

2021 WL 4343661

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Court of Chancery of Delaware.

Mary Ellen DEMARCO, as attorney
in fact for David DeMarco, Plaintiff,

v.

CHRISTIANA CARE HEALTH
SERVICES, INC., Defendant.

C.A. No. 2021-0804-MTZ

|
Date Submitted: September 23, 2021

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Date Decided: September 24, 2021

Attorneys and Law Firms

Theodore A. Kittila and William E. Green, Jr., HALLORAN FARKAS + KITTLA LLP, Wilmington, Delaware; Ralph C. Lorigo, LAW OFFICE OF RALPH C. LORIGO, West Seneca, New York, Attorneys for Plaintiff.

John D. Balaguer, Stephen J. Milewski, and Karine Sarkisian, WHITE AND WILLIAMS LLP, Wilmington, Delaware, Attorneys for Defendant.

OPINION

ZURN, Vice Chancellor.

*1 This Court has been asked to compel a healthcare provider to treat a **hospitalized** COVID-19 patient with **ivermectin**. **Ivermectin** is a safe and effective treatment for parasitic disease. While some providers are **administering ivermectin** to COVID-19 patients due to its anti-viral and anti-inflammatory properties, it is **not** part of the standard of care for the COVID-19 virus. Upon admission to the **hospital**, the patient in this case expressed a desire to be treated with **ivermectin**. As the patient's health declined, his wife sought out and obtained a prescription from a doctor who never met the patient, and who is **not** affiliated with the **hospital**. Consistent with its guidelines, the **hospital** refused to **administer** the **ivermectin** prescription. Because the patient was **hospitalized** in isolation due to his infectious disease, the only avenues to effectuate delivery of **ivermectin** were through discharge against medical advice, and through a court order. After trying the first avenue and then returning to

the **hospital**, the patient's wife has joined a legion of plaintiffs seeking to compel **hospitals** to treat COVID-19 patients with **ivermectin**.

This precedential opinion denies the requested injunction. The evidentiary proceedings before this Court focused on **ivermectin's** safety and efficacy, with the **hospital** explaining why **ivermectin** is **not** part of the standard of care and the plaintiff arguing why it should be. But this opinion denies the injunction based on two more fundamental, and reciprocal, precepts. Patients, even gravely ill ones, do **not** have a right to a particular treatment, and medical providers' duty to treat is coterminous with their standard of care. This court will wield its equitable powers only to enforce a right or duty; in their absence, relief is **not** available. The patient has this Court's sincerest sympathies and best wishes, but **not** an injunction.

I. BACKGROUND

I draw the following facts from the record as developed at yesterday's evidentiary hearing (the "Hearing") on the plaintiff's motion for a preliminary injunction (the "Motion").¹ That record includes seven Hearing exhibits,² Hearing testimony from three witnesses, and at least twenty other exhibits and declarations the parties submitted with their pleadings and briefs. I have examined that evidence, giving each document and testimony the weight deserved. I have found the following facts based on the preponderance of that evidence.³

A. David DeMarco Is **Hospitalized** With COVID-19.

*2 Plaintiff Mary Ellen DeMarco ("Plaintiff") is the attorney in fact for her husband David DeMarco ("DeMarco").⁴ Defendant Christiana Care Health Services, Inc. ("Defendant") is a private **not-for-profit** corporation authorized to do business in the State of Delaware.⁵

On September 9, DeMarco checked himself in to Wilmington **Hospital**, Defendant's Wilmington, Delaware campus (the "**Hospital**"), where he was diagnosed with COVID-19 and moved to the intensive care unit ("ICU").⁶ While in the **Hospital**, DeMarco was in isolation and only **Hospital** personnel had access to him; Plaintiff communicated with DeMarco by phone.⁷

As part of his advanced health care treatment instructions, DeMarco indicated that he did **not** wish to be placed on a **mechanical ventilator** or breathing machine.⁸ DeMarco persistently stated that he did **not** wish to be placed on a ventilator.⁹ Plaintiff discussed DeMarco's wishes with his doctors at the **Hospital** on September 10.¹⁰

The **Hospital** treated DeMarco with heated high-flow oxygen at the maximum setting of one hundred percent concentration and 60L flow, **Methylprednisolone** sodium succinate, Remdesivir (Veklury), **Solu-Medrol**, **Benzonatate** (Tessalon Perles), and Guaifenesin-Dextromethorphan (**Robitussin DM**).¹¹ DeMarco's treatment was in accordance with the **Hospital's** treatment guidelines for COVID-19.¹² Despite this care, DeMarco's condition did **not** improve, and by September 16, he was diagnosed with "severe hypoxic respiratory failure" and was "on the brink of requiring intubation with mechanical ventilation."¹³

B. Plaintiff Seeks Treatment With **Ivermectin**.

At DeMarco's request, Plaintiff has sought alternative treatment to improve her husband's condition. After he was admitted to the **Hospital**, DeMarco sent text messages to Plaintiff, requesting **ivermectin**.¹⁴ **Ivermectin** is a drug approved by the Food and Drug Administration (the "FDA") as an antiparasitic used to treat tropical diseases, including **onchocerciasis**, **helminthiasis**, and scabies.¹⁵ **Ivermectin** has anti-viral and anti-inflammatory properties, which Plaintiff asserts make it "effective in reducing ... mortality in COVID patients" with "an extremely low risk of side effects."¹⁶ Defendant's interim treatment guidelines for patients **hospitalized** with COVID-19, which are based on and updated according to evidence-based, peer-reviewed literature and recommendations from the FDA, do **not** include **ivermectin**.¹⁷

*3 On September 11, Plaintiff discussed **ivermectin** with several members of the **Hospital** staff, including DeMarco's treatment team.¹⁸ She also contacted patient advocacy.¹⁹ Consistent with its guidelines, the **Hospital** refused to treat DeMarco with **ivermectin**.²⁰

In search of a prescription, Plaintiff contacted Dr. Adam Brownstein, a family medicine specialist in Milton,

Delaware.²¹ On September 16, Dr. Brownstein prescribed **ivermectin** to DeMarco.²² Dr. Brownstein had **not** previously treated DeMarco, and prescribed the medication without examining him.²³ Plaintiff does **not** indicate that Dr. Brownstein has admitting privileges at the **Hospital**, and Defendant asserts he does **not**.²⁴ Plaintiff filled her husband's prescription at a CVS Pharmacy in Milford, Delaware.²⁵ Despite Dr. Brownstein's prescription and Plaintiff's insistence, the **Hospital** has refused to authorize, **administer**, or allow Plaintiff to **administer ivermectin** to DeMarco.²⁶ While DeMarco is **hospitalized** in isolation, Plaintiff cannot deliver the **ivermectin** to DeMarco.²⁷

