. 227, 229, 135 S.E.2d 773, 775 (1964).

Although Virginia appellate courts have not articulated an express test for permanent injunctions, guidance provided to Virginia trial judges instructs them that the prerequisites for a permanent injunction are no adequate remedy at law, irreparable injury to the movant, and “whether the burden placed on the [non-movant] is excessively out of proportion to the benefit received by the [movant].” *Virginia Civil Benchbook for Judges and Lawyers* § 8.06[2][b] (2021–22 ed. LexisNexis) (citing Virginia cases);⁴ see also David W. Lannetti & Jennifer L. Eaton, *Making the Case to Avoid Entering the eBay Marketplace: A Recommended Analytical Framework for Evaluating Requests for Permanent Injunctions in Virginia*, 32 Regent U. L. Rev. 1, 30–33 (2019–20) (summarizing the current state of Virginia permanent injunction law).

Under Virginia law, a plaintiff may assert third party rights if the plaintiff has “suffered an injury and then further demonstrate both a close relationship with the person who possesses the right and a hindrance to the possessor’s ability to protect his own interests.” *Hawkins v. Grese*, 68 Va. App. 462, 481, 809 S.E.2d 441, 450 (2018) (citing *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004)).

⁴ The *Benchbook* is a reference text—produced by Virginia circuit court judges at the direction of the Virginia Supreme Court—that is provided to Virginia circuit court judges as a resource. *Virginia Civil Benchbook for Judges and Lawyers* ii (2021–22 ed. LexisNexis).

“A physician has a duty in the exercise of ordinary care to inform a patient of the dangers of, possible negative consequences of, and alternatives to a proposed medical treatment or procedure.” *Tashman v. Gibbs*, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002). “To recover against a physician for failure to provide such information, the patient generally is required to establish by expert testimony whether and to what extent any information should have been disclosed.” *Id.* The patient must also prove that the physician’s negligence was the proximate cause of his injury. *Allison v. Brown*, 293 Va. 617, 629, 801 S.E.2d 761, 768 (2017). “[T]hat means that the patient must prove that [he] would not have agreed to the treatment or procedure had the physician made a proper disclosure of the risks and alternatives associated with the treatment or procedure.” *Id.*

Virginia’s Health Care Decisions Act provides that “[a]ny adult capable of making an informed decision may, at any time, make a written advance directive to address any or all forms of health care in the event the declarant is later determined to be incapable of making an informed decision.” *Va. Code* § 54.1-2983 (2019 Repl. Vol.). “In the event that any portion of an advance directive is invalid or illegal, such invalidity or illegality shall not affect the remaining provisions of the advance directive.” *Id.* The statute further provides as follows:

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 or is currently being provided, continued, withheld, or withdrawn 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

Id. § 54.1-2985.1.

“No temporary injunction shall be awarded unless the court shall be satisfied of the plaintiff’s equity.” *Id.* § 8.01-628. “A plaintiff seeking a [temporary] injunction must establish [(1)] that he is likely to succeed on the merits, [(2)] that he is likely to suffer irreparable harm in the absence of preliminary relief, [(3)] that the balance of equities tips in his favor, and [(4)] that an injunction is in the public interest.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). “[A]ll four requirements must be satisfied.” *The Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310 (2010), *aff’d*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (*per curiam*).

Discussion

The Court has considered the pleadings, evidence and argument presented at the Hearing, and applicable authorities. The Court now rules as follows.

1. Marik Has Third-Party Standing to Bring an Informed Consent Claim on Behalf of His Patients.

Under Virginia law, it is undisputed that *a patient* may bring an informed consent claim against a physician. *Tashman v. Gibbs*, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002). Marik relies on *Doe v. Bolton*, 410 U.S. 179 (1973), to support his position that *a physician* may also have standing to sue for a violation of informed consent. In *Bolton*, a pregnant woman, physicians, nurses, clergymen, and social workers, as well as two nonprofit corporations, challenged a Georgia statute that criminalized abortion. *Id.* at 181, 184. The U.S. Supreme Court ultimately held that the doctors had standing because they risked prosecution under the statute. *Id.* at 188. Here, by contrast, Marik is not challenging the constitutionality of a criminal statute under which he faces a risk of prosecution. And contrary to Marik's assertion, the Court finds that *Bolton* does not stand for the proposition that a physician may bring an informed consent claim under Virginia law.

Marik further argues that he has standing to bring an informed consent claim on behalf of his patients under Virginia's third-party standing doctrine. Third-party standing requires that (1) the plaintiff suffer an injury, (2) the plaintiff have a close relation to the third party, and (3) the third party have a hindrance or inability to pursue his own claim. *Hawkins v. Grese*, 68 Va. App. 462, 481, 809 S.E.2d 441, 450 (2018). Marik alleges that if he violates the Guidelines, he could be disciplined, have his Sentara hospital privileges revoked, and/or be subject to a medical malpractice suit. At the Hearing, Bundy, Sentara's Chief Quality and Safety Officer, admitted that if Marik violated the Guidelines, his hospital privileges could be at risk. The Court finds that Marik has alleged a sufficiently concrete and imminent injury. Specifically, the Court finds—based on the evidence presented—that Marik could be subject to discipline and perhaps lose his hospital privileges if he does not comply with the Guidelines.⁵ The Court therefore finds that Marik has satisfied the first element of the third-party standing doctrine.

As to the second element, several federal courts have found that the physician-patient relationship is sufficiently close to support third-party standing. *See, e.g., Planned Parenthood of N. New Eng. v. Heed*, 390 F.3d 53, 56 n.2 (1st Cir. 2004) (permitting physicians to assert patients' right to an abortion); *Pa. Psychiatric Soc'y v. Green Spring Health Servs.*, 280 F.3d 278, 295 (3d Cir. 2002) (noting that the "doctor/patient intimacy . . . supports [an] exception to the standing rule."); *New York v. Heckler*, 719 F.2d 1191, 1195 (2d Cir. 1983) (concluding that physicians may assert the interests of their unemancipated minor patients in accessing confidential contraception).

⁵ Of note, Marik alleges that he received a letter from Sentara when he reported to work on November 20, 2021, stating that, as of November 18, 2021—the date of the Hearing—his hospital privileges at Sentara Norfolk Hospital had been suspended for fourteen days. (Pl.'s Nov. 22, 2021, Letter 1.) Although Sentara maintains that Marik "would not be disciplined for discussing his protocol as a treatment alternative with his patients," it does not dispute that the suspension is related to Marik's care of his COVID-19 patients. (Def.'s Nov. 22, 2021, Letter 1.)

In support of its position, Marik cites *Aid for Women v. Foulston*, 441 F.3d 1101 (10th Cir. 2006). There, the U.S. Court of Appeals for the Tenth Circuit permitted physicians to assert the rights of minor patients. *Id.* at 1112–14. The lawsuit concerned a Kansas statute that required healthcare professionals to report to state officials if a child was engaged in voluntary sexual activity. *Id.* at 1106. The court concluded that the physicians had a sufficiently close relationship with their patients. *Id.* at 1113. Further, the court found that the patients faced a genuine obstacle to asserting their own claims because their right to privacy might be chilled if they had to file a public lawsuit. *Id.* at 1114. Additionally, because the patients were minors, they were not legally sophisticated and were potentially “hindered by the fear of reprisal from parents should information about their sexual activity be disclosed.” *Id.*

Here, the Court finds that Marik—in his role as an attending physician—has a sufficiently close relationship with his patients suffering from COVID-19. As such, he satisfies the second element of the third-party standing doctrine.

Regarding the final element, the third party must face “some hindrance” to bringing suit. *Powers v. Ohio*, 499 U.S. 400, 411 (1991). Significantly, the hindrance to litigation need not be “insurmountable.” See *Singleton v. Wulff*, 428 U.S. 106, 117 (1976) (holding that women were hindered from challenging an abortion statute due to the imminent mootness of any individual claim); see also *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183, 204–05 (D. Md. 2020) (holding that, among other things, the time-sensitivity of securing an abortion hindered patients from bringing suit); *Pa. Psychiatric Soc.*, 280 F.3d at 290 (holding that patients’ impaired condition due to mental illness may prevent them from being able to assert their claims).