C. Plaintiff Files This Litigation And The Court Denies A Temporary Restraining Order.

Plaintiff filed a Verified Complaint for Injunctive and Declaratory Relief on September 17, 2021 (the "Complaint").²⁸ The Complaint asserts two counts. Count I seeks injunctive relief "requiring Defendant to **administer** the [**Ivermectin**] prescribed by [Dr. Brownstein]."²⁹ Count II seeks a declaratory judgment "providing that the Defendant will honor Plaintiff's wishes under the power of attorney respecting the medical treatment of Mr. DeMarco."³⁰

*4 In conjunction with the Complaint, Plaintiff filed a Motion for Expedited Proceedings and a Motion for Emergency Temporary Restraining Order ("TRO") seeking an injunction compelling Defendant to **administer** DeMarco's prescribed **ivermectin**.³¹ The Court accommodated the emergency nature of her request and held a TRO hearing three hours after Plaintiff filed her Complaint. That hearing was conducted *ex parte* after neither Plaintiff's attorneys nor the Court could contact counsel for Defendant.³² The Court denied Plaintiff's TRO in a bench ruling as seeking mandatory relief on disputed facts,³³ but expedited the case and scheduled the Hearing on Plaintiff's Motion for September 23.³⁴

D. DeMarco Leaves The **Hospital**, His Condition Worsens, And He Is Readmitted.

On September 19, at his request, DeMarco was discharged from the **Hospital** against medical advice and transferred

to home hospice care so that he and Plaintiff could self-administer ivermectin.³⁵ Plaintiff attempted to treat DeMarco at home with the aid of a hospice nurse.³⁶ During this time, DeMarco took one “large” dose of the prescribed ivermectin.³⁷ Within hours, Plaintiff encountered what she described as a “catastrophic equipment failure” when DeMarco's oxygen mask broke in her hands.³⁸ His condition deteriorated rapidly and Plaintiff called 911.³⁹ Paramedics responded.⁴⁰ Plaintiff requested the ambulance bring DeMarco to a different hospital, St. Francis Hospital; the ambulance started towards St. Francis, “but they did not have any ICU beds, so [DeMarco] ended up back at [the Hospital],” where he was readmitted to the ICU.⁴¹ During that time, DeMarco rescinded his existing “do not resuscitate” directive, and consented to being intubated.⁴² Since being readmitted, DeMarco has remained in the Hospital's ICU, where he is intubated and on ventilator support.⁴³ In short, DeMarco is gravely ill.

E. Plaintiff Pursues Equitable Relief And The Court Considers The Motion.

Since the TRO hearing, Plaintiff has continued to pursue mandatory injunctive relief.⁴⁴ Counsel for Defendant entered their appearances on September 17.⁴⁵ On September 21, the Hospital answered the Complaint.⁴⁶ On September 22, the Hospital filed a Brief in Opposition to Plaintiff's Action for Injunctive and Declaratory Relief.⁴⁷

Plaintiff claims Defendant's refusal to permit the administration of ivermectin “breaches the Patient/Physician contract and the Hippocratic Oath, as well as Mr. DeMarco's right to self-determination under Delaware statutory law and the Delaware State Constitution.”⁴⁸ She seeks injunctive relief compelling the Hospital “to abide by the Patient/Physician contract and [its] Hippocratic Oath to ‘Do No Harm.’”⁴⁹

The Hospital argues Plaintiff has not clearly established a duty or right enforceable by a mandatory injunction because the Hospital does not owe Plaintiff or DeMarco a duty to treat DeMarco with ivermectin under its standard of care.⁵⁰ The Hospital also contends Plaintiff will not suffer irreparable harm if not treated with ivermectin, but the Hospital will

be harmed if forced “to act against established medical standards.”⁵¹

*5 The Court held the Hearing on Plaintiff's Motion yesterday, September 23, by video conference. At the Hearing, Plaintiff was asked whether she believed DeMarco “has the right to be administered ivermectin with a prescription.”⁵² She responded: “Yes. I absolutely believe that, especially at this stage of his life, which may end soon, without further -- further measures, that he has the right to take this medication at this time, ivermectin, yes.”⁵³

In addition to her own testimony, Plaintiff also presented testimony from a retained expert, Dr. Ryan Partovi; Dr. Brownstein was on the witness list but did not appear. Dr. Partovi is a doctor in naturopathic medicine who does not treat COVID-19 patients, though he described himself as a “consultant” on several patients' cases.⁵⁴ Dr. Partovi testified that he has prescribed ivermectin to many COVID-19 patients, primarily those in early stages of the disease.⁵⁵ In doing so, Dr. Partovi has never spoken with critical care teams or pulmonologists at the treating hospitals.⁵⁶

Dr. Partovi testified that ivermectin would “very likely” be beneficial for DeMarco's treatment and could improve his chance of survival.⁵⁷ He based this testimony primarily on his own experience prescribing ivermectin to COVID-19 patients and the computer system he uses to check for side effects.⁵⁸ While most of his experience was with early-stage patients, Dr. Partovi testified he has observed later-stage patients like DeMarco improve with ivermectin and that taking it is “certainly worth a shot.”⁵⁹

*6 In further support of her position, Plaintiff relies on a literature review by the Front Line COVID-19 Critical Care Alliance (“FLCCC Alliance”), which Dr. Partovi also referenced.⁶⁰ The FLCCC Alliance concludes that twenty-seven studies support a strong recommendation for the use of ivermectin “in both the prophylaxis and treatment of all phases of COVID-19.”⁶¹

For its part, Defendant presented the testimony of Dr. Vinay Maheshwari, a physician who is the chair of Defendant's Department of Medicine.⁶² He has played a leadership role in developing Defendant's response to the COVID-19

pandemic, including “engineering and putting together a treatment guideline pathway.”⁶³ Dr. Maheshwari is also an active clinician, working in a critical care unit and treating some of Defendant’s most ill COVID-19 patients, including those on ventilators.⁶⁴

Dr. Maheshwari testified about Defendant’s interim treatment guidelines for patients with COVID-19 and how those guidelines were developed.⁶⁵ He also testified about why those guidelines do **not** include the use of **ivermectin**:

Two reasons. There has been no high-quality, or even moderate-quality, studies that have showed its benefit or efficacy with the use of **ivermectin** in this disease process. That’s actually across all continuums, but more specifically there’s been no moderate-to high-quality studies that prove its efficacy in patients that are **hospitalized** or have severe critical illness. In addition to that, there is risk associated with **ivermectin**. There is risk for **liver failure**, there’s risk for shock or hypotension, or low blood pressure. There’s risk for seizures. This has been described in the literature. And across the country, we have had many reports from poison control centers and toxicology centers reporting severe cases of severe adverse reactions related to **ivermectin**. Many of those are related to self-administration with unknown doses outside of a **hospitalized** setting.⁶⁶