Marik alleges that his ICU patients are not in a position to file suit because they, in almost all cases, are in critical condition due to COVID-19. He alleges that many of his patients are unable to even communicate. Moreover, his patients are unaware that Sentara is withholding certain treatment options, such as the MATH+ Protocol. Further, Marik asserts that even if patients were to commence litigation, they very likely could die from COVID-19 before a hearing on the matter. The Court finds that Marik has sufficiently established that his patients are hindered from bringing a claim, thus satisfying the final element.

Because Marik faces imminent injury, Marik has a close relation to his third-party patients, and his patients are hindered from pursuing their own claims, the Court finds that Marik has standing under Virginia’s third-party standing doctrine. Sentara’s motion to dismiss is denied as to Marik’s informed consent claim.

2. Marik Lacks Standing to Bring Suit Under Virginia’s Health Care Decisions Act.

Virginia’s Health Care Decisions Act (the “Act”) permits individuals to create an enforceable advance directive specifying the health care they are to receive in the event they become incapacitated. *Va. Code* § 54.1-2981 *et seq.* (2019 Repl. Vol.). The Act permits “any person” to petition a circuit court to enforce a patient’s advanced directive if the desired care

“will be or is currently being . . . withheld.” *Id.* § 54.1-2985.1. Marik argues that the Act further provides patients the right to specify the treatment they receive while they are of sound mind. However, the express language of the Act addresses only situations in which a patient is deemed “incapable of making an informed decision.” *Id.* § 54.1-2983. Despite Marik’s argument that public policy demands a broader interpretation, the statutory language does not support such an interpretation. Hence, although Marik might have standing to bring a claim under the Act on behalf of *an incapacitated patient* whose desired care is or will be withheld, Marik has not identified any such patient.

Marik has provided multiple declarations from individuals who have advance medical directives requesting COVID-19 treatment that is prohibited by the Guidelines. Of note, however, Marik’s complaint does not identify a specific patient (1) who has executed such an advance directive, (2) who is currently incapacitated, and (3) whose desired health care is or will be withheld. As such, the Court finds that Marik lacks standing to bring a claim under Virginia’s Health Care Decisions Act.

Because Marik does not have standing under Virginia’s Health Care Decisions Act, the Court grants Sentara’s motion to dismiss Marik’s claim asserting a violation of Virginia’s Health Care Decisions Act.

3. Marik Failed to Demonstrate the Requisite Elements for a Temporary Injunction Under Virginia Law.

As discussed above, Marik lacks standing to bring a claim under Virginia’s Health Care Decisions Act. Accordingly, the Court’s temporary injunction analysis relates only to Marik’s informed consent claim.

a. Virginia’s Temporary Injunction Test.

A temporary injunction under Virginia law, like a federal preliminary injunction, is an extraordinary remedy. *Levisa Coal Co. v. Consolidation Coal Co.*, 276 Va. 44, 60, 662 S.E.2d 44, 53 (2008). The Supreme Court of Virginia has opined that this form of preliminary relief “allows a court to preserve the status quo between the parties while litigation is ongoing.” *May v. R.A. Yancey Lumber Corp.*, 297 Va. 1, 18, 822 S.E.2d 358, 367 (2019). Although the *Code of Virginia* provides that “[n]o temporary injunction shall be awarded unless the court shall be satisfied of the plaintiff’s equity,” *Va. Code* § 8.01-628 (2015 Repl. Vol.), the Virginia General Assembly and Virginia appellate courts have not yet provided additional guidance regarding how Virginia circuit courts should evaluate motions for temporary injunctions.

In 1988, when evaluating a federal preliminary injunction related to an underlying claim that the defendant had violated a Virginia statute, the U.S. Court of Appeals for the Fourth Circuit opined that “there is no great difference between federal and Virginia standards for preliminary injunctions” and that “[b]oth draw upon the same equitable principles.” *Capital Tool & Mfg. Co. v. Maschinenfabrik Herkules*, 837 F.2d 171, 173 (4th Cir. 1988). Since then, many

Virginia circuit courts implicitly have relied on the Fourth Circuit's proclamation and have applied federal preliminary injunction law when analyzing Virginia temporary injunctions.

The Fourth Circuit has opined that the purpose of a preliminary injunction is to “protect the *status quo* and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits.” *Pashby v. Delia*, 709 F.3d 307, 319 (4th Cir. 2013) (quoting *Sun Microsystems, Inc. v. Microsoft Corp.* (In re *Microsoft Corp. Antitrust Litig.*), 333 F.3d 517, 525 (4th Cir. 2003), *abrogated on other grounds by eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)). Additionally, the court defined the *status quo* as the “last uncontested status between the parties which preceded the controversy.” *Id.* at 319 (quoting *Aggarao v. MOL Ship Mgmt. Co., Ltd.*, 675 F.3d 355, 378 (4th Cir. 2012)).

Although Sentara acknowledges the Fourth Circuit's definition of *status quo*, it contends that the current *contested* status—with the Guidelines in effect—is in fact the last *uncontested* status. Regardless, this Court therefore gives very little weight to the argument of counsel that their respective positions support the *status quo* or the resultant effect of the *status quo* on the temporary injunction analysis because (1) the definition of *status quo* in the context of preliminary relief is subject to interpretation; (2) some courts and many modern commentators have criticized the imposition of a heightened requirement for mandatory injunctions, claiming that the mandatory/prohibitory classification is a distinction without a difference; and (3) there is scant evidence that courts have actually incorporated a separate *status-quo* analysis as part of some bifurcated temporary injunction evaluation. *See generally* David W. Lannetti, *The “Test” — or Lack Thereof— for Issuance of Virginia Temporary Injunctions: The Current Uncertainty and a Recommended Approach Based on Federal Preliminary Injunction Law*, 50 U. Rich. L. Rev. 273, 282–87, 313–14 (2015) (discussing the impact, or lack thereof, of the *status quo* on Virginia's temporary injunction analysis).

Against a backdrop where virtually every federal circuit court of appeals evaluated preliminary injunctions differently, the U.S. Supreme Court in 2008 decided *Winter v. Natural Resources Defense Council, Inc.* In *Winter*, the Court held that “[a] plaintiff seeking a preliminary injunction must establish [(1)] that he is likely to succeed on the merits, [(2)] that he is likely to suffer irreparable harm in the absence of preliminary relief, [(3)] that the balance of equities tips in his favor, and [(4)] that an injunction is in the public interest.” 555 U.S. 7, 20 (2008).

In 2009, the Fourth Circuit decided its first post-*Winter* preliminary injunction case: *The Real Truth About Obama, Inc. v. Federal Election Commission*. 575 F.3d 342 (4th Cir. 2009), *vacated on other grounds, Citizens United v. FEC*, 558 U.S. 310 (2010), *aff'd, The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (*per curiam*). It held that “[b]ecause a preliminary injunction affords, on a temporary basis, the relief that can be granted permanently after trial, the party seeking the preliminary injunction must demonstrate by ‘a clear showing’ that, among other things, it is likely to succeed on the merits at trial.” *Id.* at 345 (quoting *Winter*, 555 U.S. at 22). The court then declared that “the Supreme Court articulated clearly what must be shown to obtain a preliminary injunction” and pointed out that “all four requirements must be satisfied.” *Id.* at 346.

Since the Fourth Circuit decided *Real Truth About Obama*, most Virginia circuit courts have evaluated temporary injunctions using that court's sequential analysis. *See, e.g., State Bd. of Health v. Gourmeltz, LLC*, No. CL21-518, 2021 Va. Cir. LEXIS 51, at *10–11 (Spotsylvania Cnty. Mar. 22, 2021); *Dillon v. Northam*, No. CL20-3812, 2020 Va. Cir. LEXIS 109, at *17 (Virginia Beach July 30, 2020); *Fontaine v. Watson*, 106 Va. Cir. 430, 437 (Henry Cnty. 2020); *Freemason St. Area Ass'n v. City of Norfolk*, 100 Va. Cir. 172, 183–84 (Norfolk 2018); *CG Riverview, LLC v. 139 Riverview, LLC*, 98 Va. Cir. 59, 62 (Norfolk 2018); *In re Volkswagen "Clean Diesel" Litig.*, 94 Va. Cir. 189, 206 (Fairfax Cnty. 2016); *Wings, LLC v. Capitol Leather, LLC*, 88 Va. Cir. 83, 89 (Fairfax Cnty. 2014); *McEachin v. Bolling*, 84 Va. Cir. 76, 77 (Richmond 2011); *Strong Found. Youth Initiative LLC v. Ashford*, No. CL09-4538, 2009 Va. Cir. LEXIS 140, at *1 (Richmond Nov. 4, 2009). Consistent with this approach, the *Virginia Civil Benchbook* refers to the *Winter* four-factor test—and the Fourth Circuit's interpretation of the *Winter* factors as applied in *Real Truth About Obama*—in the section regarding motions for temporary injunctions. *See Virginia Civil Benchbook for Judges and Lawyers* § 8.06[3][b] (2021–22 ed. LexisNexis).