He described warnings against **ivermectin’s** use in COVID-19 patients from several national clinical authorities.⁶⁷

Defendant provided the Court with evidence of those warnings. In February 2021, one month after the FLCCC review, the National Institutes of Health (“NIH”) conducted its own literature review of thirty-two studies and concluded

that the studies provide “insufficient evidence for the ... Panel to recommend either for or against the use of **ivermectin** for the treatment of COVID-19.”⁶⁸ “[M]ost of these studies had incomplete information and significant methodological limitations.”⁶⁹ The NIH also noted that achieving antiviral efficacy in patients “would require administration of doses up to 100-fold higher than those approved for humans.”⁷⁰

Other medical agencies have gone further. On September 1, the American Medical Association (“AMA”), together with the American Pharmacists Association and the American Society of Health-System Pharmacists, issued a statement to “strongly oppose the ordering, prescribing, or dispensing of **ivermectin** to prevent or treat COVID-19 outside of a clinical trial.”⁷¹ The statement goes on:

*7 The U.S. Centers for Disease Control [(“CDC”)] and the FDA have issued advisories indicating that **ivermectin** is **not** authorized or approved for the prevention or treatment of COVID-19. The National Institutes of Health, World Health Organization, and Merck (the manufacturer of the drug) all state there is insufficient evidence to support the use of **ivermectin** to treat COVID-19. The Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 also recommend against the use of **ivermectin** outside of a clinical trial.⁷²

The statements from the CDC and Merck are in the record as well.⁷³ Dr. Maheshwari also cited a statement from the Infectious Disease Society of America warning against using **ivermectin** for COVID-19.⁷⁴ He went on to testify that there are no well-regarded healthcare agencies, research-governing bodies, or regulatory bodies that have recommended or approved such a use.⁷⁵

II. ANALYSIS

Plaintiff seeks a preliminary injunction directing the **Hospital** to **administer** DeMarco's **ivermectin** prescription. This mandatory injunction, requiring the **Hospital** to take affirmative action, may be granted only if Plaintiff demonstrates: (1) entitlement to judgment as a matter of law on the merits of her claim; (2) that the failure to issue the injunction will result in immediate and irreparable injury; and (3) that the balance of hardships weighs in Plaintiff's favor.⁷⁶ "Even where the applicant's chance of success on the merits appears reasonably probable, the Court of Chancery will deny a motion for a mandatory preliminary injunction if there is a bona fide dispute as to an essential issue."⁷⁷ Plaintiff's requested preliminary injunction is also her final relief sought, albeit **not** presented on a motion for summary judgment or at a final hearing.⁷⁸ In that circumstance, where "a result after trial could **not** practically reverse the grant of preliminary relief[,] then absent an extraordinary circumstance, the court ought **not** to grant such relief where material facts are in substantial dispute."⁷⁹

*8 Plaintiff must meet all three factors to prevail, but she falls short on them all. Defendant does **not** have an enforceable duty to treat DeMarco with **ivermectin**, and DeMarco does **not** have an enforceable legal right to that treatment. Plaintiff has failed to demonstrate irreparable harm: the material fact of whether DeMarco will be harmed if deprived of **ivermectin** is hotly disputed, and the weight of the record to date favors Defendant on that point. Finally, the balance of the equities tips against the requested injunction.

A. Plaintiff Has Failed To Demonstrate That She Is Entitled To Judgment On the Merits.

When a party seeks mandatory injunctive relief, the applicant must clearly establish the legal right she seeks to protect or the duty she seeks to enforce.⁸⁰ "The showing on the merits required by the 'clearly established' standard is 'more than a reasonable probability of success.'" ⁸¹

Plaintiff has **not** clearly established Defendant owes DeMarco a duty to treat him with **ivermectin**. Plaintiff "seeks an order that Defendant be compelled to abide by the Patient/Physician contract."⁸² Plaintiff is correct that by seeking and accepting treatment from Defendant, DeMarco and

his doctors are in an implicit contractual relationship.⁸³ By statute, that relationship imposes on Defendant the "duty to the patient to render health care that meets the applicable standard of skill and care required of every health care provider within the same field of medicine."⁸⁴ The healthcare provider must exercise the same "degree of skill and care ordinarily employed in the same or similar field of medicine as [the provider], and the use of reasonable care and diligence."⁸⁵ "[T]he standard of care by which the conduct of the defendant is tested is the professional standard as it existed at the time."⁸⁶ The Delaware General Assembly has specifically enumerated that "a health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires medically ineffective treatment or health care contrary to generally accepted health-care standards applicable to the health-care provider or institution."⁸⁷

*9 Plaintiff admits **ivermectin's** efficacy is disputed and that **ivermectin** is **not** part of the standard for treating COVID-19.⁸⁸ Treating COVID-19 with **ivermectin** is undisputedly contrary to generally accepted health care standards.⁸⁹ Preeminent institutions representing numerous facets of the national medical establishment, including the FDA, CDC, AMA, World Health Organization, and Infectious Disease Society of America, have criticized the use of **ivermectin** as a treatment for COVID-19.⁹⁰ Accordingly, Defendant's standard of care undisputedly does **not** contemplate treating COVID-19 with **ivermectin**.⁹¹ Plaintiff seeks that treatment despite its nonconformance to the standard of care.

But Defendant's duty to DeMarco within the patient-physician relationship does **not** extend beyond the standard of care. Because **ivermectin** is **not** part of the "professional standard" for treating COVID-19, a physician refusing to **administer** the drug is **not** deviating from the applicable standard of care. Defendant is statutorily free to decline to comply with Plaintiff's instruction to **administer ivermectin**.⁹² Under the present standard of care, healthcare providers have no duty to **administer ivermectin** to a COVID-19 patient.

In addition to asserting a duty by Defendant, Plaintiff also broadly contends that DeMarco has a "right to self-determination under Delaware statutory law and the Delaware State Constitution."⁹³ But DeMarco's statutory "right of self-

determination” in the health care setting is limited to “the right to *refuse* medical or surgical treatment if such refusal is **not** contrary to existing public health laws.”⁹⁴ The Delaware Supreme Court has recognized the Delaware Constitution affords a right to self-determination that encompasses “the right of every individual to the possession and control of his or her own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”⁹⁵ That right to be free of bodily restraint corresponds to a “right to withhold or withdraw” medical treatment, or to “accept ... or [] refuse it.”⁹⁶ Delawareans’ statutory and state constitutional rights to self-determination afford them the right to accept treatment and to refuse, withhold, or withdraw treatment. Plaintiff points to no authority granting the right to compel a particular treatment outside the standard of care, and I could find none. Defendant’s enumerated patient rights and responsibilities are consistent with the legal authority, as they explain patients have a right to share in their care and help make choices about their care, but do **not** enumerate any right to demand a nonstandard treatment.⁹⁷

*10 Other courts considering patient requests for treatments that fall outside the standard of care have concluded the patient does **not** have a right to obtain the medication of her choice. “[M]ost 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.”⁹⁸ Even the terminally ill do **not** have a constitutional right to procure and use experimental drugs.⁹⁹ Desperation in the face of severe illness appears to be an unabating part of the human condition: in the late 1970s and early 1980s, several courts concluded that patients did **not** have a right to an unapproved substance called laetrile, which the petitioners believed would prevent or cure **cancer** but which was **not** within the standard of care.¹⁰⁰

*11 So too here. While **ivermectin** has been approved as safe and effective to treat human **parasitic infections**, and so is distinct from a wholly unapproved new drug, DeMarco still has no right to compel its use to treat COVID-19 outside the standard of care.