b. Applying Virginia's temporary injunction analysis to the facts before the Court.

As noted above, the true purpose of a temporary injunction is to prevent irreparable harm during the pendency of the suit. This is most clearly evident in the second factor of the four-factor temporary injunction analysis—irreparable injury to the petitioner if the temporary injunction is not granted. Irreparable harm also normally plays an important role in the third factor—the balance of the equities—as the petitioner's side of the scale normally consists of the same irreparable harm. The petitioner's alleged irreparable harm can also come into play in the fourth factor, the public interest, as the harm often extends beyond the petitioner himself.

At least with respect to the balance of the equities factor, the petitioner's alleged irreparable harm without preliminary relief is compared to respondent's position with the temporary injunction. When the respondent claims a corresponding irreparable injury with the requested temporary injunction, however, a court's temporary injunction analysis is extremely difficult, especially absent the discovery that is available at the permanent relief phase. The petitioner must prove that his irreparable injury outweighs the irreparable injury of the respondent.

Here, the Court finds that Marik, who is undoubtedly a highly qualified critical care physician,⁶ has a sincerely held belief that the Guidelines prevent him from administering medications that promise life-saving aid to his patients. At the same time, the Court finds that Sentara put the Guidelines in place because it believes, based on generally accepted national

⁶ Marik is, *inter alia*, a licensed physician, a tenured professor at the Eastern Virginia Medical School ("EVMS"), Chief of EVMS's Division of Pulmonary and Critical Care Medicine, and Director of the General Intensive Care Unit at Sentara Norfolk General Hospital. (Compl. 1–2.)

studies,⁷ that the Medications Marik seeks to use pose a danger to patients and that other treatments for COVID-19 supported by Sentara save more lives. Human death of course is an irreparable injury, but to say that the Court is ill-equipped to determine the proper COVID-19 treatment protocols or the safety of such protocols—especially when experienced physicians disagree—at a preliminary relief stage, before discovery has even commenced, is a huge understatement.

The Court ultimately finds that it does not need to delve into the thorny issue of whether a controversial COVID-19 protocol actually saves lives and is more effective than other Sentara-supported COVID-19 treatments. The fundamental issue at trial will be whether a physician who disagrees with hospital guidelines is free to violate those guidelines if he believes, based on his professional medical opinion, that the violation will provide appropriate treatment for his patient. As discussed below, the Court finds that Marik has failed to demonstrate that he is likely to succeed on the merits.

c. *Marik has failed to demonstrate that he is likely to succeed on the merits of his informed consent claim.*

The U.S. Court of Appeals for the Fourth Circuit has opined that “the Supreme Court in *Winter*, recognizing that a preliminary injunction affords relief before trial, requires that the plaintiff make a clear showing that it likely will succeed on the merits at trial.” *The Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310 (2010), *aff’d*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (*per curiam*) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22–23 (2008)). In other words, Marik must clearly prove that he is likely to succeed on the merits of his underlying claim, *i.e.*, his informed consent claim, to receive his requested permanent relief, *i.e.*, a declaratory judgment that the Guidelines are unlawful and an injunction enjoining Sentara from applying or enforcing the Guidelines.