In the absence of a clearly established duty or right, mandatory injunctive relief is unavailable to Plaintiff.

B. Plaintiff Has Failed To Demonstrate Irreparable Harm.

A mandatory injunction will only issue if the plaintiff demonstrates it is necessary to prevent irreparable injury.¹⁰¹ As explained, **ivermectin’s** efficacy in treating COVID-19 is disputed. This is why **ivermectin** is **not** within the scope of a provider’s duty; it is also why Plaintiff cannot show its administration is necessary to avoid irreparable harm. “[B]ut, of course, that proposition cannot be proven. The efficacy of [**ivermectin**] in the treatment of [COVID-19] has **not** been scientifically established.”¹⁰²

In fact, the weight of authority shows it is **not** an effective treatment.¹⁰³ Nearly all of Plaintiff’s evidence that refusing **ivermectin** would lead to irreparable harm is found in the FLCCC materials and in Dr. Partovi’s testimony.¹⁰⁴ Both are inconsistent with the great weight of medical authority and are based on dubious methodologies.¹⁰⁵ Whether depriving DeMarco of **ivermectin** will cause irreparable harm is disputed and the preponderance of the evidence on this record favors Defendant. This factor does **not** support a mandatory injunction.

C. The Balance Of The Equities Favor Defendant.

*12 In order to obtain injunctive relief, Plaintiff must also prove that denying the injunction would cause DeMarco greater harm than granting the injunction will cause Defendant.¹⁰⁶ It is also appropriate to consider public policy¹⁰⁷ and “the impact an injunction will have on the public and on innocent third parties.”¹⁰⁸

Earlier this month, an Ohio Court denied a similar request to mandate treatment of COVID-19 with **ivermectin**. That Court found that granting the injunction would adversely impact

the safe and effective development of medications and medical practices. ... a **hospital’s** standard of care decisions, mandating doctors and nurses to provide care they believe unnecessary,

ethical concerns of all doctors involved, patient autonomy, fiduciary duty, accreditation standards for patient protections, obligating one doctor to carry out the treatment regimen/plan of another doctor, ... and whether a court should medicate or legislate from the bench.¹⁰⁹

I find that reasoning persuasive. Compelling Defendant to provide a treatment outside the standard of care—on the prescription of a doctor who did **not** see the patient, has never treated the patient, and does **not** have privileges at that **hospital**—risks substantial harm to Defendant and the health care system at large. Requiring a healthcare provider to **administer** such a treatment harms the stability of **hospital** administration and admitting privileges.¹¹⁰

More fundamentally, it would undermine the “traditional consensual nature of the physician-patient relationship” that undergirds the safe delivery of health care.¹¹¹ Granting Plaintiff’s injunction would be detrimental to the public policy of allowing and compelling a healthcare provider to deliver the standard of care based on prevailing scientific and ethical norms and regulations, as enshrined in the Delaware Code.¹¹² Dr. Maheshwari explained that physicians have an ethical duty **not** to harm their patients.¹¹³ He further testified that the proposed injunction could interfere with the “basis of medical practice to deliver evidence-based medicine and

offer patients treatment that may be beneficial or is indeed beneficial. And to avoid treatment that is nonbeneficial.”¹¹⁴ Dr. Maheshwari observed that **not** only has **ivermectin** “**not** been shown to have benefit,” but it also “has the potential for harm.”¹¹⁵

*13 Finally, compelling a provider to operate outside the standard of care would improperly and imprudently move health care treatment decisionmaking from the patient’s bedside to a judge’s bench.¹¹⁶

III. CONCLUSION

For the foregoing reasons, Plaintiff’s request for a mandatory preliminary injunction must be **DENIED**. My decision is animated both by Plaintiff’s failure to show she is entitled to the relief she seeks at this procedural stage, and by her more fundamental failure to identify any established right that would serve as a basis for that relief. Despite the finality of my second conclusion, my decision today is limited to the Motion before me, which is one for interlocutory injunctive relief. Because of this procedural posture, I recognize Plaintiff’s ability to pursue review of my decision is limited by Delaware [Supreme Court Rule 42](#).¹¹⁷ As I indicated at yesterday’s Hearing, I am prepared to expeditiously consider an application by Plaintiff to certify an interlocutory appeal.

All Citations

--- A.3d ----, 2021 WL 4343661

Footnotes

- 1 Though the plaintiff has **not** filed a formal motion, the parties and the Court have treated her request in this highly expedited case as one for a preliminary injunction. See Docket Item (“D.I.”) 12 at 7 [hereinafter “TRO Hr’g Tr.”]; D.I. 8; D.I. 9. Citations in the form “PI Hr’g Tr.” refer to the September 23 Hearing transcript, available at D.I. 13.
- 2 The parties submitted their Hearing exhibits to the Court electronically, but have **not** yet filed them on the docket. Citations in the form “PX —” refer to plaintiff’s Hearing exhibits; citations in the form “DX —” refer to defendant’s Hearing exhibits.
- 3 See, e.g., *Everett v. Lanouette*, 1994 WL 681106, at *4 (Del. Ch. Nov. 10, 1994) (denying plaintiffs’ mandatory injunction because they failed to prove their case by a preponderance of the evidence); *C&J Energy Servs., Inc. v. City of Miami Gen. Empls.’ & Sanitation Empls.’ Ret. Tr.*, 107 A.3d 1049, 1053–54 (Del. 2014) (footnote

omitted) (“Mandatory injunctions should only issue with the confidence of findings made after a trial or on undisputed facts.”); *Agilent Techs., Inc. v. Kirkland*, 2010 WL 610725, at *13 (Del. Ch. Feb. 18, 2010) (internal quotation marks omitted) (“Proof by a preponderance of the evidence means proof that something is more likely than **not**. It means that certain evidence, when compared to the evidence opposed to it, has the more convincing force and makes you believe that something is more likely true than **not**.”).

4 D.I. 1, Verified Complaint for Injunctive and Declaratory Relief ¶¶ 3, 7 [hereinafter “Compl.”]; Compl. Ex. A.
5 *Id.* ¶ 4.

6 *Id.* ¶ 8; TRO Hr’g Tr. 29.

7 Compl. ¶ 12; PI Hr’g Tr. 10–12.

8 Compl. Ex. A at 6. DeMarco’s health care directive indicated that it was “only guidance” and his health care agent, Plaintiff, “shall have final say and may override any of my instructions.” *Id.* at 7.

9 PI Hr’g Tr. 6.

10 *Id.* 12.

11 Compl. ¶¶ 9–10; D.I. 11 [hereinafter “Def. Br.”] at 3. At the Hearing, Plaintiff testified that DeMarco, at least initially, did **not** wish to be treated with Remdesivir. See PI Hr’g Tr. 9–10.

12 PI Hr’g Tr. 54; see also DX 1 (describing the **Hospital’s** “Interim Inpatient Treatment Guidelines for SARS-CoV-2 Infection (COVID-19)”).

13 Compl. ¶¶ 10–12.

14 PI Hr’g Tr. 12.

15 Def. Br. Ex. G.

16 D.I. 1, Unsworn Declaration of Mary Ellen DeMarco Pursuant to 10 *Del. C. § 3927* in Support of Motion for an Emergency Temporary Restraining Order [hereinafter “Decl.”] at ¶¶ 14–16; Def. Br. Ex. G (noting in vitro studies suggest **ivermectin** can inhibit viral infection mechanisms and that some studies “have also reported potential anti-inflammatory properties”).

17 PI Hr’g Tr. 42–51.

18 *Id.* 12.

19 *Id.* 13.

20 *Id.* 12–13.

21 Compl. ¶ 17; PI Hr’g Tr. 13–14.

22 Compl. ¶ 18.

23 TRO Hr’g Tr. 10 (“THE COURT: Did [Dr. Brownstein] treat your husband before he came down with COVID? MS. DEMARCO: No, he did **not**.”). In her Complaint, Plaintiff alleged Dr. Brownstein prescribed **ivermectin** “based on a detailed discussion of Mr. DeMarco’s condition with Mrs. DeMarco.” See Compl. ¶¶ 12, 18. At yesterday’s Hearing, Plaintiff testified that Dr. Brownstein spoke with DeMarco, as well as one of his doctors, before prescribing **ivermectin**. PI Hr’g Tr. 13–14 (“Q. And you mentioned earlier that David has a prescription for **ivermectin**. Can you walk us through how that came about? A. Yes. So once I understood that David wanted to receive **ivermectin** and the **hospital** would **not** give that, I began the process, with the help of many friends and family, to find a way to get it. One of my friends reached out to Dr. Adam Brownstein, and I spoke with him on several occasions. And he spoke with David and he spoke with David’s doctor, and he prescribed the medication.”).

24 See Compl. ¶ 17; Def. Br. 4.

25 Compl. Ex. B.

26 Compl. ¶¶ 1, 19, 31, 34.

27 PI Hr’g Tr. 14.

28 See generally Compl. Plaintiff sought to join other petitioners who have obtained injunctions ordering treatment of COVID-19 with **ivermectin**. See, e.g., Emergency Order, *Estate of Fype*, No. 2021P00542 (Ill. Cir. Ct. DuPage County, Apr. 30, 2021) (Orel, J.); Order to Show Cause, *Kulbacki v. Kaleida Health*, No. 800259/2021 (N.Y. Supr. Ct. Erie County, Jan. 8, 2021) (Nowak, J.); Order to Show Cause, *Dickinson v. Rochester Gen. Hosp.*, No. 21-47013 (N.Y. Supr. Ct. Orleans County, Jan. 21, 2021) (Caruso, J.); Order to

Show Cause, *Swanson v. United Mem'l Med. Ctr.*, No. E69026, 2021 WL 1897154 (N.Y. Supr. Ct. Genesee County, Apr. 3, 2021) (Marshall, J.); *but see* Judgment Entry, *Smith v. W. Chester Hosp., LLC (Smith I)*, 12th Dist. Butler No. 2021 08 1206, 2021 WL 4316593 (Ohio C.P. Aug. 23, 2021) (Howard, J.), *overruled by* Decision Denying Plaintiff's Action for a Preliminary Injunction, *Smith v. W. Chester Hosp., LLC (Smith II)*, 12th Dist. Butler No. 2021 08 1206, 2021 WL 4129083 (Ohio C.P. Sept. 6, 2021) (Oster, J.). All the plaintiffs in these actions were represented by Plaintiff's New York counsel.

29 Compl. ¶¶ 29–32.

30 *Compare id.* ¶¶ 33–35, *with id.* at 10 ¶ B. Defendant has admitted DeMarco has executed a durable healthcare power of attorney designating Plaintiff as his healthcare agent in the event of his incapacitation, which Defendant will honor “subject to its healthcare providers’ obligation and right to refuse to **administer** treatment they do **not** believe to be safe and effective or in the patient's best interest.” D.I. 10 ¶¶ 3, 7, 23 [hereinafter “Answer”]. I do **not** believe Count II is independently at issue at the preliminary injunction stage.

31 D.I. 1.

32 D.I. 3; TRO Hr'g Tr. 30.

33 TRO Hr'g Tr. 29–38; D.I. 7.

34 D.I. 6; D.I. 8.

35 PI Hr'g Tr. 15, 54–55.

36 *Id.* 14–15.

37 *Id.* 15.

38 *Id.*

39 *Id.*

40 *Id.*

41 *Id.* 6, 15.

42 *Id.* 15.

43 Def. Br. Ex. A; PI Hr'g Tr. 15; *id.* 55 (“He was, however, discharged home, with hospice services put in place, and returned back to the Wilmington emergency room within, I believe, a six-hour – eight-hour time frame. And at that point, he was in such severe extremis and respiratory failure that he required the placement of an **endotracheal tube**, being placed on mechanical ventilation, and then required fairly significant amounts of ventilator support and what we call deep sedation and paralysis to help support his overall ventilation.”).

44 D.I. 5; *see* D.I. 8.

45 D.I. 5.

46 *See generally* Answer.

47 *See generally* Def. Br.

48 Compl. ¶ 22.

49 *Id.*

50 Def. Br. 6–13.

51 *Id.* 14–15.

52 PI Hr'g Tr. 16.

53 *Id.*

54 *Id.* 30. Dr. Partovi has a doctorate in naturopathic medicine from Southwest College of Naturopathic Medicine. *Id.* 18. He specializes in naturopathic generative medicine, which he described as “the application of computer analysis to personalized medicine.” *Id.* 21. He has never spoken to DeMarco. *Id.* 31–32. He does **not** have an M.D., nor does he treat ICU patients. *See id.* 27–29. He is certified only by the Board of Naturopathic Generative Medicine. *Id.* 28.