⁷ See, e.g., *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19*, AMA (Sept. 1, 2021), <https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19> (releasing a joint statement strongly opposing the use of ivermectin to treat COVID-19 outside of clinical trials); *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*, FDA, <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19> (advising that large doses of ivermectin are dangerous); *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19*, CDC (Aug. 26, 2021), <https://emergency.cdc.gov/han/2021/han00449.asp> (warning of increasing ivermectin overdoses); *Ivermectin*, NIH (Feb. 11, 2021), <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/> (stating there is insufficient evidence to support the use of ivermectin to treat COVID-19); *WHO Advises That Ivermectin Only Be Used to Treat Covid-19 Within Clinical Trials*, WHO (Mar. 31, 2021), <https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials> (advising that current evidence on the use of ivermectin to treat COVID-19 is inconclusive and that the drug be solely used in clinical trials).

In order to succeed on a third-party informed consent claim, the plaintiff must establish that a physician breached the standard of care by failing to disclose material risks associated with the medical treatment or the existence of alternative treatments, which precluded the third party from making an informed decision about the third party's course of treatment. *See Tashman v. Gibbs*, 263 Va. 65, 73–74, 556 S.E.2d 772, 777–78 (2002). Further, the plaintiff must prove that the physician was negligent and that the negligence was a proximate cause of the third party's injuries. *Id.* at 76, 556 S.E.2d at 779. In other words, the plaintiff must establish that the third party would not have agreed to the treatment had the physician properly disclosed the risks and alternatives. *See id.*

For Marik to prevail on his informed consent claim based on Sentara's alleged prohibition against physicians advising patients about alternative COVID-19 treatments, he must prove that his patients would not have agreed to their specific COVID-19 treatment, had they known about the alternative MATH+ Protocol, and that they were injured as a result. Marik alleges in his complaint and motion for temporary injunction that, *inter alia*, the Guidelines prohibit him from informing his patients about the MATH+ Protocol. At the Hearing, however, Marik acknowledged that he was allowed to inform his patients about the MATH+ Protocol and that the patients presumably were free to transfer to another hospital that offered the alternative treatment, but he asserted that his patients were usually in an acute condition and therefore unable to receive information from him. He also conceded that, absent the patient's ability to consent, he was free to call patients' families and inform them of alternative treatments not supported by Sentara; however, Marik claimed that it would be cruel and unusual punishment to notify a patient's family about a treatment that was not available at the hospital, especially in light of the typical non-feasibility of transporting a COVID-19 patient who was already in the ICU. Accordingly, the Court finds that, based on the evidence presented, Sentara is not prohibiting its physicians from informing their patients of alternative COVID-19 treatments that Sentara does not support.

Marik therefore is left with his argument that the Guidelines violate Virginia's informed consent law because they prevent him from *administering* alternative COVID-19 treatments that Sentara does not support. He argues that a hospital *must* obey the instructions of a patient's physician as long as those instructions are not obviously negligent or dangerous. Hence, according to Marik, Sentara cannot prohibit him from treating his COVID-19 patients with the MATH+ Protocol, including prescribing the Medications, and any Sentara guidelines that provide otherwise are unenforceable and must be repealed. This is a broad reading of Virginia's informed consent law, and it is an interpretation that the Court finds that Marik, at least at this early stage of the litigation, has failed to demonstrate that he is likely to prevail on the merits.⁸

As an initial matter, federal courts have held that neither a patient nor a physician has a constitutional right to access scientifically unproven medical treatments. *See, e.g., Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695, 711 (D.C. Cir. 2007) (concluding that terminally ill patients have no constitutional right to take drugs that the FDA has not found to be effective); *Mitchell v. Clayton*, 995 F.2d 772, 775 (7th Cir. 1993)

⁸ The issue of whether Marik's professional medical judgment can somehow trump the Guidelines ultimately may be an issue of law that can be resolved short of a trial.

(noting that “most federal courts have held that a patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider”); *N.Y. State Ophthalmological Soc’y v. Bowen*, 854 F.2d 1379, 1389 (D.C. Cir. 1988) (“We disagree that the constitutional right to privacy comprehensively protects all choices made by patients and their physicians or subjects to ‘strict scrutiny’ all government interference with choice of medical treatment. There is no basis under current privacy case law for extending such stringent protection to every decision bearing, however indirectly, on a person’s health and physical well-being.”); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) (opining that “the patient[’s] . . . selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health”).