55 *Id.* 20 (“Q. So roughly how many patients have you treated with **ivermectin**? A. I would say over 100. I would say less than 250. So somewhere in that range. I don't have an exact number.”); *id.* 29–30 (describing patients for whom Dr. Partovi prescribed **ivermectin**, “around a dozen” of which were on ventilator support).

56 *Id.* 31.

- 57 *Id.* 20 (“I would say that the one medication that I've found is the most effective by itself has been **ivermectin**.”), *id.* 24–25 (“Q. You're saying there's a 58 percent overall better chance of survival if David DeMarco receives **ivermectin**. Is that what you're telling us? A. Correct. And what I would say we have -- what we have -- what we do know is that when it comes to **ivermectin** treatment, the earlier, the better. So basically, you know, for every day that goes by, that number goes down. Q. So there is damage being done to Mr. DeMarco in the -- as the days go by, without **ivermectin**; is that what you're -- correct? A. Yeah. And I would say that it's -- it's damage which is quite possibly irreparable.”).
- 58 *See, e.g., id.* 21, 33–34.
- 59 *Id.* 34 (“Q. And it's your belief, after doing your studies on **ivermectin**, that, in fact, it would benefit David DeMarco in his current situation? A. Oh, yeah. I mean, I've absolutely seen situations where someone is in the late-stage pulmonary phase. They got **ivermectin**, they got it at a sufficiently high dose, they got it for a sufficient amount of time, and it pulled them out of comas. You know, like, that's something that I have absolutely seen. So I would just say that, you know, they've been able to get off the ventilator and go home. So I think it's very likely that it would help him. Absolutely. I mean, obviously, I can't guarantee it, right? There's no guarantees in life. And, I mean, it's certainly worth a shot.”).
- 60 Decl. ¶ 18 (citing Decl. Ex. A); *accord* PI Hr'g Tr. 22.
- 61 Decl. Ex. A.
- 62 PI Hr'g Tr. 37–40. Dr. Maheshwari has an M.D. from the Medical College of Virginia and completed his residency there. *Id.* 38. He completed a fellowship at Tufts Medical Center in pulmonary and critical care medicine. *Id.* 39. He is certified in pulmonology and critical care by the American Board of Internal Medicine. *Id.*
- 63 *Id.* 40.
- 64 *Id.* 41.
- 65 *Id.* 42–47; DX 1.
- 66 PI Hr'g Tr. 51–52.
- 67 *Id.* 52–53.
- 68 Def. Br. Ex. G at 1.
- 69 *Id.* at 2.
- 70 *Id.* at 1.
- 71 Decl. Ex. B.; Def. Br. Ex. B; *accord* Def. Br. Ex. C.
- 72 Def. Br. Ex. B; *see also* Def. Br. Ex. C.
- 73 Def. Br. Ex. D; Def. Br. Ex. E.
- 74 PI Hr'g Tr. 52.
- 75 *Id.* 53.
- 76  *La. Mun. Police Emp. Ret. Sys. v. Crawford*, 918 A.2d 1172, 1185 (Del. Ch. 2007); *Pitts v. City of Wilm.*, 2009 WL 1204492, at *3 (Del. Ch. Apr. 27, 2009) (internal quotation marks omitted) (quoting  *Alpha Builders, Inc. v. Sullivan*, 2004 WL 2694917, at *3 (Del. Ch. Nov. 5, 2004)); *see also Alpha Nat. Res., Inc. v. Cliff's Nat. Res., Inc.*, 2008 WL 4951060, at *2 (Del. Ch. Nov. 6, 2008) (“This requires more than simply a showing of a reasonable probability of success (as required when seeking a merely prohibitory preliminary injunction).”).
- 77 Donald J. Wolfe, Jr. & Michael A. Pittenger, *Corporate and Commercial Practice in the Delaware Court of Chancery* § 14.03[b][6], at 14-03.44 (2021) (internal quotation marks omitted) (quoting *Chadha v. Szeto*, 1993 WL 498186, at *2 (Del. Ch. Nov. 18, 1993)); *see also*  *C&J Energy*, 107 A.3d at 1071 & n.107 (“To issue a mandatory injunction requiring a party to take affirmative action—such as to engage in the go-shop process the Court of Chancery required—the Court of Chancery must either hold a trial and make findings of fact, or base an injunction solely on undisputed facts.”); *Alpha Nat. Res.*, 2008 WL 4951060, at *2 (“[Granting a mandatory injunction] requires, in addition, a showing that the petitioner is entitled as a matter of law to the relief it seeks based on undisputed facts.”).

- 78 [Stahl v. Apple Bancorp, Inc.](#), 579 A.2d 1115, 1118 (Del. Ch. 1990).
- 79 [Id.](#) at 1120 (citing [City Cap. Assocs. Ltd. v. Interco, Inc.](#), 551 A.2d 787, 795 (Del. Ch. 1988)).
- 80 [Arkema Inc. v. Dow Chem. Co.](#), 2010 WL 2334386, at *3 (Del. Ch. May 14, 2010); see also, e.g., [Opportunity P'rs L.P. v. Hill Int'l, Inc.](#), 2015 WL 3582350, at *2 (Del. Ch. June 5, 2015), *aff'd*, [119 A.3d 30](#) (Del. 2015) (“When the relief sought is in the nature of a mandatory injunction, this Court will **not** order such relief unless the right to be protected is clearly established and based on undisputed facts or post trial factual findings.” (internal quotations marks omitted)); [Stahl](#), 579 A.2d at 1120 (“Upon an application for mandatory preliminary relief, however, plaintiff must show more than a reasonable probability of success on the merits; he must clearly establish the legal right he seeks to protect or the duty he seeks to enforce.”).
- 81 Donald J. Wolfe, Jr. & Michael A. Pittenger, *Corporate and Commercial Practice in the Delaware Court of Chancery* § 14.03[b][6], at 14-03.44 (2021) (quoting [Stahl](#), 579 A.2d at 1120).
- 82 Compl. ¶ 22.
- 83 [Anderson v. Russell](#), 2012 WL 1415911, at *5 (Del. Super. Apr. 18, 2012) (“[T]he voluntary acceptance of the physician-patient relationship creates a prima facie presumption of a contractual relationship between them” (quoting 61 Am. Jur. 2d Physicians, Surgeons, Etc. § 130 (citations omitted))). Regular readers of this Court’s commercial opinions should **not** expect rigid adherence to contractual principles in this relationship. Indeed, a physician’s breach of her duty of care is a tort, **not** a breach of contract.
- 84 [Anderson](#), 2012 WL 1415911, at *5 (quoting 18 Del. C. § 6801(7)); accord [Storm v. NSL Rockland Place, LLC](#), 898 A.2d 874, 885 (Del. Super. 2005); [Doe 30’s Mother v. Bradley](#), 58 A.3d 429, 461, 471 (Del. Super. 2012) (discussing the statutory “duty of care owed by a physician to his patients while rendering ‘healthcare’ ” in a doctor-patient relationship).
- 85 18 Del. C. § 6801(7); see also 16 Del. C. § 2508 (describing the statutory obligations of health care providers); [Reg. v. Wilm. Med. Ctr., Inc.](#), 377 A.2d 8, 9–10 (Del. 1977) (“It is settled law in Delaware that a physician is bound to exercise the same degree of care and to perform with the same competence ordinarily exercised and performed by other physicians in good standing in the same community.” (citations omitted)).
- 86 [Loftus v. Hayden](#), 379 A.2d 1136, 1139 (Del. Super. 1977), *aff’d*, 391 A.2d 749 (Del. 1978) (citing [Wilm. Med. Ctr., Inc. v. Redden](#), 312 A.2d 625 (Del. 1973)).
- 87 16 Del. C. § 2508(f). Section 2510(a)(5) specifies a health care provider is immune from civil and criminal liability, and from discipline for unprofessional conduct, for “[d]eclining to comply with a health-care decision ... because the instruction is contrary to the ... good faith medical judgment of the health-care provider or the written policies of the institution.”
- 88 See Decl. ¶ 21; TRO Hr’g Tr. 16–18; PI Hr’g Tr. 73 (“Q. You’re aware that there’s this controversy out there about **ivermectin**; right?”).
- 89 Decl. ¶ 21; Hr’g Tr. 52–53, 96.
- 90 Decl. ¶ 21; Decl. Ex. B; P.I. Hr’g Tr. 52–53.
- 91 Def’s Ex. 1; PI Hr’g Tr. 46–47 (“Q. Doctor, why does the medication management team rely on the FDA recommendations? ... A. And so the FDA, part of their role is to provide an opportunity to review [medical literature] and then provide guidance to the rest of us, as healthcare practitioners, in terms of what may be effective, as well as safe, in the management of a disease. So it’s a very high bar, and the United States is known, in terms of the FDA, of having a high bar in terms of safety threshold and then efficacy, approving efficacy for management before recommending something.”); *Id.* 50 (“Q. And is **ivermectin** part of these treatment guidelines that Christiana Care uses? A. No.”); *Id.* 64 (“A. They were made aware that we have treatment guidelines and they were made aware particularly when questioned about the use of **ivermectin**, that **ivermectin** is **not** part of our treatment guidelines and then they were explained the rationale for the exclusion of **ivermectin** from those treatment guidelines. Q. So I understand, they were told that you don’t do **ivermectin**.”).
- 92 See 16 Del. C. § 2508(a)(5).

- 93 Compl. ¶ 22.
- 94 16 *Del. C.* § 2502 (emphasis added); see *In re L.M.R.*, 2008 WL 398999, at *2 (Del. Ch. Jan. 24, 2008) (MASTER'S REPORT) (noting Section 2502 “in part” legislatively affirms the “right to autonomy over one’s body, including freedom to choose what medical treatment shall be imposed upon one’s body,” as protected by the due process guarantees of the United States Constitution).
- 95 *Matter of Tavel*, 661 A.2d 1061, 1068 (Del. 1995) (alterations omitted) (quoting *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251, 11 S.Ct. 1000, 35 L.Ed. 734 (1891)); accord *id.* at 1070 (affirming there is “a constitutionally protected right to refuse [medical treatment, including] lifesaving hydration and nutrition” (quoting *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 279, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990))).
- 96 *Id.* at 1068 (citing *Severns v. Wilm. Med. Ctr., Inc.*, 421 A.2d 1334, 1347 (Del. 1980)); *L.M.R.*, 2008 WL 398999, at *3 (equating the “fundamental right to self determination” to the “right to withhold or withdraw life-sustaining medical treatment” and the right to “accept or refuse medical treatment”); *In re Truselo*, 846 A.2d 256, 265 (Del. Fam. 2000) (relating the “right to forego medical treatment”).
- 97 See P.I. Hr’g Tr. 60.
- 98 *Mitchell v. Clayton*, 995 F.2d 772, 775–76 (7th Cir. 1993) (considering a right to access acupuncturists who did **not** attend chiropractic school, and collecting cases); accord *Rutherford v. U.S.*, 616 F.2d 455, 457 (10th Cir. 1980) (“[T]he decision by the patient whether to have a treatment or **not** is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health.”), *cert. denied*, 449 U.S. 937, 101 S.Ct. 336, 66 L.Ed.2d 160 (1980); *U.S. v. Cannabis Cultivator’s Club*, 1999 WL 111893, at *3 (N.D. Cal. Feb. 25, 1999) (noting other authorities “hold ... that there is no fundamental right to obtain the medication of choice”); *Peckmann v. Thompson*, 745 F. Supp. 1388, 1391 (C.D. Ill. 1990) (“There is no constitutional right to select a particular treatment or procedure over the rational objections of a governmental licensing authority.”); see also *Mont. Cannabis Indus. Ass’n v. State*, 366 Mont. 224, 286 P.3d 1161, 1166 (2012) (“[N]o court has acceded to the notion that the right to privacy encompasses an affirmative right to access a particular drug or treatment.”). The fact that there is no right to any particular treatment allows regulation of treatments subject to rational basis review. *People v. Privitera*, 23 Cal.3d 697, 153 Cal.Rptr. 431, 591 P.2d 919, 921 (1979) (“The appropriate standard of review, therefore, is the rational basis test, rather than the compelling state interest test.”); *Abigail All. for Better Access to Dev. Drugs v. Eschenbach*, 495 F.3d 695, 710 n.18 (D.C. Cir. 2007) (“It is too well settled to require discussion at this day that the police power of the States extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine.” (quoting *Watson v. Maryland*, 218 U.S. 173, 176, 30 S.Ct. 644, 54 L.Ed. 987 (1910))).
- 99 See generally *Abigail All.*, 495 F.3d at 695 (finding terminally ill adult patients do **not** have a fundamental right protected by Due Process Clause to have access to investigational drugs); *Smith v. Shalala*, 954 F. Supp. 1, 3 (D.C. Cir. 1996) (“While there are decisions recognizing that competent adults have a fundamental right to refuse medical treatment, ... and to determine the time and manner of their death, free from governmental interference, ... nothing in those decisions suggests that the government has an affirmative obligation to set aside its regulations in order to provide dying patients access to experimental medical treatments.” (citations omitted) (citing *Cruzan*, 497 U.S. at 261, 110 S.Ct. 2841, and citing *Compassion in Dying v. Washington*, 79 F.3d 790 (9th Cir. 1996))).
- 100 See *Carnohan v. U.S.*, 616 F.2d 1120, 1122 (6th Cir. 1980); *Rutherford*, 616 F.2d at 457; *Privitera*, 153 Cal.Rptr. 431, 591 P.2d at 921 (“[T]he asserted right to obtain drugs of unproven efficacy is **[n]ot**

encompassed by the right of privacy embodied in either the federal or the [California] Constitutions.”); see also [id.](#), 153 Cal.Rptr. 431, 591 P.2d at 922 (distinguishing reproductive rights).