Further, the Court is unaware of anything in Virginia’s informed consent doctrine that compels a particular provider, such as a hospital or physician, to administer a specific treatment or procedure. Although Marik relies on North Carolina case law in support of his proposition that Sentara cannot interfere with his treatment decisions, even those cases recognize that this does not extend to treatment that could be dangerous to patients. Under North Carolina law, a “hospital has a duty to make a reasonable effort to oversee and monitor the physician’s treatment of a patient.” *Burns v. Forsyth County Hospital Authority*, 81 N.C. App. 556, 562–63, 344 S.E.2d 839, 844–45 (1986). Additionally, a hospital “has a duty to obey instructions of a doctor, absent the instructions being obviously negligent or dangerous.” *Id.* at 563, 344 S.E.2d at 845. These duties arise under the doctrine of corporate negligence. *Id.* However, Marik has failed to identify any Virginia cases that have adopted a similar doctrine.

Rather, Virginia’s informed consent doctrine traditionally focuses only on a physician providing a patient with sufficient information to make an informed choice about his or her treatment. *See, e.g., Tashman v. Gibbs*, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002) (describing a health provider’s duty to disclose). The Court also is unaware of any statute or case law—and Marik has provided no legal authorities—that support the proposition that the informed consent doctrine compels a hospital to provide all potentially available alternative procedures or treatments.

Based on the limited evidence presented in support of a request for preliminary relief, the Court finds that Marik is unlikely to succeed—on the merits of his informed consent claim—in demonstrating that Sentara did not follow appropriate procedures in establishing the Guidelines or that Sentara did not reasonably prohibit use of the Medications. At the Hearing, Bundy described the relevant federal and state regulatory and statutory provisions and accreditation guidelines regarding the provision of pharmaceutical services to hospital in-patients. He also testified about the requirements related to Sentara’s P&T Committee⁹ and the committee’s development of the Guidelines, which preclude use of the Medications outside clinical trials.

⁹ According to Sentara, the P&T Committee is composed of physicians, pharmacists, nurses, hospital administrators, and other hospital staff and has the goal of “promot[ing] rational, appropriate and safe use of drugs used to treat hospital patients while fostering cost-effective therapy.” (Mem. Opp’n Pl.’s Mot. Temporary Inj. 22.)

With respect to ivermectin specifically, Bundy testified that the committee found persuasive a September 1, 2021, joint statement released by the American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists, which indicates that these organizations “strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial”; states that “[u]se of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients”; and references a CDC Health Alert Network Advisory that “recommends that healthcare professionals should counsel patients against use of ivermectin as a treatment for COVID-19, including emphasizing the potentially toxic effects of this drug.” *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19*, AMA (Sept. 1, 2021), <https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19>.

In sum, the Court finds that Marik has not demonstrated that he is likely to succeed on the merits of his informed consent claim. His position that physicians should be able to demand that hospitals support their alternative treatments, even if the hospital has reasonably determined those treatments to be unsafe, does not appear to be consistent with Virginia’s informed consent law and arguably could set a dangerous precedent against established medical standards.


It is well established that a plaintiff seeking a temporary injunction must satisfy all four temporary-injunction factors in order to prevail. *Real Truth About Obama*, 575 F.3d at 346. Because Marik has failed to satisfy the first factor—that he is likely to succeed on the merits of his claim—the Court need not address the remaining three factors. The Court therefore denies Marik’s motion for a temporary injunction.

Conclusion

Based on the above, the Court finds that Marik has third-party standing to bring an informed consent claim on behalf of his patients but lacks standing to bring a claim under Virginia’s Health Care Decisions Act. The Court further finds that Marik is unlikely to succeed on the merits of his informed consent claim. The Court therefore GRANTS IN PART AND DENIES IN PART Sentara’s “Motion to Dismiss for Lack of Standing” and DENIES Marik’s “Motion for Temporary Injunction.”

Attached is an Order incorporating the Court’s ruling. Any objections shall be filed with the Court within fourteen days.

Sincerely,



David W. Lannetti
Circuit Court Judge