[Privitera](#) quoted the FDA Commissioner's explanation of the quest for laetrile treatment:

In the Commissioner's opinion, the use of Laetrile in the United States has become a genuine public health problem. Increasingly, doctors dealing with cancer patients are finding that the patients are coming to legitimate therapy too late, having delayed while trying Laetrile. It seems clear that another substantial group of persons afflicted with cancer is avoiding effective therapy altogether and using Laetrile instead. The question has become one of life and death for these patients and for others who may be convinced to use Laetrile in the future.

[Id.](#), 153 Cal.Rptr. 431, 591 P.2d at 924 (citing 42 Fed. Reg. 39769).

101 [Richard Paul, Inc. v. Union Improvement Co.](#), 32 Del.Ch. 332, 86 A.2d 744, 747–48 (1952).

102 [Shalala](#), 954 F. Supp. at 3.

103 See, e.g., [Smith II](#), No. 2021 08 1206, at 7–10.

104 See PI Hr'g Tr. 21–25. Plaintiff stopped short of asserting, in full voice, that DeMarco will face deterioration or death if **not** treated with **ivermectin**. To me, Plaintiff's position appears based more on principles of patient choice than on a belief that **ivermectin** will prevent irreparable harm to DeMarco's health. Plaintiff's testimony is more fairly characterized as relating DeMarco's standalone preference for **ivermectin** over the standard treatments of Remdesivir, intubation, and ventilation, and belief that DeMarco had a right to take **ivermectin**. [Id.](#) 10, 12, 54, 65; Compl. ¶ 26; see [Al Odah v. U.S.](#), 406 F. Supp. 2d 37, 44 (D.D.C. 2005) (declining to find irreparable injury where “on th[e] record, irreparable injury in this case is caused **not** by Respondents' treatment of Petitioner but by Petitioner's own actions”). While it is reasonable to infer that DeMarco prefers **ivermectin** over standard treatments because he believes it is more effective, Plaintiff stopped short of voicing that inference.

105 See, e.g., Def. Br. Ex. G; PI Hr'g Tr. 74 (“A. [T]he studies that have been put out there that espouse the potential benefit of **ivermectin** have many flaws, including the small sample size, the variability or heterogeneity of the study groups, the lack of consistency as it relates to the dosing, the lack of reporting as it relates to safety events and adverse events, the lack of clarity in terms of how they adjusted for variables for different patient populations, the lack of methodology as it relates to the study design.”); [id.](#) 59 (“A. “I'd also say that [Dr. Partovi's] experience is anecdotal, at best, as it relates to patients that he's treated. He did **not** provide any specific evidence; and, quite honestly, concerning that he consulted and potentially treated on **hospitalized** and intensive care patients for which he acknowledges he does **not** have privileges, nor has board certification in either pulmonary or critical care medicine.”).

106 [Cantor Fitzgerald, L.P. v. Cantor](#), 724 A.2d 571, 587 (Del. Ch. 1998).

107 E.g., [Belle Isle Corp. v. Corcoran](#), 49 A.2d 1, 4 (Del. 1946); [Del. River & Bay Auth. v. Del. Outdoor Advert., Inc.](#), 1998 WL 83056, at *4–5 (Del. Ch. Feb. 20, 1998).

108 [Cantor Fitzgerald](#), 724 A.2d at 587.

109 [Smith II](#), No. 2021 08 1206, at 10.

110 Cf. [Ass'n of Cmty. Cancer Ctrs. v. Azar](#), 509 F. Supp. 3d 482, 502–03 (D. Md. 2020) (weighing the potential effects of a TRO on healthcare providers and doctors' ability to treat their patients and manage their practices when balancing the equities and ultimately granting plaintiffs' request for injunction).

111 See [Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.](#), 472 F. Supp. 3d 183, 228 (D. Md. 2020) (granting a preliminary injunction after considering the doctors' ability to exercise their “medical judgement” when treating patients using telehealth, where they complied with all laws and regulations and “plainly promote[d] the public interest in ... safeguarding public health” (internal quotation marks omitted) quoting [Pashby v. Delia](#), 709 F.3d 307, 331 (4th Cir. 2013))), *order clarified sub nom. Am. Coll. of*

Obstetricians & Gynecologists ex rel. Council of Univ. Chairs of Obstetrics & Gynecology v. U.S. Food & Drug Admin., 2020 WL 8167535 (D. Md. Aug. 19, 2020), and *appeal dismissed sub nom. Am. Coll. of Obstetricians & Gynecologists v. Indiana*, 2021 WL 3276054 (4th Cir. May 19, 2021); P.I. Hr'g Tr. 99 (“The traditional consensual nature of the physician-patient relationship will be undermined. The autonomy of physicians to make medical judgments about what is and is **not** in the best interest of their patients will be undermined.”).

- 112 See  *Mayor & City Council of Balt. v. Azar*, 392 F. Supp. 3d 602, 619 (D. Md. 2019) (granting an injunction after considering the public health problems that may result from a rule that would prohibit doctors receiving Title X funding from discussing abortion with their patients because it would “forc[e] doctors to engage in the unethical practice of medicine, thus endangering the lives of patients and residents”), *appeal dismissed as moot sub nom.*  *Mayor of Balt. v. Azar*, 973 F.3d 258 (4th Cir. 2020), *cert. granted sub nom. Cochran v. Mayor & City Council of Balt.*, — U.S. —, 141 S. Ct. 1369, 209 L.Ed.2d 118 (2021), and *cert. dismissed sub nom. Becerra v. Mayor & City Council of Balt.*, — U.S. —, 141 S. Ct. 2170, 209 L.Ed.2d 747 (2021).
- 113 P.I. Hr'g Tr. 57.
- 114 *Id.* 58.
- 115 *Id.* 57–58 (“A. There are multiple case reports currently active as it relates to potential harm with shock, **liver failure**, and other adverse reactions.”).
- 116 *Cf. Pharm. Prod. Dev., Inc. v. TVM Life Sci. Ventures VI, L.P.*, 2011 WL 549163, at *5 (Del. Ch. Feb. 16, 2011) (describing a judicial officer’s “law-trained scientific ... observation” about a drug’s efficacy and potency as “oxymoronic”); *Del. Bd. of Nursing v. Francis*, 195 A.3d 467, 469 (Del. 2018) (noting the Court is comprised of “law-trained judges, **not** medical professionals”).
- 117 Supr. Ct. R. 42.